AN INTEGRATED MAINTENANCE MANAGEMENT SYSTEM MODEL FOR THE PHARMACEUTICAL INDUSTRY

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DECLARATION BY CANDIDATE

I, Kribban Coopoosamy, hereby declare that:

- This work has not been previously accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

- This dissertation is being submitted in partial fulfilment of the requirements for the degree of Masters in Business Administration.

- This dissertation is the result of my independent work and investigation, except where otherwise stated. Other sources are acknowledged by complete referencing. A reference list is attached.

- I hereby give consent for my dissertation, if accepted, to be available for photocopying and for interlibrary loan, and for the title and summary to be made available to outside organisations.

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ABSTRACT

Organisations are continuously seeking for strategies to improve operations and gain competitive advantage. Maintenance tends to be a key management issue for many industrial companies. Maintenance management, being an integral part of manufacturing, can influence competitive companies’ priorities, such as cost, quality and flexibility, and, hence, business strategy directly.

The pharmaceutical industry also faces some unique challenges such as increasingly stringent safety and quality regulations, the effect of innovations in medical science and healthcare and a complex and costly design-to-market process (from product concept and development to market delivery). The industry is also going through turbulent times as it has to cope with challenges common to many other industries, how to deal with increasing competition, hold down costs, and expand.

Regulatory compliance is one of the significant industry drivers for pharmaceutical companies. Regulations are enacted by government authorities to ensure public health and safety. The focus of regulation is on quality assurance and control in all areas such as receiving, manufacturing, storing, packaging, despatching and delivering. Apart from the required quality and safety checks, the regulations also mandate extensive record keeping of procedures, processes and systems.

This treatise will investigate the maintenance management system of a pharmaceutical company and compare it to best practices. The true name of the pharmaceutical company that will be researched will not be disclosed for confidentiality reasons, instead it will be called My Pharmaceuticals. The company is based in Port Elizabeth. The research consists of a preliminary study to identify the problem areas in the maintenance management system within the company. A literature review of best practices in maintenance management systems combined with an investigation into the best pharmaceutical practices in maintenance management systems and regulatory controls are investigated and a model will be proposed to improve the current situation at the company.
# TABLE OF CONTENTS

DECLARATION BY CANDIDATE ........................................................................................................ ii
ACKNOWLEDGMENTS ...................................................................................................................... iii
ABSTRACT ........................................................................................................................................ iv
LIST OF ABBREVIATIONS ................................................................................................................ xii
LIST OF FIGURES ............................................................................................................................ xiii
LIST OF TABLES ............................................................................................................................... xv
LIST OF CHARTS .............................................................................................................................. xvii
LIST OF ANNEXURES ...................................................................................................................... xvii

## Chapter 1: Introduction and Problem Statement

1.1 Introduction ............................................................................................................................... 1
1.2 Main problem ............................................................................................................................ 2
1.3 Research questions .................................................................................................................... 3
1.4 Objectives of the research ......................................................................................................... 3
1.5 Delimitation of the Research .................................................................................................... 4
1.6 Definitions of concepts ............................................................................................................. 4  
   1.6.1 Assets ................................................................................................................................. 4
   1.6.2 Maintenance ....................................................................................................................... 5
   1.6.3 Best Practice ...................................................................................................................... 5
   1.6.4 Validation ........................................................................................................................... 5
   1.6.5 Good Engineering Practice (GEP) ................................................................................... 5
   1.6.6 Standard Operating Procedure (SOP) ............................................................................. 5
   1.6.7 Overall Equipment Effectiveness (OEE) ............................................................................ 6
1.7 Significance of the research ....................................................................................................... 6
1.8 Research methodology .............................................................................................................. 6  
   1.8.1 Research approach ............................................................................................................ 6
      1.8.1.1 Literature study ......................................................................................................... 7
      1.8.1.2 Case Study ................................................................................................................. 7
      1.8.1.3 Preliminary Study ....................................................................................................... 8
   1.8.2 Data Collection .................................................................................................................. 8
Chapter 2: Maintenance Management Systems Best Practices and the Results of the Preliminary Survey

2.1 Introduction ............................................................................................................................................. 11
2.2 The need for maintenance .................................................................................................................. 12
2.3 Maintenance policies .......................................................................................................................... 13
2.4 Maintenance objectives ....................................................................................................................... 13
2.5 Maintenance best practice .................................................................................................................. 14
2.6 Levels of maintenance ......................................................................................................................... 14
  2.6.1 Organisation maintenance level ....................................................................................................... 14
  2.6.2 Intermediate maintenance level ...................................................................................................... 15
  2.6.3 Supplier, manufacturer, depot maintenance level ............................................................................. 15
2.7 Types of Maintenance .......................................................................................................................... 15
  2.7.1 Corrective Maintenance .................................................................................................................. 16
  2.7.2 Preventative Maintenance .............................................................................................................. 16
  2.7.3 Predictive Maintenance .................................................................................................................. 16
  2.7.4 Reliability Centred Maintenance ................................................................................................. 17
2.8 Availability, Reliability and Maintainability ...................................................................................... 17
2.9 Maintenance Management Process ................................................................................................... 18
  2.9.1 Maintenance Work Identification ................................................................................................. 19
    2.9.1.1 Types of Work Orders ........................................................................................................... 20
    2.9.1.2 Planned and schedule work orders ....................................................................................... 21
    2.9.1.3 Standing or blanket work orders .......................................................................................... 21
    2.9.1.4 Emergency or breakdown work orders ................................................................................. 21
    2.9.1.5 Shutdown or outage work orders ......................................................................................... 21
  2.9.2 Maintenance Work Planning and Scheduling ................................................................................. 22
    2.9.2.1 Maintenance Work Planning .............................................................................................. 22
2.9.2.2 Maintenance Scheduling ................................................................. 22
2.9.2.3 Integrating Maintenance Planning with Production Planning ............ 23
2.9.3 Maintenance Work Execution ............................................................ 24
2.9.4 Maintenance History Recording ......................................................... 25
2.9.5 Maintenance Analysing .................................................................... 26
2.9.5.1 Selecting a FMCEA method ............................................................ 26
2.10 The need for spares management ......................................................... 28
2.10.1 Inventory accuracy ......................................................................... 29
2.11 Computerised Maintenance Management System (CMMS) ..................... 30
2.11.1 The need for CMMS ..................................................................... 30
2.11.2 CMMS data support ..................................................................... 31
2.11.3 Current deficiencies in existing off-the-shelf CMMSs ......................... 32
2.11.4 Standard Operating Procedures (SOP) for CMMS ............................. 33
2.12 Staffing the Organisation for Maintainability ....................................... 33
2.12.1 Maintainability Engineer ................................................................ 35
2.12.2 Maintenance Supervisors ............................................................... 35
2.12.3 Artisans/Technicians ..................................................................... 36
2.12.4 Maintenance Planner .................................................................... 36
2.12.4.1 Principles of the planner ............................................................. 36
2.13 Maintenance audits ........................................................................... 37
2.14 Literature summary .......................................................................... 38
2.15 My Pharmaceuticals ....................................................................... 38
2.15.1 Port Elizabeth site ........................................................................ 39
2.15.2 Current maintenance management system problems ......................... 39
2.15.2.1 Problem P1 - Maintenance Work Planning and Scheduling ............. 40
2.15.2.2 Problem P2 - Process Validation ................................................ 41
2.15.2.3 Problem P3 and P4 - Performing Types of Maintenance ................ 41
2.15.2.4 Problem P5 - Maintenance Management Process ......................... 41
2.15.2.5 Problem P6 - The need for a CMMS ............................................ 41
2.15.2.6 Problem P7 - The need for Spares Management ........................... 42
2.15.2.7 Problem P8 - Staffing the Organisation for Maintainability ............ 42
2.15.2.8 Problem P9 - Pharmaceutical Systems Maintenance Strategies .......... 42
2.15.2.9 Problem P10 - Maintenance Analysing ........................................ 43
Chapter 3: Pharmaceutical Industry Good Engineering Practices
Guidelines and Regulatory Controls

3.1 Introduction ........................................................................................................... 44
3.2 International Society for Pharmaceutical Engineering (ISPE) Guide ............... 45
  3.2.1 Maintenance practice ....................................................................................... 46
  3.2.2 Maintenance program ..................................................................................... 47
  3.2.3 Systems maintenance strategy ......................................................................... 48
  3.2.4 Maintenance plans ......................................................................................... 48
  3.2.5 Production and Maintenance ......................................................................... 49
  3.2.6 Spare parts and materials ............................................................................... 49
  3.2.7 Maintenance documentation .......................................................................... 49
  3.2.8 Roles and responsibilities .............................................................................. 50
  3.2.9 Computerised Maintenance Management Systems in the Pharmaceutical Industry .................................................................................................................. 50
3.3 Pharmaceutical process validation ....................................................................... 51
  3.3.1 Stages in process validation ............................................................................. 52
    3.3.1.1 Installation qualification (IQ) .................................................................... 52
    3.3.1.2 Operation qualification (OQ) .................................................................... 53
    3.3.1.3 Performance qualification (PQ) ................................................................. 53
    3.3.1.4 Process validation (PV) ............................................................................ 54
3.4 Quality assurance in the pharmaceutical industry (QA) .................................... 54
  3.4.1 Change control and deviations ......................................................................... 55
3.5 The maintenance qualification for pharmaceuticals ............................................. 55
  3.5.1 Methodology for maintenance qualification ...................................................... 56
  3.5.2 Pre-screening .................................................................................................. 56
  3.5.3 Impact assessment .......................................................................................... 57
3.6 Environmental Health and Safety in the maintenance environment (EHS) ........ 57
3.7 Summary ............................................................................................................... 58
Chapter 4: Developing the Integrated Maintenance Management System Model

4.1 Introduction

4.2 The maintenance management framework (model)

4.3 A proposed approach to maintenance management system

4.3.1 Strategic levels of the maintenance management system framework

4.3.2 Tactical levels of the maintenance management system framework

4.3.3 Operational levels of the maintenance management system framework

4.4 Developing the integrated maintenance management system model for My Pharmaceuticals

4.4.1 Maintenance policy

4.4.2 Steering committee – senior management

4.4.3 Maintenance objectives

4.4.4 Multi skilled engineering staff with pharmaceutical regulatory training.

4.4.5 Compliance

4.4.6 Validation

4.4.7 Quality assurance (QA)

4.4.8 Maintenance identification and qualification

4.4.9 Production planning

4.4.10 Integration between production and maintenance planning

4.4.11 Maintenance planning and scheduling

4.4.12 Maintenance execution

4.4.13 Maintenance history

4.4.14 Optimisation and self audits

4.4.15 Maintenance policy re-evaluation

4.4.16 Complete proposed integrated maintenance management system model

4.5 Summary

Chapter 5: Research and Design Methodology

5.1 Introduction

5.2 Definition of research
5.3 Types of research

5.3.1 Exploratory, descriptive and explanatory research

5.3.2 Applied and basic research

5.3.3 Quantitative and qualitative research

5.4. The method of research applied for this study

5.4.1 Literature study

5.4.2 Preliminary study

5.4.3 Development of the proposed integrated maintenance management system model

5.4.4 Empirical Study

5.4.4.1 Sample design

5.4.4.2 Data collection methods

5.4.4.3 Data analysis

5.4.4.4 Reliability and validity

5.5 Summary

Chapter 6: Research Findings

6.1 Introduction

6.2 Analysis of the empirical results

6.2.1 Response rate

6.2.2 Main study questionnaire

6.2.2.1 Section A: Biographical data

6.2.2.2 Section B: Preliminary study problem statements

6.2.2.3 Summary for research findings in Section B

6.2.2.4 Section C1: Proposed Integrated Maintenance Management System Model

6.2.2.5 Summary for research findings in Section C1

6.2.2.6 Section C2: Respondents' opinions

6.2.2.7 Summary for research findings in Section C2

6.3 Conclusion

Chapter 7: Conclusions and Recommendations

7.1 Introduction
7.2 Summary of the research ................................................................. 122
7.2.1 Main research question RQ_m ..................................................... 122
7.2.2 Research question RQ1 .............................................................. 123
7.2.3 Research question RQ2 .............................................................. 124
7.2.4 Research question RQ3 .............................................................. 124
7.2.5 Research question RQ4 .............................................................. 124
7.2.6 Research question RQ5 .............................................................. 125
7.2.7 Research question RQ6 .............................................................. 126
7.3 Recommendations ...................................................................... 127
7.4 Limitations of the study .............................................................. 130
7.5 Future research .......................................................................... 130
7.6 Summary ................................................................................... 130
References ...................................................................................... 132
## LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
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<tr>
<td>cGMP</td>
<td>Current Good Manufacturing Practice</td>
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<tr>
<td>CMMS</td>
<td>Computerised Maintenance Management System</td>
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<tr>
<td>EC</td>
<td>European Commission</td>
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<tr>
<td>ERP</td>
<td>Enterprise Resource Planning</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>GEP</td>
<td>Good Engineering Practice</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>HVAC</td>
<td>Heating, Ventilation and Air-conditioning</td>
</tr>
<tr>
<td>ISPE</td>
<td>International Society for Pharmaceutical Engineering</td>
</tr>
<tr>
<td>OAE</td>
<td>Overall Asset Effectiveness</td>
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<tr>
<td>OEE</td>
<td>Overall Equipment Effectiveness</td>
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<tr>
<td>OFE</td>
<td>Overall Factory Effectiveness</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>OPE</td>
<td>Overall Plant Effectiveness</td>
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<tr>
<td>OTE</td>
<td>Overall Throughput Effectiveness</td>
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<td>PEE</td>
<td>Production Equipment Effectiveness</td>
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<tr>
<td>PM</td>
<td>Preventative Maintenance</td>
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<tr>
<td>QA</td>
<td>Quality Assurance</td>
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<tr>
<td>TEEP</td>
<td>Total Equipment Effectiveness Performance</td>
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<tr>
<td>TPM</td>
<td>Total Productive Maintenance</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
</tbody>
</table>
LIST OF FIGURES

Figure 2.1: Component failure rate over time for component population ........................................ 12
Figure 2.2: Simple vision of the relationship of availability, reliability and maintainability ................................................................. 18
Figure 2.3: Maintenance Process .................................................................................................................. 19
Figure 2.4: Maintenance/plant organisational arrangements .................................................................. 34
Figure 2.5: Professional Planning .............................................................................................................. 37
Figure 3.1: Reliability Curve ...................................................................................................................... 47
Figure 3.2: Validation stages, a functional view ......................................................................................... 53
Figure 3.3: Maintenance qualification ...................................................................................................... 56
Figure 4.1: Proposed generic model for maintenance management. ...................................................... 60
Figure 4.2: Maintenance process, course of action and feedback operating at the three levels of business activities .................................................................................................................................. 62
Figure 4.3: Developing the integrated maintenance management system model at the tactical level for My Pharmaceuticals ......................................................................................................................... 64
Figure 4.4: Developing the integrated maintenance management system model at the strategic level for My Pharmaceuticals ......................................................................................................................... 68
Figure 4.5: Developing the integrated maintenance management system model at the operational level for My Pharmaceuticals ......................................................................................................................... 74
Figure 4.6: Complete proposed integrated maintenance management system model for My Pharmaceuticals .................................................................................................................................. 76
Figure 6.1: Response to P1 per department .............................................................................................. 93
Figure 6.2: Response to P2 per department .............................................................................................. 93
Figure 6.3: Response to P3 per department .............................................................................................. 94
Figure 6.4: Response to P4 per department .............................................................................................. 95
Figure 6.5: Response to P5 per department .............................................................................................. 95
Figure 6.6: Response to P6 per department .............................................................................................. 96
Figure 6.7: Response to P7 per department .............................................................................................. 97
Figure 6.8: Response to P8 per department .............................................................................................. 98
Figure 6.9: Response to P9 per department ............................................................................................. 99
Figure 6.10: Response to P10 per department ......................................................................................... 99
Figure 6.11: Proposed integrated maintenance management system model ........................................ 101
Figure 6.12: Response to S1 per department .......................................................................................... 102
Figure 6.13: Response to S2 per department .......................................................................................... 103
Figure 6.14: Response to S3 per department .......................................................................................... 103
Figure 6.15: Response to S4 per department .......................................................................................... 104
Figure 6.16: Response to S5 per department .......................................................................................... 105
Figure 6.17: Response to S6 per department .......................................................................................... 105
Figure 6.18: Response to S7 per department .......................................................................................... 106
Figure 6.19: Response to S8 per department .......................................................................................... 107
Figure 6.20: Response to S9 per department .......................................................................................... 107
Figure 6.21: Response to S10 per department ....................................................................................... 108
Figure 6.22: Response to S11 per department ....................................................................................... 109
Figure 6.23: Response to S12 per department .......................................................... 110
Figure 6.24: Response to S13 per department .......................................................... 110
Figure 6.25: Response to S14 per department .......................................................... 111
Figure 6.26: Response to S15 per department .......................................................... 112
Figure 6.27: Response to S16 per department .......................................................... 112
Figure 6.28: Response to S17 per department .......................................................... 113
Figure 6.29: Improved proposed integrated maintenance management system model 121
Figure 7.1: Improved proposed integrated maintenance management system model .. 127
LIST OF TABLES

Table 2.1: Main maintenance management system problems at My Pharmaceuticals... 40
Table 3.1: Roles and Responsibility Assignment................................................................. 50
Table 5.1: Sample targeted ........................................................................................................ 83
Table 6.1: Sample response rate .............................................................................................. 89
Table 6.2: Response to P1 per position..................................................................................... 93
Table 6.3: Response to P2 per position..................................................................................... 93
Table 6.4: Response to P3 per position..................................................................................... 94
Table 6.5: Response to P4 per position..................................................................................... 95
Table 6.6: Response to P5 per position..................................................................................... 95
Table 6.7: Response to P6 per position..................................................................................... 96
Table 6.8: Response to P7 per position..................................................................................... 97
Table 6.9: Response to P8 per position..................................................................................... 98
Table 6.10: Response to P9 per position................................................................................... 99
Table 6.11: Response to P10 per position............................................................................... 99
Table 6.12: Response to S1 per position................................................................................ 102
Table 6.13: Response to S2 per position................................................................................ 103
Table 6.14: Response to S3 per position................................................................................ 103
Table 6.15: Response to S4 per position................................................................................ 104
Table 6.16: Response to S5 per position............................................................................... 105
Table 6.17: Response to S6 per position............................................................................... 105
Table 6.18: Response to S7 per position............................................................................... 106
Table 6.19: Response to S8 per position............................................................................... 107
Table 6.20: Response to S9 per position............................................................................... 107
Table 6.21: Response to S10 per position............................................................................. 108
Table 6.22: Response to S11 per position............................................................................. 109
Table 6.23: Response to S12 per position............................................................................. 110
Table 6.24: Response to S13 per position............................................................................. 110
Table 6.25: Response to S14 per position............................................................................. 111
Table 6.26: Response to S15 per position............................................................................. 112
Table 6.27: Response to S16 per position............................................................................. 112
Table 6.28: Response to S17 per position............................................................................. 113
Table 6.29: Respondents opinion to open ended question 1............................................. 115
Table 6.30: Respondents opinion to open ended question 2.............................................. 116
LIST OF CHARTS

Chart 6.1: Number of respondents according to length of service. .......................... 90
Chart 6.2: Number of respondents by department....................................................... 90
Chart 6.3: Number of respondents by position .............................................................. 91
Chart 6.4: Number of respondents by length of service in current position ............... 92
LIST OF ANNEXURES

ANNEXURE 1: PRELIMINARY STUDY COVER PAGE AND QUESTIONNAIRE 136
ANNEXURE 2: MAIN STUDY COVER PAGE AND QUESTIONNAIRES.................... 139
ANNEXURE 3: MAIN STUDY OVERALL BIOGRAHICAL DATA............................ 144
ANNEXURE 4: MAIN STUDY OVERALL RESPONSE TO MAIN PROBLEMS..... 145
ANNEXURE 5: OVERALL DEPARTMENTAL RESPONSE TO THE MAIN PROBLEMS PRESENTED IN THE MAIN STUDY ......................... 146
ANNEXURE 6: MAIN STUDY OVERALL RESPONSE TO THE PROPOSED INTEGRATED MAINTENANCE MANAGEMENT SYSTEM MODEL........................................................................................................ 147
ANNEXURE 7: MAIN STUDY OVERALL DEPARTMENTAL RESPONSE TO THE PROPOSED INTEGRATED MAINTENANCE MANAGEMENT SYSTEM MODEL ................................................................. 148
ANNEXURE 8: MAIN STUDY OVERALL RESPONSE TO THE RESPONDENTS OPINION ON THE TWO OPEN ENDED QUESTIONS............... 149
Chapter 1

Introduction and Problem Statement

1.1 Introduction

Presence of a well organised maintenance system helps an organisation to increase machine availability, reduce production downtime, production losses and overtime costs. It also lowers labour requirements for maintenance personnel, leaving them with more time for ordinary adjustments and repairs than on breakdown repairs. Good maintenance practice also leads to fewer large-scale repairs and repetitive repairs, fewer product rejects and better quality control of the products. Plant reliability comes as a benefit from an effective maintenance system. Another good result is greater safety for workers and improved protection of the plant which leads to lower compensation and insurance costs (Fore & Zuze, 2010).

The importance of maintenance is recognised both theoretically and commercially. Maintenance, which involves highly paid trades, is generally considered to be one of the largest expenses in operating a plant. Its cost may, in some cases, represent 4 to 7 percent of the sales costs and as much as 20 to over 50 percent of the costs of the plant labour force (Worrall & Mert, 1980). Installation of increasingly complex production and control equipment creates new and varied maintenance needs. Management must therefore use maintenance resources wisely by limiting the number of non-productive hours spent on repair jobs (Worrall & Mert, 1980).

As noted by Muchiri & Pintelon (2008), the competitiveness of manufacturing companies depends on the availability and productivity of their production facilities. It also states that due to intense global competition, companies are striving to improve and optimise their productivity in order to remain competitive. This would be possible if the production losses were identified and eliminated so that the manufacturers could bring their products to the market at a minimum cost. This situation has led to a need for a rigorously defined performance measurement system that is able to take into account different important elements of productivity in a manufacturing process.

According to Jin et al. (2009), production scheduling and preventive maintenance (PM) planning are among the most important problems in the manufacturing industry. Production scheduling aims to respond rapidly to the market and to meet customer requirements, by
effectively assigning jobs or operations to the production system. At the same time preventive maintenance planning is carried out to maintain the manufacturing system or to restore it to an acceptable operating condition.

1.2 Main problem

In the pharmaceutical industry, the equipment is more complex and therefore more difficult to clean, maintain, and operate. Poor cleaning procedures can result in cross contamination of batches. Product can also be contaminated by worn or poorly maintained equipment.

The Food and Drug Administration (FDA) citations for manufacturing deficiencies have even caused delays in FDA approval of new drugs, resulting in losses estimated at over a million Rand a day for a single drug delayed. Packaging process validation requires more rigorous documentation, testing of equipment, and change control procedures because it is a more complex process. Packaging machine controls are usually not modular in design and involve multiple types of controls, thus FDA audits become more time consuming. Inspectors often find it difficult to determine if good engineering practices are being used (Blanchard & Spada, 2003).

Maintenance can impact both the quality of products and the compliance of pharmaceutical processes. Maintenance programs have long been recognised as critical to the success of the operations they support. In recent years, there has been an escalation of requirements imposed on maintenance operations, in many cases resulting in added cost, slower execution and little or no added value (ISPE, 2009).

The fulfilment of maintainability objectives is highly dependent on the proper mix of resources and the development of good communication. The uniqueness of tasks and the many different interfaces that exist, require not only good communication skills, but an understanding of the system as an entity and of the many design disciplines that contribute to its development. Maintainability is only one of these design disciplines. However the successful implementation of maintainability program functions requires a thorough understanding not only of system-level requirements, but also of the many organisational interfaces that exist (Blanchard et al., 1995).
Based on the above statements, it is clear that the pharmaceutical industry, as it is very regulated and faces unique challenges for quality assurance, must also ensure that it keeps its equipment maintained and its costs down. This forces organisations to review their existing practice which introduces the main research question of this study:

**RQm:** *Can an integrated maintenance management system model be developed for the pharmaceutical industry in South Africa?*

### 1.3 Research questions

To analyse the above main research problem effectively, the following research questions are identified:

- **RQ1:** What best practices does the literature identify about maintenance management systems within organisations?
- **RQ2:** What main problems are My Pharmaceuticals experiencing with its current maintenance management system?
- **RQ3:** What good engineering practice guidelines are there for pharmaceutical organisations?
- **RQ4:** What regulatory controls have an influence on maintenance management systems in the pharmaceutical industry?
- **RQ5:** Can an integrated maintenance management system model be developed for My Pharmaceuticals?
- **RQ6:** Can an integrated maintenance management system model be evaluated for My Pharmaceuticals?

### 1.4 Objectives of the research

The main research objective of this study is:

**ROm:** *To develop an integrated maintenance management system model for the pharmaceutical industry in S.A.*
The research objectives of this study are:

- **RO1**: To identify best practices from the literature about maintenance management systems within organisations;
- **RO2**: To investigate the main maintenance management system problems being experienced at My Pharmaceuticals;
- **RO3**: To explore the good engineering practice guidelines for the pharmaceutical industry;
- **RO4**: To understand the regulatory controls that influences the maintenance management systems in the pharmaceutical industry;
- **RO5**: To develop an integrated maintenance management system model for My Pharmaceuticals;
- **RO6**: To evaluate an integrated maintenance management system model for My Pharmaceuticals.

### 1.5 Delimitation of the Research

The research will be limited to a pharmaceutical manufacturing company in the Port Elizabeth area namely My Pharmaceuticals. The departments, namely Production, Engineering, Validation and Quality Assurance, are those within the company that have direct influence on the maintenance management system. The scope of this study is limited to the employees within these departments.

### 1.6 Definitions of concepts

In order to provide a better understanding of the key concepts contained within this study, the following definitions and their meanings are provided.

#### 1.6.1 Assets

Assets are the physical resources of an organisation, such as equipment, machines, mobile fleet, systems or their parts and components, including software that performs a specific function or provides a service, sometimes referred to as physical assets (Gulati, 2009).
1.6.2 Maintenance

Maintenance is the routine, recurring upkeep required to keep facilities and equipment in a safe, effective condition enabling them to be utilised at original design capacity and efficiency or some other level specific by management as the maintenance objective (Kister & Hawkins, 2006).

1.6.3 Best Practice

Best practice is an idea which asserts that there is a technique, method or process that is more effective at delivering a desired outcome than any other technique, method or process. The idea is that with this technique, a project or an activity such as maintenance can be completed with fewer problems and unforeseen complications. A best practice, when implemented appropriately, should improve performance and efficiency in a specific area (Gulati, 2009).

1.6.4 Validation

Process validation is a comprehensive activity that comprises, among other things, a well-defined and well-designed set of tests and inspections on the overall process. This includes the facility, the equipment and procedures to verify that the process conforms to preset specifications and conditions and assures its ability to produce the final product to the desired quality characteristics (Aleem et al., 2003).

1.6.5 Good Engineering Practice (GEP)

Good Engineering Practices (GEPs) consist of proven and accepted engineering methods, procedures, and practices that provide appropriate, cost-effective, and well-documented solutions to meet user-requirements and compliance with applicable regulations. GEP underpins activities in the day-to-day operations and forward planning of a pharmaceutical business. The adoption of this methodology leads to a balance of expenditure and activity. In addition, GEP documentation can be used to support verification work (ISPE, 2009).

1.6.6 Standard Operating Procedure (SOP)

It is an authorised procedure that instructions be given in writing for performing operations, not necessarily specific to a given product or material (e.g. equipment operation, maintenance
and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation (Quality Assurance, 2010).

1.6.7 Overall Equipment Effectiveness (OEE)

According to Kister & Hawkins (2006), one of the fundamental measures of performance used in total productive maintenance (TPM) is overall equipment effectiveness (OEE) and can be formulated as follows:

\[ \text{OEE} = \text{Equipment Availability} \times \text{Performance Efficiency} \times \text{Rate of Quality} \]

1.7 Significance of the research

This research investigation aims to gain insight if an integrated maintenance management system model can be developed to improve the maintenance management system in the pharmaceutical industries.

The research will also be useful for:

- Pharmaceutical organisations that are revising their maintenance management systems;
- Pharmaceutical organisations that are beginning to implement a maintenance management system;
- Senior management, maintenance teams and group leaders who determine the implementation level and new areas of focus for maintenance improvement within the pharmaceutical industry.

1.8 Research methodology

The research methodology will address the research approach, data collection and data analysis.

1.8.1 Research approach

This study will be a qualitative research and will comprise a literature and a case study. Qualitative research seeks a better understanding of complex situations. It is typically used to answer questions about the complex nature of phenomena, often with the purpose of
describing and understanding the phenomena from the participant’s point of view (Leedy & Ormrod, 2001).

1.8.1.1 Literature study

The literature study was performed to establish the key concepts related to the topic of best practices for maintenance management systems as well as good engineering practices for the pharmaceutical industry. The information on this theory will be collected from secondary sources which include:

- Text books and other published materials which are directly related or indirectly related to the topic;
- On-line databases.

1.8.1.2 Case Study

In a case study, a particular individual, program or event is studied in depth for a defined period of time. Sometimes researches focus on a single case, perhaps, because its unique or exceptional qualities can promote understanding or inform practice for similar situations. A case study may be especially suitable for learning more about a little known or poorly understood situation (Leedy & Ormrod, 2001).

A case study for this particular research, will enable the researcher to collect data on the operations within My Pharmaceuticals and being an employee at the company, the researcher can spend an extended period of time on site and interact regularly with the people and departments that are being studied.

The empirical study consists of:

- Surveys (questionnaires) at My Pharmaceuticals.

The survey will enable the researcher to:

- Make direct contact with the management team, team leaders, team members and maintenance artisans within the various departments to establish their expectations of maintenance management systems;
- Observe the activities that support the assessment of the maintenance management system.

1.8.1.3 Preliminary Study

A preliminary study will be conducted to identify the problems in the current main maintenance management system at My Pharmaceuticals. These main problems will be discussed in Chapter 2.

1.8.2 Data Collection

The primary data was collected by means of questionnaires. The questionnaire used in this research was formatted according to the five-point Likert Scale that ranges from (1) Strongly Disagree to (5) Strongly Agree. A sample should be carefully chosen so that, through it, the researcher is able to see all the characteristics of the total population in the same relationship that they would be seen were the researcher, in fact, to impact the total population (Leedy & Ormrod, 2001).

1.8.3 Data analysis

All research requires logical reasoning, where qualitative research makes considerable use of inductive reasoning where many specific observations are made and then inferences are drawn about larger and more general phenomena (Leedy & Ormrod, 2001).

The data collected by the questionnaires will be analysed on an individual basis which means that each question will be handled separately, and conclusions and recommendations will be made individually.

1.9 Key assumptions

The key assumptions are that the literature study, combined with the results of the case study, will provide insight into the maintenance management systems being practised at My Pharmaceuticals and to identify areas for improvement.

It is therefore assumed the literature study, combined with the results of the case study, will provide insight into the assessment of the maintenance management system at My Pharmaceuticals and identify areas for improvement. It is also assumed that the management
of My Pharmaceuticals is committed and has motivated, involved and committed employees to make the necessary improvements.

1.10 Ethics clearance

The completed pro-forma for Ethics Clearance was submitted to the NMMU Business School, however, as there were no vulnerable groups involved in this study, full ethics clearance was not applied for.

1.11 Contents of the final report

The treatise is arranged as follows:

- Chapter 1 will outline the scope of the study, the problem statement, the objectives, key assumptions, methodology and the importance of the topic as well as provide a description of the approach, delimitations and the proposed chapter headings of the research treatise.
- Chapter 2 will provide a literature overview on the elements of maintenance management systems, which include the levels of maintenance, the types of maintenance, maintenance management process, maintenance planning and scheduling and staffing maintainability. The current main problems in the maintenance management system at My Pharmaceuticals will be explained in this chapter as part of a preliminary study. This chapter will address research questions RQ1 and RQ2 and research objectives RO1 and RO2.
- Chapter 3 will outline the best engineering guidelines for pharmaceutical industries and for the different departments that have an influence in the maintenance management system. This chapter will address research questions RQ3 and RQ4 and research objectives RO3 and RO4.
- Chapter 4 will outline a literature study on generic maintenance models and how the proposed integrated maintenance management system model was designed for My Pharmaceuticals. This chapter will address research question RQ5 research objective RO5.
- Chapter 5 will outline the research methodology, which includes the research paradigm, sampling design and measuring instruments.
Chapter 6 will present and discuss the results. This chapter will address research question RQ6 research objective RO6.

Chapter 7 will consist of conclusions and recommendations.

1.12 Summary

In this chapter, the researcher sketched the regulatory controls behind the pharmaceutical industry and questions the capability of the industry’s maintenance management systems. Key definitions and an overview of the construct of the research paper were also presented. In Chapter 2, a literature review of the relevant theory pertaining to research question RQ1 and research objective RO1 will be conducted. A preliminary study to answer research question RQ2 and research objective RO2 will also be conducted in Chapter 2.
Chapter 2

Maintenance Management Systems Best Practices and the Results of the Preliminary Survey

2.1 Introduction

An outline of the research paper was given in Chapter 1 where the researcher introduced the reader to the research questions and research objectives which need to be investigated. In Chapter 2 the research question RQ₁ and research objective RO₁ will be addressed which is to identify the best practices that the literature identifies about maintenance management systems within organisations. The chapter will also include a preliminary study that will be performed and explained. This will answer research question RQ₂ and research objective RO₂ which need to investigate the main problems being experienced in the maintenance management system at My Pharmaceuticals.

Past and current maintenance practices in both the private and government sectors would imply that maintenance is the actions associated with equipment repair after it is broken. Maintenance should be actions taken to prevent a device or component from failing or to repair normal equipment degradation experienced with the operation of the device to keep it in proper working order (O&M Best Practices Guide, Release 3.0., 2009).

Data obtained in many studies over the past decade unfortunately indicates that most private and government facilities do not expend the necessary resources to maintain equipment in proper working order. They would rather wait for equipment failure to occur and then take whatever actions are necessary to repair or replace the equipment. All equipment has associated with it some predefined life expectancy or operational life. For example, equipment may be designed to operate at full design load for 5,000 hours and may be designed to go through 15,000 starts and stop cycles (O&M Best Practices Guide, Release 3.0., 2009).

In order to develop an appropriate maintenance management system, maintenance must be considered holistically. Factors that describe the interrelations and interactions between the different systems as well as factors that describe the general organisational structure should be addressed (Panayiotou et al., 2009). In this chapter the concept of maintenance management
systems will be examined which includes the levels of maintenance in Section 2.6. The types of maintenance will be explained in Section 2.7 and the maintenance management process described in Section 2.9. The elements of a Computerised Maintenance Management System (CMMS) will be covered in Section 2.11 and staffing the organisation for maintenance explained in Section 2.12. Section 2.15 gives brief background information on My Pharmaceuticals where Section 2.15.2 identifies the current maintenance management system problems at My Pharmaceuticals.

2.2 The need for maintenance

The need for maintenance is predicated on actual or impending failure. Ideally, maintenance is performed to keep equipment and systems running efficiently for at least the design life of the component(s). As such, the practical operation of a component is a time-based function. If one were to graph the failure rate a component population versus time, it is likely the graph would take the “bathtub” shape shown in Figure 2.1. In the figure, the Y axis represents the failure rate and the X axis is time. The curve can be divided into three distinct sections: infant mortality, useful life, and wear-out periods.

Figure 2.1: Component failure rate over time for component population

![Component failure rate over time for component population](source)


The initial infant mortality period of bathtub curve is characterised by high failure rate followed by a period of decreasing failure. Many of the failures associated with this region are linked to poor design, poor installation, or misapplication. The infant mortality period is followed by a nearly constant failure rate period known as useful life. There are many theories why components fail in this region. Most acknowledge that poor operations and maintenance
(O&M) often play a significant role. It is also generally agreed from Figure 2.1 on the previous page, a component failure rate over time for component population, that exceptional maintenance practices encompassing preventive and predictive elements can extend this period. The wear-out period is characterised by a rapid increasing failure rate over time. In most cases this period encompasses the normal distribution of design life failures (O&M Best Practices Guide, Release 3.0., 2009).

Equipment failure or breakdown losses are a contributing factor of overall equipment effectiveness (OEE). OEE measures productivity of individual equipment in a factory. It identifies and measures losses of important aspects of manufacturing, namely, availability, performance and quality rate. This supports the improvement of equipment effectiveness and thereby its productivity (Muchiri & Pintelon, 2008).

Manufacturers in other industries have also embraced OEE to improve their asset utilisation (Muchiri & Pintelon, 2008). According to Bernstein (2005), OEE = availability rate × performance rate × quality rate where world class OEE is considered to be 85 percent. The availability rate expresses losses due to unplanned stoppages, the performance rate expresses losses due to machine performance lower than ideal, or standard, operating rates and the quality rate expresses losses due to rejects and reworks (Bernstein, 2005).

2.3 Maintenance policies

Each maintenance department should have, as a driving force, a document that states what the department wants to achieve. The maintenance policy describes, in broad terms, the direction in which the maintenance management team wants to steer the maintenance organisation. This policy should address every block (element) on the maintenance cycle diagram and it must state the company’s stand on each of these fundamental issues. This policy document is usually drawn up and revised annually by the maintenance management team (Coetzee, 1997).

2.4 Maintenance objectives

The maintenance management team should, on least an annual basis, maintain and update the maintenance department’s objectives. These should be based on, and should be in line with the framework as defined in the maintenance policy (Coetzee, 1997). The objectives should be developed by first doing an analysis of how well the maintenance organisation is already
performing in terms of the management team’s direction as set out in the policy document. The results of maintenance audits should also be reviewed at this time. After this, it should be no more than formality to set the objectives for the year ahead. In line with good management practices the objectives that must be achieved and the dates for achieving such results should be very specific (Coetzee, 1997).

2.5 Maintenance best practice

In real world applications, best practice according to Gulati (2009) is a very useful concept. Despite the need to improve on processes as times change and things evolve, best practice is considered by some as a business buzzword used to describe the process of developing and following a standard way of doing activities that any organisation can use or implement to obtain better results. Implementing best practice in the area of maintenance and reliability can help an organisation to (Gulati, 2009):

- Increase output with the same assets;
- Reduce the need for capital replacement;
- Reduce maintenance cost per unit;
- Reduce total cost per unit;
- Improve performance, cost, productivity and safety;
- Increase competitiveness;
- Increase market share.

2.6 Levels of maintenance

Maintenance levels pertain to the division of functions and tasks for each area where maintenance is performed. The establishment of maintenance levels evolves from the definition of system operational requirements, that is, the geographical distribution of the system components, performance factors, technology applications and requirements for system effectiveness and the anticipated frequencies of maintenance (Blanchard et al., 1995).

2.6.1 Organisation maintenance level

Organisational maintenance is accomplished on the prime elements of the system at the consumer’s operational site, for example on a manufacturing line or at the facility itself. Generally, it includes tasks performed by the using organisation on its own equipment by
personnel usually involved with the operation and use of the equipment and having minimum time available for detailed system maintenance. Maintenance at this level, normally, is limited to periodic checks of equipment performance, visual inspections, cleaning of equipment, some servicing, external adjustments and the removal and replacement of components (Blanchard et al., 1995).

2.6.2 Intermediate maintenance level

According to Blanchard et al. (1995), intermediate maintenance tasks are performed by mobile, semi-mobile and/or fixed specialised organisations and installations. At this level, end items, removed from the operating system, may be repaired through the removal and replacement of major modules, assemblies and/or piece parts. Scheduled maintenance requiring equipment disassembly may also be accomplished. Available maintenance personnel are usually more skilled and better equipped than those of the organisational level and are responsible for accomplishing more detailed maintenance.

2.6.3 Supplier, manufacturer, depot maintenance level

The supplier at depot level constitutes the highest type of maintenance and supports the accomplishment of tasks above and beyond the capabilities available at the intermediate level. Physically, this may be a specialised repair facility supporting a large number of systems, equipment or software in the inventory or it may constitute the manufacturer’s main plant. Depot facilities are “fixed” and mobility is not a problem. The supplier, manufacturer, depot level of maintenance includes the complete overhauling, rebuilding and calibration of equipment as well as the accomplishment of other highly complex maintenance actions (Blanchard et al., 1995).

2.7 Types of Maintenance

The design life of most equipment requires periodic maintenance. Belts need adjustment, alignment needs to be maintained, and proper lubrication on rotating equipment is required, and so on. In some cases, certain components need replacement, (e.g., a wheel bearing on a motor vehicle) to ensure the main piece of equipment (in this case a car) lasts for its design life. If maintenance is not carried out, as intended by the equipment’s designer, the operating life of the equipment is shortened. Over the last 30 years, different strategies on how
maintenance can be performed to ensure that equipment reaches or exceeds its design life have been developed in the United States. In addition to waiting for a piece of equipment to fail (reactive maintenance/corrective maintenance), preventive maintenance, predictive maintenance or reliability centred maintenance can be used (O&M Best Practices Guide, Release 3.0., 2009).

2.7.1 Corrective Maintenance

Corrective maintenance includes all unscheduled maintenance actions performed as a result of system or product failure to restore the system to a specified condition. The corrective maintenance cycle includes failure identification and verification (based on some symptom), localisation and fault isolation, disassembly to gain access to the faulty item, item removal and replacement with a spare or repair of the item in place, reassembly, checkout and condition verification (Blanchard et al., 1995).

2.7.2 Preventative Maintenance

Preventative maintenance includes all scheduled maintenance actions performed to maintain a system or product in a specified operational condition. Scheduled maintenance covers periodic inspections, condition monitoring, critical-item replacements (prior to failure), periodic calibration and the like. There are certain tasks of this type of maintenance that will result in system downtime, whereas other tasks can be accomplished while the system is operating or in standby status. Scheduled maintenance can be measured in terms of frequency, down time, where applicable, and labour hours (Blanchard et al., 1995).

2.7.3 Predictive Maintenance

Predictive maintenance often refers to a condition monitoring preventative-maintenance program where direct monitoring methods are used to determine the exact status of equipment for predicting possible degradation and for the purposes of highlighting areas where maintenance is desired. The objective is to predict when failures will occur and to take preventative measures accordingly. Various test methods like vibration signature analysis, thermography and tribology are used (Blanchard et al., 1995).
2.7.4 Reliability Centred Maintenance

Reliability Centred Maintenance (RCM) can be defined as:

“A process used to determine the maintenance requirements of any physical asset in its operating context” (Methods Apparel Consultancy India, 2001).

RCM methodology deals with some key issues not dealt with by other maintenance programs. It recognises that all equipment in a facility is not of equal importance to either the process or facility safety. It recognises that equipment design and operation differ and that some equipment will have a higher probability to undergo failures from different degradation mechanisms than others. It also approaches the structuring of a maintenance program recognising that a facility does not have unlimited financial and personnel resources and that the use of both needs to be prioritised and optimised (Methods Apparel Consultancy India, 2001).

RCM is a systematic approach to evaluate a facility’s equipment and resources how best to mate the two and achieve a high degree of facility reliability and cost-effectiveness. RCM is highly reliant on predictive maintenance but also recognises that maintenance on equipment, that is inexpensive and unimportant to facility reliability, may best be left to a reactive maintenance approach (Methods Apparel Consultancy India, 2001).

2.8 Availability, Reliability and Maintainability

Reliability and maintainability are performance characteristics that combine to determine availability and can be defined as follows:

- Reliability is the time between failures under planned operating conditions. It could be described as a period of continuous, trouble-free functioning.
- Maintainability is the time needed to maintain and return failed or shut down plant elements for service.
- Availability is the fraction, ratio or percentage of time that the plant, or its subsystems is physically able to perform (Lamb, 1995).

Reliability, similar to availability, involves equivalent concepts of probability. It is depicted as a probability distribution for time-to-failure or the need to shutdown the plant, a subsystem
or a piece of equipment. Defined operating conditions are the realm in which the probability distribution applies. If these change, so should the probability distribution (Lamb, 1995).

Maintainability is also a probability distribution. It is the probability that the plant, subsystem or piece of equipment can be restored to service in a period of time. Maintainability includes the expectation that the cost of maintenance tasks and their support requirements will fall within some range (Lamb, 1995).

Figure 2.2 provides a simple vision for how reliability, maintainability and availability are related. A plant, subsystem or equipment item will be able to operate for some period of time between down states. This is its characteristic reliability. It will then remain down for some interval of time as a function of its characteristic maintainability. Availability is a function of both reliability and maintainability characteristics (Lamb, 1995).

**Figure 2.2: Simple vision of the relationship of availability, reliability and maintainability**

![Diagram showing the relationship between availability, reliability, and maintainability](image)

**Source:** Lamb, 1995.

According to Lamb (1995), the relationship represented in Figure 2.2 between reliability, maintainability and availability is mathematical. The following equation applies the times for reliability and maintainability in the calculation of availability as a ratio, fraction or percentage of time:

\[
\text{Availability} = \frac{\text{Reliability}}{\text{Reliability} + \text{Maintainability}}
\]

**2.9 Maintenance Management Process**

The first step toward a formal maintainability process is to develop maintainability awareness at the corporate level. Management should become familiar with maintainability objectives,
methods, and concepts. After gaining a basic understanding of maintainability and its impact on the project, the management team can then establish the relationship of maintainability to overall business objectives (Meier & Russell, 2000).

In general terms, the Maintenance Management Process can be considered as having six phases, as illustrated below in Figure 2.3 and will be explained in the following sub-sections.

**Figure 2.3: Maintenance Process**

![Maintenance Process Diagram](source: Fore & Zuze, 2010)

2.9.1 Maintenance Work Identification

The first phase of the maintenance process as seen in Figure 2.3 in block A is work identification. Work order systems are crucial for successful maintenance management. A work order is the document used to collect all necessary maintenance information. Work orders should not be implemented by the maintenance department alone without regard for other parts of the organisation (Wireman, 1990).

According to Wireman (1990), maintenance would be the primary user of the work order. Maintenance requires information such as:

- What equipment the work needs to be performed on?
- What resources are required?
- A description of the work.
- Priority of the work.
- Date needed by.
Other information may be required, depending on the type of facility or plant in which the work order system is being used. The main point is, that the maintenance organisation must obtain the information needed for good management decisions. If the information cannot be obtained from the work order, it is unlikely that reliable information will ever be available from another source (Wireman, 1990).

Operations or facilities also need to give input into the work order process. They must be able to request work from maintenance easily. The work order system, whether manual or computerised, must be easy for the operations or facilities personnel to use. They should only be required to fill in brief information, such as (Wireman, 1990):

- Equipment requiring attention;
- Brief description of the request;
- Date needed;
- Requestor.

This information can then be used by a planner to complete the work request and convert it to a work order. Without accurate information, the preventative maintenance programs become guess work, so the engineering staff will need information such as:

- Mean time between failures (MTBF);
- Mean time to repair (MTTR);
- Cause of failure;
- Repair type;
- Corrective action taken;
- Date of repair.

Proper use of this information will enable the engineering staff to optimise the preventative maintenance program (Wireman, 1990).

2.9.1.1 Types of Work Orders

In any work order system, it is necessary to have several types of work orders. The most common are (Wireman, 1990):

- Planned and scheduled;
- Standing or blanket;
• Emergency;
• Shutdown or outage.

2.9.1.2 Planned and schedule work orders

Planned and schedule work orders are requested and screened by a planner. The resources are then planned, the work is scheduled, work information is entered in the completion process and the work order filed (Wireman, 1990).

2.9.1.3 Standing or blanket work orders

The types of jobs these work orders are written for are the five (5) to thirty (30) minute jobs such as resetting a circuit breaker or making a quick adjustment. These standing work orders are written against the equipment charge or against an accounting number (Wireman, 1990).

According to Wireman (1990), one problem with standing work orders is that people felt that they could be used like credit cards for charging time for the artisans that was not accounted for. This does happen occasionally, but when the chargers are closed out on the work order, offenders can be spotted.

2.9.1.4 Emergency or breakdown work orders

Emergency or breakdown work orders are generally written after the job is performed. Breakdowns require quick action and there is usually not enough time to go through the planning and scheduling of the work order. In most cases the artisan, the supervisor or production supervisor will make out the emergency work order after the job is completed (Wireman, 1990).

2.9.1.5 Shutdown or outage work orders

Shutdown or outage work orders are for work that is going to be performed as a project or when the equipment is shutdown for an extended period. These jobs are marked as outage or shutdown and should not appear in the regular artisan backlog. This work is still planned, ensuring that the maintenance resource requirements for the shutdown are known and ready before the shutdown begins (Wireman, 1990).
2.9.2 Maintenance Work Planning and Scheduling

The second and third phases of the maintenance process as seen in Figure 2.3 in block B and C (see page 19) are work planning and work scheduling respectively. One of the most important aspects in the design of a production system is the design of the maintenance subsystem which has the responsibility of keeping the physical plant in operating condition. The function of the maintenance system can be defined as the total process of planning, scheduling, organising and controlling the total maintenance operation to achieve optimum benefit of the cost of repair. The maintenance system, therefore, can be described as a production unit possessing many of the characteristics of a workshop. An essential part of maintenance planning and scheduling is to be able to forecast future orders and to balance work load between different categories (Worrall & Mert, 1980).

2.9.2.1 Maintenance Work Planning

Maintenance planning is the advance preparation of selected jobs so that they can be executed in an efficient and effective manner when the job is to be performed at some future date. It is a process of detailed analysis, first to determine and then to describe the work to be performed, by task sequence and methodology. This planning provides for the identification of all required resources, including skills, crew size, labour-hours, spare parts and materials, special tools and equipment. It also includes developing an estimate of total cost and it encompasses essential preparatory, post maintenance and restart efforts of both operations and maintenance (Kister & Hawkins, 2006).

2.9.2.2 Maintenance Scheduling

In its most simple meaning, maintenance scheduling is the matching of maintenance labour and materials resources to the requests for the maintenance labour and materials resources. However, if it were that simple, maintenance scheduling would not be listed as one of the major problems for maintenance managers. The flow of scheduling starts with good job plans, prioritising the work order, scheduling the work when resources are available and completing the work when scheduled (Wireman, 1990).
2.9.2.3 Integrating Maintenance Planning with Production Planning

Maintenance is the set of all activities meant to keep a system in a condition where it can perform its function. Quite often these systems are production systems. Some maintenance can be done during production and some can be done during regular production stops in evenings, weekends and on holidays. However, in many cases, production units need to be shut down for maintenance and this may lead to tensions between the production and maintenance departments of a company. On one hand the production department needs maintenance for the long-term well-being of their equipment and on the other hand it needs to shut these down in periods that could well be used for production (Budai et al., 2006).

The importance of the maintenance function has increased because of its role in keeping and improving system availability, safety and product quality. Indeed, a new role for maintenance exists to enhance the eco-efficiency of the product lifecycle. The concept of ‘lifecycle maintenance’ emerged to promote, at the manufacturing stage, an innovative culture wherein maintenance activities become of equal importance to actual production activities. This equivalence mainly requires considering the integration of maintenance and production strategy planning developing opportunistic maintenance tasks which conjointly preserve performance of product production equipment (Levrat et al., 2008).

The concept mainly requires considering the integration of maintenance planning into the production strategy planning in order to develop opportunistic maintenance tasks synchronised with production. An opportunity is usually defined as a moment (i) at which the units to be maintained are less needed for their function than normally, (ii) that occurs occasionally and (iii) that is difficult to predict in advance. These opportunities appear not only in the case of failure of other elements, but also at an interruption (or stoppage) of the production. Opportunistic maintenance is often criticised as not being ‘plannable’ long in advance and therefore no work preparation is possible. Moreover the length of the finite horizons considered is often much shorter than the lifespan of a component. It is admitted, however, that opportunistic maintenance can help save set-up costs and guarantee the expected performances of the system (Levrat et al., 2008).

According to Levrat et al. (2008), the definition of an opportunity explicitly encompasses the production planning, which is viewed as a constraint. The difference between joined
scheduling for maintenance and production and opportunistic preventative maintenance is that in the latter, production planning is not modeled as such, but occurs in the form of requirements for the maintenance strategy. It is now commonly admitted that integrating maintenance planning with production planning leads to time savings and cost savings. This integration with production is crucial because production and maintenance have a direct relationship. Any breakdown in machine operation results in disruption of production and leads to additional costs due to downtime, loss of production, decrease in productivity and quality, and inefficient use of personnel, equipment and facilities (Levrat et al., 2008).

If maintenance tasks are performed during the stoppages planned by the production department, such as those for cleaning, shift, batch or tool changes, then the time spent on performing these maintenance tasks can be used to assess savings on maintenance. If, however, these maintenance tasks are not performed in conjunction with the production department’s planned stoppages, failures could occur during planned production time. The more maintenance tasks are performed during planned stoppages, the more savings can be achieved (Levrat et al., 2008).

2.9.3 Maintenance Work Execution

The fourth phase of the maintenance process as seen in Figure 2.3 in block D (see page 19) is work execution. Effective control of the maintenance work execution function depends upon clear accountability for each type of demand placed upon the organisation. The three principal types of demand are routine or preventative, emergency and planned work. The most common structure is composed of three major operating groups dedicated to each of the three principal types of demand. The basic concept of this structure is the establishment of two minimally sized crews to meet the routine and emergency demands and a larger third group devoted to planned maintenance (Kister & Hawkins, 2006):

a) The routine or preventative maintenance group is responsible for the performance of all management approved routine tasks in accordance with detailed schedules and established quality levels. Their work,

- Is specifically designed;
- Is performed according to a known schedule;
- Is performed in planned pattern;
- Involves a consistent work content;
- Requires a predictable amount of time.

The group is not interrupted by emergencies or backlog and thereby protects the integrity of the preventative maintenance schedule.

b) The emergency group has the responsibility of handling essentially all emergency demands, using assistance only when necessary. This allows the planned maintenance group to apply their labour resources to backlog relief.

c) The planned maintenance group is responsible for all work other than emergency and routine. The group is divided into two crews, one covering work performed primarily in the workshops and the other covering work performed in the field (Kister & Hawkins 2006).

2.9.4 Maintenance History Recording

The fifth phase of the maintenance process as seen in Figure 2.3 in block E (see page 19) is history recording. Maintenance history for specific equipment is one of the foundation elements of maintenance management. It is essential for the refinement of the preventative or predictive maintenance program. It is also the primary tool of reliability engineering to evaluate and analyse the current program in order to direct necessary refinements. Equipment history also supports the information needs of engineering, operations, accounting and other members of maintenance (Kister & Hawkins 2006).

Meaningful and readily usable history of retrievable equipment is dependent upon a thorough, intelligent and consistently used equipment-numbering system. Equipment history systems that are properly designed and effectively administered facilitate (Kister & Hawkins 2006):

- Identification of equipment requiring abnormally high levels of maintenance;
- Analysis of maintenance history for high maintenance equipment to identify specific repetitive failures to which engineering discipline should be applied. To determine how equipment or instrumentation might be modified to reduce premature equipment failures, frequency of repetitive failures and the general level of required maintenance;
- Comparison of equipment maintenance costs with replacement costs as a tool in capital planning;
Justification and refinement of the preventative maintenance program.

Equipment maintenance history is primarily the result of data generated from completed work orders. The maintenance management information system (CMMS) should contain the capability to generate, on demand, the history of work order activity for any piece of equipment to which unique identification has been assigned. To provide for the accumulation of equipment history, it is necessary to establish a reference (numbering) system to identify processes, equipment, components, instrumentation loops devices, etc., for which it is believed that history would be useful (Kister & Hawkins, 2006).

2.9.5 Maintenance Analysing

The sixth phase of the maintenance process as seen in Figure 2.3 in block F (see page 19) is analysis. The failure mode, effects and criticality analyses (FMECA) is a design technique systematically to identify and investigate potential system (product or process) weaknesses. It consists of a methodology for examining all the ways in which a system failure can occur, potential effects of failure on system performance and safety and the seriousness of these effects. The FMECA consists of two distinct analyses, namely the failure mode and effect analysis (FMEA), which is then extended to analyse failure mode critically, called critically analysis (CA) (Blanchard et al., 1995).

2.9.5.1 Selecting a FMCEA method

Many methods of failure analysis can be identified. The most common is the tabular method. Fault-tree analysis is another form. The point is that a method must be selected to fit the subject project, organisation and other initiatives (Lamb, 1995).

a) Accomplishing functional analysis

Functional analysis involves defining the system in functional terms. System functionality is clearly delineated using a symbolic representation such as functional flow diagram (Blanchard et al., 1995).
b) Identify failure modes

The manner in which the system element fails to accomplish its function is called a failure mode. For example, a switch fails in “open” position, a pipe ‘ruptures or “shears” due to stress. This is true whether the focus of the analysis is a process or a piece of equipment (Blanchard et al., 1995).

c) Determine the causes of failure

This involves analysis of the process or product in order to delineate the cause(s) responsible for the occurrence of any particular failure. While experience with similar systems is a definite “plus” in the analysis process, techniques such as Ishikawa’s cause and effect diagram, also called the “fishbone diagram,” can prove to be highly effective in delineating potential causes responsible for a failure (Blanchard et al., 1995).

d) Determine the effects of failure

Failures impact, often in multiple ways, the performance and effectiveness of not only the associated functional element but the overall system. When conducting a FMECA, it is important to consider the effects of failures on the next higher level functional entity along with the impacts on the overall system (Blanchard et al., 1995).

e) Rating the severity of a failure mode

This task is to rank the consequences of each failure according to its category. One method is to develop a multidimensional index, which is a composite of the following factors;

- The severity of the consequences;
- The probability of their occurrence;
- The ability to detect the failure in advance;

Severity ranking must be developed as a classification system for the subject plant. An example of ranking is as follows (Lamb, 1995):

- Results in a death or loss of the system;
Results in an injury or in the loss of the system to short and longer term production cycles;
- Results in a minor injury or in the damage of a subsystem. The latter will reduce the plant’s capacity to produce;
- Significantly reduces the short term probability of using the specified availability.

2.10 The need for spares management

Spares management includes all spares (repairable units, assemblies, and modules), repair parts (non-repairable components and piece parts), consumables (lubricants, fuels and gases), special supplies and related inventories needed to support the prime operating equipment, test and support equipment, transportation and handling equipment, training equipment, facilities and software (Blanchard et al., 1995).

Excessive levels of inventory may ideally respond to the demand for spares. However this may not be a cost effective solution and a significant amount of capital may be tied up in maintaining inventories. Further, losses may result from system design changes that render certain components obsolete and no longer required. Providing too little support, on the other hand, may result in frequent stock-outs, shortage costs and possible penalties (Blanchard et al., 1995).

Some of the relevant terms identified are defined as follows (Blanchard et al., 1995):

- Operating level – denotes the material item quantity required to support normal system operations in the interval between orders and successive material shipment arrivals;
- Safety stock – refers to additional stock required to compensate for unexpected demands, repair and recycle times, pipeline, procurement lead time and unforeseen delays;
- Reorder cycle – is the time interval between successive orders;
- Procurement lead time – denotes the time span between the date of the material order to receipt of the shipment in the inventory;
- Pipeline – reflects the distance between the supplier and consumer, measured in days of supply. An increase in the demand rate may require more items in the pipeline;
• Order point (OP) – is the point in time when orders are initiated for additional spare and repair parts. This point is often tied to a particular stock level and will likely be different for different times.

The right time to decide what parts and material should be stocked and in what quantity is before placing an asset or system into service. The manufacturer of the assets and systems usually provides a recommended list of spare parts (Gulati, 2009).

2.10.1 Inventory accuracy

Gulati (2009) states that achieving a high level of inventory accuracy is a critical factor in the success of store room operations. Accurate inventory is defined as the actual quantity and types of parts in the right location in the storeroom matching exactly what is shown on the inventory system in the computerised maintenance management system (CMMS). Inventory accuracy is important for several reasons. Achieving a high level of inventory accuracy requires ensuring the following (Gulati, 2009):

• All parts and materials received against a purchased order should be recorded in an inventory system or CMMS;
• Additional information regarding parts specific data, such as manufacturer’s number, serial number, lot size, cost and shelf life, should be recorded in the system;
• All parts and materials issued to a work order should be recorded accurately along with the employee name, number, equipment and projects;
• All parts and materials not used after a repair should be returned and recorded in the system and put back in the right location.

The consequences of inaccurate inventory are (Gulati, 2009):

• If the part is not found in the location indicated in the CMMS records, the repair cannot be completed on time, thus delaying the asset availability for operations;
• An out-of-stock condition can occur because parts were not ordered on time if the actual quantity is lower than the system record;
• If the system record number is lower than the actual inventory record, then the parts will be flagged for re-order by the system, even if not required, resulting in unnecessary inventory;
- Maintenance and operations will lose confidence in the inventory system, CMMS and in stores management. This situation can encourage proliferation of stock items stored in technicians’ tool boxes or floor cabinets.

2.11 Computerised Maintenance Management System (CMMS)

Without computer-assisted prompts, operators carry out unnecessary preventative routines or leave them till too late. The prompts might come from sensors - condition monitoring systems on pumps or gearboxes warning of machine wear – from counters recording the number of hours or cycles worked, or from an enterprise resource planning (ERP) system that spotted a gap in the production schedule. While manual asset registers often include plant that is no longer used and may miss recently acquired items, CMMSs maintain accurate asset registers, not just for a plant, but for an enterprise. They allow managers to schedule the people, tools and materials for keeping the assets in good order and to manage, usually on line, a spares purchasing function usually larger than production's requirement for raw materials or components (Dwyer, 2006).

2.11.1 The need for CMMS

As in almost every sphere of organisational activity, modern computational facilities have offered dramatic scope for improved effectiveness and efficiency. Maintenance is one area in which computing has been applied, and CMMSs have existed, in one form or another, for several decades. The software has evolved from relatively simple mainframe planning of maintenance activity to Windows-based, multi-user systems that cover a multitude of maintenance functions. The capacity of CMMSs to handle vast quantities of data purposefully and rapidly has opened up new opportunities for maintenance, facilitating a more deliberate and considered approach to managing an organisation’s assets (Labib, 2004).

The CMMS is now a central component of many companies’ maintenance departments, and it offers support on a variety of levels in the organisational hierarchy which are as follows (Labib, 2004):

- It can support condition based monitoring (CBM) of machines and assets, to offer insight into wear and imminent failures;
- It can track the movement of spare parts and requisition replacements when necessary;
- It allows operators to report faults sooner, thus enabling maintenance staff to respond to problems more quickly;
- It can facilitate improvement in communication between operations and maintenance personnel, and is influential in improving the consistency of information passed between these two departments;
- It provides maintenance planners with historical information necessary for developing PM schedules;
- It provides maintenance managers with information in a form that allows for more effective control of their department’s activities;
- It offers accountants information on machines to enable capital expenditure decisions to be taken;
- It affords senior management a crucial insight into the state of asset healthcare within their organisation.

2.11.2 CMMS data support

The most important part of ensuring complete and accurate CMMS data is getting support for the system. If there is no “buy-in” from those involved with maintaining the system and from top management, the CMMS is destined for failure. Top management and users should be educated on how CMMS paints an accurate picture of where time and money is being lost or saved in a maintenance department, helping target areas where efforts, such as RCM analysis, should be focused. In addition, they should understand that CMMS is one of the few investments that keeps paying back year after year through the automation of manual processes such as generating PMs and reports, procuring stocked parts, locating parts, gathering part information, building work order history etc. (CMMS Data Group, 1997).

A company also must understand that, in addition to the initial investment of the CMMS, additional resources such as time, training, and additional staff are needed to gain maximum value from the system. The most common failure of maintenance software is purchasing the software and not committing sufficient time and resources to the planning, implementation, and full execution of it. Oftentimes, the success of CMMS is assigned to just one person. That person is made responsible for the selection, planning, implementation, data collection, data entry, data analysis, and maintenance of the CMMS. If this is the case, the person and the CMMS have been set up for failure. A group effort is needed to support the CMMS and
ensure its success. Tools and strategies need to be engaged that send out a message to the organization that top management supports the CMMS and that it is a priority (CMMS Data Group, 1997).

2.11.3 Current deficiencies in existing off-the-shelf CMMSs

According to Labib (2004), companies consume a significant amount of management and supervisory time compiling, interpreting and analysing the data captured within the CMMS. Companies then encounter difficulties analysing equipment performance trends and their causes as a result of inconsistency in the form of the data captured and the historical nature of certain elements of it. In short, companies tend to spend a vast amount of capital in acquisition of off-the-shelf systems for data collection and their added value to the business is questionable.

All CMMS systems offer data collection facilities, more expensive systems offer formalised modules for the analysis of maintenance data, the market leaders allow real time data logging and networked data sharing. Yet, despite the observations made above regarding the need for information to aid maintenance management, virtually all the commercially available CMMS software lacks any decision analysis support for management (Labib, 2004).

Lack of decision support is a definite problem, because the key to systematic and effective maintenance is managerial decision making that is appropriate to the particular circumstances of the machine, plant or organisation. This decision-making process is made all the more difficult if the CMMS package can only offer an analysis of recorded data. As an example when a certain preventive maintenance (PM) schedule is submitted to a CMMS, say to change the oil filter every month, the system will simply produce a monthly instruction to change the oil filter. In other words it is no more than a diary (Labib, 2004).

A step towards decision support is to vary the frequency of PMs depending on the combination of failure frequency and severity. A more intelligent feature would be to generate and to prioritise PMs according to modes of failure in a dynamic real time environment. PMs are usually static and theoretical in the sense that they do not reflect shop floor realities. In addition, the PMs that are copied from machine manuals are not usually applicable because of the following (Labib, 2004):
Each machine works in a different environment and would therefore, need different PMs;

Machines designers often do not have the same experience of machines failures, and means of prevention, as those who operate and maintain them;

Machine vendors may have a hidden agenda to maximise replacements of spare parts through frequent PMs.

2.11.4 Standard Operating Procedures (SOP) for CMMS

The best way to ensure that desired data is properly collected and entered into a CMMS is by the use of standard operating procedures (SOPs). SOPs increase process efficiency by reducing variation, clearly stating what the procedure is and the policy how the procedure is to be carried out. Variation can be detrimental to operations because it leads to waste and unnecessary cost. Once an SOP has been created, it can be perfected over time to further minimise variation. In addition, SOPs ensure efficient training and quality control (CMMS Data Group, 1997).

SOPs need to be established for all CMMS work processes to ensure that complete and accurate data exists in the CMMS. Complete and accurate CMMS data is needed so that accurate analyses and decisions can be made to achieve business goals and objectives. An SOP that has the greatest impact on the ability to select the highest value candidates for RCM analysis using CMMS data is one that states the following (CMMS Data Group, 1997):

- No work is to be performed without a work order;
- All work order information is to reside in the CMMS.

The SOP will ensure that 100 percent of all maintenance activity is tracked in the system. Tracking 100 percent of all work performed paints an accurate and clear picture of what is being done to maintain a plant. The more accurate tracking is, the better any analysis will be. If specific data is needed to ensure that a goal is met, an SOP must be created to support that goal (CMMS Data Group, 1997).

2.12 Staffing the Organisation for Maintainability

In overall reporting schemes, it is important for the operations, engineering and maintenance managers to report to the same individual, as indicated in Figure 2.4 (see page 34). Since all
three groups are reporting to the same level, the necessary, balanced input for the plant management to make decisions is provided. For example, if the maintenance department needs equipment for preventative maintenance or needed repairs and operations want to continue running the equipment instead of offloading the production to some other equipment, management can hear both sides and make the appropriate decision. If maintenance reports to operations, plant management may never hear how important the repairs are and when the equipment does fail, the maintenance organisation is blamed unfairly (Wireman, 1990).

**Figure 2.4: Maintenance/plant organisational arrangements**

![Organisational chart](image)

**Source: Wireman, 1990.**

An organisation constitutes the combining of resources in such a manner as to fulfil some specific need. Organisations involve a group of individuals of varying levels of expertise combined into a social structure of some type to accomplish one or more functions within the maintenance structure. Organisational maintenance structures vary with the functions to be performed and the results depend on the established goals and objectives, the resources available, the communications and working relationships of the individual participants, personnel motivation and many other factors (Blanchard *et al.*, 1995).

If the workforce (Gulati, 2009) is not adequately prepared and trained to do a job right, variation and defects will be introduced. New skills are required to keep up with changes in materials, products and services. A well developed training program based on a job task analysis and maintenance skills assessment can provide solution to inadequate maintenance skills availability. The training must be focused to produce results quickly as possible and must also meet an organisation’s long term goals. Maintenance training, when developed and implemented properly can help organisations to save money, increase productivity and product quality and improve employee morale (Gulati, 2009).
2.12.1 Maintainability Engineer

An entry level Maintainability Engineer should have the following (Blanchard et al., 1995):

- A basic formal education in some recognised field of engineering, that is, a baccalaureate degree in engineering or its equivalent;
- An understanding of the overall design process (and the system life cycle) as it applies to the systems and products being developed by the company;
- An understanding of the system engineering process and the methods and tools that can be effectively utilised in bringing a system or product into being;
- An understanding of the relationships among functions, including marketing, contract management, purchasing, system engineering, electrical engineering, mechanical engineering, reliability engineering, human factors, configuration management, production (manufacturing), quality control, customer and supplier operations.

2.12.2 Maintenance Supervisors

Although the Maintenance Supervisor should have done an apprenticeship or have some engineering training in the industry he or she is working in, the following job description is applicable (Wireman, 1990):

- Motivating the artisans/craft technicians that they are ready to perform their job each day by using good management skills;
- Responsible for determining who works on each job by matching the job to the skill level of the artisan/craft technicians;
- Responsible for coordination and follow-up of each job performed by the artisan/craft technicians;
- Responsible for the safety and quality of the job by being out with the artisans/craft technicians;
- Responsible for the hiring, firing and pay reviews of the employees assigned to his/her supervision and must have been trained properly to do so;
- The supervisor must be technically competent to recommend improvements and cost reductions and have a basic understanding of the engineering principles involved in the design of the equipment being maintained;
• Responsible in identifying the causes of failures or repetitive breakdowns;
• Recommending the necessary skills and training programs for the artisans/craft technicians by knowing what they can do and what they cannot do.

2.12.3 Artisans/Technicians

Artisans and technicians should generally have an educational level of at least standard 8 (grade 10) or N1, while preference should be given to artisans/technicians with an educational level of standard 10 (grade 12) or N3 or higher (Coetzee, 1997).

2.12.4 Maintenance Planner

According to Kister & Hawkins (2006), the Maintenance Planner must have the requisite personal skills as well as professional skills derived from experience and thorough, comprehensive training in order to execute “professional” maintenance planning. When these attributes are in place, the effective utilisation of maintenance personnel can be increased by as much as 65 percent and job execution time can be reduced by as much as 40 to 50 percent as indicated in Figure 2.5 (see page 37).

2.12.4.1 Principles of the planner

The listing that follows might be referred to as principles for the planner to strive for in his or her day to day planning activities (Kister & Hawkins, 2006):

• Understand the department’s mission in relation to the objectives of the company;
• Always be aware of the magnitude and trend of backlog;
• Quantify effectively the resources available for relief of the backlog;
• Establish a plan for the allocation of available resources to a balanced workweek, considering both long-range importance and short-range necessity;
• Categorise work consistent with planned resource allocation categories;
• Assign a planning priority to each job;
• Break each job into logical sequence tasks or activities;
• Prepare a “Planning Week” schedule, by phases of work planning and by task, to determine progress toward completion of each week’s work planning;
• Work to meet this schedule. Protect it. Do not superimpose new work unless that new work represents an overriding course of action for work planning;
To measure progress and contribution.

Figure 2.5: Professional Planning

<table>
<thead>
<tr>
<th>Planning activity</th>
<th>Work activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Job ‘A’ planned and worked “on the run”</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Planning activity disorganised. As obstacles are encountered, planning is segmented. Frequent work interruptions and restarts. Total job duration excessive</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Planning activity</th>
<th>Work activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Job ‘A’ “professionally” planned and then worked</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Planning activity organised, performed up-front and professionally. Few, if any, work interruptions and restarts. Total job duration minimised.</td>
<td></td>
</tr>
</tbody>
</table>

Source: Kister & Hawkins, 2006

2.13 Maintenance audits

A formal audit of the department should be done, at least, on an annual basis. This includes both hard and soft audits. The hard audit consists of a proper inspection of the plant, using a well-defined checklist and scoring mechanism. The soft audit on the other hand audits the department’s management and technical systems ability to ensure long term achievements and retention of the results required by the policy and objectives (Coetzee, 1997).

If the maintenance function in the organisation achieves its goals in achieving a high level of maintenance performance this will help assure high levels of plant profitability. If on the other hand the performance of the maintenance function is poor, then the effect on the plant profitability can be devastating due to high levels of downtime and high maintenance costs and if the department does not start measuring the performance of the maintenance function, through a proper audit, performance improvements cannot be realised. It is only through the knowledge of present performance levels afforded by the auditing process, that insight can be developed regarding the future directions for improvement (Coetzee, 1997).
2.14 Literature summary

In the first part of this chapter the definition of maintenance management systems was explained. It was determined, that to analyse any maintenance management process, the current system should be looked at holistically by taking into account the levels of maintenance, the different strategies, the maintenance process, work planning and scheduling, maintenance analysing, spares management, the computerised maintenance management system in place (CMMS) and the staffing required. Also highlighted in this chapter, was that a proper maintenance management system contributes directly to the overall equipment effectiveness (OEE) where availability, performance and quality rate is measured. This first part of the chapter answered research question RQ1 and research objective RO1 which was to identify the best practices that the literature identifies about maintenance management systems within organisations.

The second part of this chapter is to identify what main maintenance management system problems does My Pharmaceuticals experience. In order to accomplish this, a preliminary study was performed. The open-ended questions in the questionnaire (Annexure 1) of this preliminary study included elements from the best practice literature in Chapter 2 and was handed to a small sample (n=12) within the company. The findings will be identified and explained in this second part of the chapter to answer research question RQ2 and research objective RO2 which is to investigate the main maintenance management system problems being experienced at My Pharmaceuticals.

2.15 My Pharmaceuticals

My Pharmaceuticals is a supplier of branded and generic pharmaceuticals in approximately 100 countries across the globe and of consumer and nutritional products in selected territories. The company has production capabilities for a wide variety of product types including tablets, capsules, steriles, injectables, oral contraceptives, penems, nutritional products, lyophilised vials, cytotoxics, suppositories, vials, form-filled seals, liquids, semi-solids and specialist, active pharmaceutical ingredients. These products are developed under the direction of highly skilled scientists employed by My Pharmaceuticals and in collaboration with other global pharmaceutical companies and research facilities.
2.15.1 Port Elizabeth site

My Pharmaceuticals’ primary manufacturing site, based in Port Elizabeth, is the largest on the continent and employs significant expertise in its manufacturing facilities. This long established site is the leading producer of tablets and capsules in South Africa. This site comprises three GMP compliant facilities, namely, two (2) Oral Solid Dose (OSD) Facilities (Unit 1 and Unit 2) and the General Facility (GF). The company also has off-site stores which warehouse the raw materials and finished goods. Manufacturing facilities also comply with the regulatory requirements of the various domestic and export markets into which products are supplied. The company has been transformed from a domestic producer into a manufacturer with the capacity and capability to supply various dosage forms to almost any market in the world.

The Engineering department consists of a senior engineering manager, maintenance managers, maintenance artisans, maintenance planners and data administrators. The different departments within engineering are Electrical Services, Mechanical Services, HVAC, Calibration and Production Maintenance. Some of the maintenance activities are performed by outside contractors as well.

A preliminary study was conducted to identify the main maintenance management system problems currently being experienced at My Pharmaceuticals. This was achieved by means of handing out an open-ended questionnaire (Annexure 1) to the maintenance, production, quality assurance and validation personnel within My Pharmaceuticals.

2.15.2 Current maintenance management system problems

The preliminary study questionnaire (Annexure 1) contains questions to identify the main problems of the maintenance management system strategy at My Pharmaceuticals. These questions are derived from the literature presented earlier in this Chapter. The questionnaire makes provision for the respondent to express general problems that may be experienced with the maintenance management system.

The questionnaire was presented to the different departments within My Pharmaceuticals namely the Engineering, Validation, Quality Assurance and Production departments. This was done to obtain a holistic view of the main maintenance management system problems. A
summary of the problems that were identified are listed in Table 2.1 and are discussed in the following sub sections.

Table 2.1: Main maintenance management system problems at My Pharmaceuticals

<table>
<thead>
<tr>
<th>Problem</th>
<th>Main Problems</th>
<th>Percentage agree n = 12 (all departments)</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>There is a lack of maintenance and production planning integration</td>
<td>83%</td>
<td>Maintenance Work Planning and Scheduling</td>
</tr>
<tr>
<td>P2</td>
<td>There is no understanding between Engineering, Validation, QA and Production on the importance of maintenance and periodically validation reviews</td>
<td>50%</td>
<td>Process Validation</td>
</tr>
<tr>
<td>P3</td>
<td>Predictive maintenance is not being practised</td>
<td>75%</td>
<td>Performing Types of Maintenance</td>
</tr>
<tr>
<td>P4</td>
<td>Reliability Centred Maintenance is not being practised</td>
<td>75%</td>
<td>Performing Types of Maintenance</td>
</tr>
<tr>
<td>P5</td>
<td>Poor senior management interaction</td>
<td>50%</td>
<td>Maintenance Management Process</td>
</tr>
<tr>
<td>P6</td>
<td>There are 2 CMMS systems/databases for one central engineering department</td>
<td>58%</td>
<td>The need for a CMMS</td>
</tr>
<tr>
<td>P7</td>
<td>There is no proper spares management system</td>
<td>66%</td>
<td>The need for Spares Management</td>
</tr>
<tr>
<td>P8</td>
<td>There is a lack of training of Eng Staff in the latest technology</td>
<td>50%</td>
<td>Staffing the Organisation for Maintainability</td>
</tr>
<tr>
<td>P9</td>
<td>There is a lack of understanding of equipment that are validated and no clear process of when change controls and deviations are needed.</td>
<td>75%</td>
<td>Pharmaceutical Systems Maintenance Strategies</td>
</tr>
<tr>
<td>P10</td>
<td>There is no value adding maintenance analysis performed on maintenance data.</td>
<td>50%</td>
<td>Maintenance Analysis</td>
</tr>
</tbody>
</table>

2.15.2.1 Problem P1 - Maintenance Work Planning and Scheduling

A total of 83 percent of the respondents identified that there is no integration between maintenance and production planning at any level. Production plans are planned for the year ahead, but change constantly if targets are not met. Engineering tries to gain access to the machines to perform maintenance in this tight production schedule and sometimes the work orders have to be superseded and cancelled until the next schedule is due.

The end of the year shutdown is also indefinite as production will only shutdown if all the production targets are met for the year and engineering may be allocated two to three weeks for maintenance. This has many constraints as, even though the engineering team plan to do major maintenance during this period, they will not know when the actual shutdown dates are until the last few days before shutdown. Another problem is that not all contractors are available at the end of the year as they close for the holidays. Most of the maintenance tasks require complete strip-down of machines which is not possible in the two or three weeks given especially since there is no predetermined date. This causes engineering to be cautious and not to take chances to do major overhauls.
2.15.2.2 Problem P2 – Process Validation

A lack of understanding of the importance of maintenance and validation reviews between the different departments namely Engineering, Production, Validation and Quality Assurance exists as 50 percent of the respondents have identified. The perception is that the Engineering department do not understand the importance of validation and quality assurance roles in equipment installation qualification, operational qualification and performance qualifications and when Validation and Quality Assurance departments perform equipment reviews, they do not understand the dynamics of engineering maintenance and the constraints that exist. Production does not understand the importance of maintenance and the intervals needed for scheduled work.

2.15.2.3 Problem P3 and P4 - Performing Types of Maintenance

There are 75 percent of the respondents that identified that the Engineering department does not perform predictive and reliability centred maintenance (RCM), only preventative and corrective maintenance is performed. Preventative maintenance is performed on equipment at different intervals predetermined by the CMMS. Corrective maintenance is performed when repair work is required. This corrective maintenance work can stem from follow-up work required from the scheduled work or breakdown work that is required on site.

2.15.2.4 Problem P5 - Maintenance Management Process

A total sum of 50 percent of the respondents have indentified that there is poor senior management involvement and guidance when indentifying the maintenance policy. There is no buy-in from top management to set out maintenance objectives.

2.15.2.5 Problem P6 - The need for a CMMS

To have two CMMS databases is a problem as identified by 50 percent of the respondents. The company has two identical CMMS databases. The one database has the Unit 1 facility’s assets loaded while the other database has Unit 2, GF and the offsite assets loaded. The reason for this was that the engineering departments were decentralised where each facility had its own engineering department with its own structures and procedures.
The Engineering department has now been centralised, but there are still two CMMS databases being controlled by one planning department. There is no link between the databases which makes reporting and analysis difficult especially when the same artisans are working in the different units.

2.15.2.6 Problem P7 - The need for Spares Management

There are 66 percent of the respondents that identified that there is no proper spares management system in the company. My Pharmaceuticals does not have inventory loaded onto the current CMMS. The inventory is managed by a finance system which does not make allowance for inventory reports. There is no integration between this finance system and the CMMS. The company struggles to obtain accurate inventory reports within the stores. This also makes having a complete maintenance costing and budgeting on maintenance activities a problem.

2.15.2.7 Problem P8 - Staffing the Organisation for Maintainability

Lack of training of maintenance staff in the latest technology of process equipment is a problem as 50 percent of the respondents have identified. The pharmaceutical industry has integrated machines that are technology advanced and if the maintenance staff is not equipped by training in the latest technology then this lack of training impacts negatively on breakdowns and overall equipment efficiency (OEE).

2.15.2.8 Problem P9 - Pharmaceutical Systems Maintenance Strategies

There are 70 percent of the respondents that have identified that there is a lack of understanding of equipment that is validated and there is no clear process when change controls and deviations are needed. The Validation department does periodic reviews on equipment to make sure that it is still in its validated state, but there are constant irregularities with the maintenance performed on the equipment. Irregularities such as changes made to equipment without consulting Validation or Quality Assurance about the change and the impact the change has had.
2.15.2.9 Problem P10 - Maintenance Analysing

Half of the respondents (50 percent) have identified that there is no value-adding maintenance analysis performed on maintenance data. The Engineering department does not perform failure mode, effects and criticality analyses (FMECA) on equipment historical data.

2.15.3 Problem conclusion

The maintenance management system is a set of all the elements combined to keep the system in a condition where it can perform its function. In this case the maintenance function is a combination of standard maintenance and pharmaceutical maintenance best practices. The preliminary questionnaire revealed ten (P1-P10) main problems in the maintenance management system within the company identified by the different departments. These main problems were categorised by the maintenance management system elements that were discussed in Chapter 2 and with the relevant experience of the researcher in the industry.

2.16 Summary

The research question RQ₁ and research objective RO₁ was to identify best practices from the literature about maintenance management systems within organisations was answered in this chapter. The research question RQ₂ and research objective RO₂, which was to investigate the main problems in the maintenance management system being experienced at My Pharmaceuticals, was answered as well. In Chapter 3, the good engineering practice guidelines for the pharmaceutical industries are identified and how pharmaceutical equipment qualifications are performed within the industry.
Chapter 3

Pharmaceutical Industry Good Engineering Practice Guidelines and Regulatory Controls

3.1 Introduction

In Chapter 2, a literature summary was conducted to explain the maintenance management system best practices. This was done by taking into account the different concepts of maintenance management systems within organisations. A preliminary study was also conducted in Chapter 2 to investigate the main problems in the maintenance management system being experienced at My Pharmaceuticals. In this chapter, the research question RQ3 and research objective RO3 will be addressed, which is to identify the good engineering practice guidelines for pharmaceutical organisations. The chapter will also address the research question RQ4 and research RO4 which is to understand the regulatory controls that influence the maintenance management systems in the pharmaceutical industry.

The Food and Drug Administration (FDA) expects appropriate current good manufacturing practices (cGMPs) to be applied to all steps of an active pharmaceutical ingredient (API) manufacturing process, beginning with the use of starting materials. Such practices include the validation of processes determined to impact the quality and purity of the API. The agency recognises that the stringency of cGMPs in API production, such as the extent of written instructions, in-process controls, sampling, testing, monitoring and documentation, should increase as the process proceeds from early steps to final synthesis and purification stages (Food and Drug Administration, 1998).

Any building and machines used in the manufacture, processing, packing, or holding of APIs and intermediates should be properly maintained and repaired. Written procedures should be established and followed for cleaning and maintaining equipment, including utensils and storage vessels, used in the manufacture, processing, packing, or holding of APIs and intermediates. Procedures should, at a minimum, include (Food and Drug Administration, 1998):

- Assigning responsibility for cleaning and maintaining equipment;
Establishing maintenance and cleaning schedules, including, where appropriate, sanitising schedules;

Developing a complete description of the methods and materials used to clean and maintain equipment and, when necessary, instructions for disassembling and reassembling each article of equipment to ensure proper cleaning and maintenance;

Removing or obliterating previous batch identification;

Protecting clean equipment from contamination prior to use;

Inspecting equipment for cleanliness immediately before use, if practical;

Establishing the maximum time that may elapse between the completion of processing and equipment cleaning.

An organisation, which has played a large part in facilitating this process, is the International Society for Pharmaceutical Engineering (ISPE) which, although formed in the USA, is now a worldwide organisation that acts to promote awareness of such issues and acts as a forum where industry and regulators can exchange views. Particular notes of interest are the "Baseline Guides" series produced as a partnership between the FDA, ISPE and a broad spectrum of the pharmaceutical industry. The aim of these guides is to provide engineers and other professionals, within the pharmaceutical industry, with baseline information on the design, construction and commissioning of new and renovated facilities, equipment and systems to achieve regulatory compliance (Tunnicliffe, 2003).

3.2 International Society for Pharmaceutical Engineering (ISPE) Guide

The guide is intended to be used as a tool for the development, implementation and execution of a maintenance program in a pharmaceutical manufacturing environment. The guide focuses on maintenance in a good manufacturing practice (GMP) environment. It is intended to facilitate pharmaceutical maintenance and such as it does not attempt to address applicable codes, standards and policies beyond the current good manufacturing practices (cGMPs), which need to be considered in the development and execution of a maintenance program (ISPE, 2009). Most of the literature for the ISPE guidelines is found in the guides itself and only the critical elements are highlighted for this research study.
3.2.1 Maintenance practice

The concept of maintenance practice introduces a range of maintenance practices according to this guide which are organised into three categories namely that is illustrated in Figure 3.1 (see page 47):

a) **Maintenance basic practices**

The basic practice should be performed on equipment, systems and facilities to ensure a level of reliability and asset performance as determined by the organisation (ISPE, 2009).

b) **Maintenance good practices**

Good practice should be performed in addition to Maintenance Basic Practices. Maintenance Good Practices are recommended for systems, equipment and components where risk assessment indicates that patient safety and product quality could be impacted significantly (ISPE, 2009).

c) **Maintenance best practices**

The best practice goes beyond Maintenance Good Practices and typically applies only for business purposes (ISPE, 2009).

The cGMP requirements permit flexibility and provide scope for innovation and improvement. The regulations are not intended to prescribe exactly what needs to be done for any particular activity, including maintenance. In general, the regulations require that maintenance is performed and documented to ensure that affected operations consistently produce drug product that meets predefined specifications. However, how maintenance is performed is subject to change, depending upon an organisation’s philosophies, requirements and capabilities (ISPE, 2009).

The pharmaceutical industry should be using more condition-driven maintenance programs based upon operating data derived from predictive maintenance (PdM) technologies, rather than performing maintenance on calendar basis. PdM practices are mature and have been in
use in other industries for years (ISPE, 2009). Figure 3.1 shows a matrix illustrating the relationships between Maintenance Basic, Good and Best Practices.

Figure 3.1: Reliability Curve

Source: (ISPE, 2009).

3.2.2 Maintenance program

A maintenance program should document an organisation’s approach to performing maintenance regarding aspects and requirement. The maintenance program should outline the policies for (ISPE, 2009):

- Maintenance plans and work orders (WO);
- Maintenance classifications (preventative, predictive, condition monitoring, corrective);
- Maintenance systems and execution (e.g., equipment identification, documentation, work order management, resource planning, scheduling, maintenance materials management);
- Risk assessment;
- Spare part application;
- Discrepancies;
- Roles and responsibilities;
• Training programs/training plans;
• Performance management (e.g. continuous improvement);
• Deferred maintenance;
• Maintenance interfaces;
• Inventory management;
• Change control;
• Contract management and outsourcing;
• Self audits and assessments.

The maintenance program should also include management processes and controls, e.g., incorporating a new system and associated equipment, supervision and overview of the processes and activities, authority to approve and make changes (ISPE, 2009).

3.2.3 Systems maintenance strategy

The systems maintenance strategy is the set of criteria upon which the maintenance plans are developed. A systems maintenance strategy typically includes the following inputs (ISPE, 1998):

• Original equipment manufacturers recommendations;
• Experience with similar equipment;
• Review of historical data (trending);
• Process requirements;
• Risk assessment.

3.2.4 Maintenance plans

Maintenance plans are the tactical maintenance tasks or steps that are executed to maintain systems (and/or their components) in proper working order, and/or to monitor performance in order to detect discrepancies or conditions that might lead to failure. Maintenance Plans are prepared in accordance with requirements established in the maintenance program and systems maintenance strategy (ISPE, 1998).
3.2.5 Production and Maintenance

Production operators should act as “continuous equipment monitors.” When problems occur, operators can provide valuable troubleshooting insight as well as diagnosis when initiating work orders (WO). Which maintenance activities should be performed by the operating departments and which should be performed by the maintenance unit should be clearly defined. Methods used and record keeping in the pharmaceutical industry should be harmonised between operations and maintenance (ISPE, 2009).

3.2.6 Spare parts and materials

When parts and materials (lubricants, etc.) are applied, there should be some verification that the qualified state of the system has not been affected. Spare parts and materials management is not a specific requirement of the cGMP regulations. However, when a part is installed, there should be a predetermination as to whether the part is suitable for its application. This includes establishing criteria to determine whether a part is identical, and whether it requires additional evaluation or possibly change control, prior to its application. Criteria should include defined roles to assess and implement part and material replacements. The Maintenance Baseline Practices approach to spare parts and material application is to establish criteria for identifying them such as, “like for like” (ISPE, 1998).

3.2.7 Maintenance documentation

Pharmaceutical type documentation is generated in the Maintenance operations. Typically this includes the following (ISPE, 1998):

- Procedures (governing procedures that provide a framework for maintenance practices or specific procedures that are associated with an individual work process);
- Discrepancies on direct impact systems and non-direct impact systems;
- Continuous improvement (to trend maintenance failures or deficiencies encountered on direct impact systems);
- Equipment records of maintenance done shall be kept.
3.2.8 Roles and responsibilities

It is important to document roles and responsibilities of the maintenance staff, to the extent that they might impact the quality of a drug. The regulations specifically state that assignment of responsibility for maintenance and maintenance scheduling shall be included in the written procedures for maintenance as in Table 3.1.

**Table 3.1: Roles and Responsibility Assignment**

<table>
<thead>
<tr>
<th>Maintenance Activity for Direct Impact Systems</th>
<th>Maintenance Unit</th>
<th>Subject Matter Expert</th>
<th>System Owner</th>
<th>Quality Control Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Program</td>
<td>Prepare and Approve</td>
<td>Prepare and Approve</td>
<td>Approve</td>
<td></td>
</tr>
<tr>
<td>Impact Assessments</td>
<td>Prepare and Approve</td>
<td>Prepare and Approve</td>
<td>Approve</td>
<td></td>
</tr>
<tr>
<td>System Maintenance Strategy and Maintenance Plans</td>
<td>Prepare and Approve</td>
<td>Prepare and Approve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Control</td>
<td>Prepare and Approve</td>
<td>Prepare and Approve</td>
<td>Approve</td>
<td>Approve</td>
</tr>
<tr>
<td>Deferred Maintenance</td>
<td>Prepare and Approve</td>
<td>Prepare and Approve</td>
<td>Approve</td>
<td></td>
</tr>
<tr>
<td>Training Program</td>
<td>Prepare and Approve</td>
<td>Prepare and Approve</td>
<td>Approve</td>
<td></td>
</tr>
<tr>
<td>Training Plans</td>
<td>Prepare and Approve</td>
<td>Prepare and Approve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discrepancies</td>
<td>Prepare and Approve</td>
<td>Prepare and Approve</td>
<td>Approve</td>
<td>(process only)</td>
</tr>
<tr>
<td>Spare Part Allocation (like for like)</td>
<td>Assess and Approve</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spare Part Allocation (not like for like)</td>
<td>Assess and Approve</td>
<td></td>
<td>Approve</td>
<td>Approve</td>
</tr>
</tbody>
</table>

**Source:** (ISPE, 1998).

3.2.9 Computerised Maintenance Management Systems in the Pharmaceutical Industry

Computerised Maintenance Management Systems (CMMS) are often used to provide scheduling and documentation capabilities that facilitate maintenance management. CMMS are increasing in popularity, however, manual systems still tend to be used in smaller plants and can be equally effective from a regulatory perspective (ISPE, 1998).

Maintenance good practice would be to have all maintenance and related work performed under a single maintenance program at a site. To ensure that equipment history is preserved, only one system should be used to document performed maintenance and repair activity on
equipment. The recommended approach is to have a single system that the operations and maintenance departments share (ISPE, 2009).

### 3.3 Pharmaceutical process validation

Process Validation is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics. Other definitions exist, such as those by the World Health Organization (WHO) and the European Commission (EC), among others. While the wording may vary, the essence of all the definitions is the same, i.e. ensuring that the process, when operated under the same prescribed conditions, will consistently produce a product that meets the preset specifications and quality attributes. In brief and simple terms, process validation is ensuring that the process does what it purports to do (Aleem et al., 2003).

Furthermore, the FDA, in the same guideline document, states that assurance of product quality is derived from careful attention to a number of factors including selection of quality parts and materials, adequate product and process design, control of the process, and in-process and end-product testing. Indeed, process validation is a comprehensive activity that comprises, among other things, a well defined and well-designed set of tests and inspections on the process at large, including the facility, the equipment and the procedures, to verify its conformance to the preset specifications and conditions in order to assure its ability to produce the final product to the desired quality characteristics.

Process validation interfaces and interacts with many other different activities related to the construction and operation of the facility and the process which involves a flow of data and documents that, in many cases, may be bidirectional. The roots of the validation activity in a project can be traced back to as early a phase as product development, in which product specifications and quality characteristics will be set. The purpose of validation is then to prove that the process can consistently achieve these specifications and quality characteristics. Process development will specify the critical process parameters and their acceptable ranges of variations, and these again will have to be verified and tested by process validation (Aleem et al., 2003).

Part of validation, the actual facility in which the process will take place has to be ‘qualified’ to ensure that it is suitable for the process which includes the facility and the different services
such as the heating, ventilation and air conditioning (HVAC) system, water, steam. A similar concept applies to the equipment used for processing. It too has to be qualified to ensure that it is fit to purpose. This is done by testing its operation and performance. A major task is that of ensuring that all these individually qualified items work together as a system, as expected, and use predefined procedures and materials (Aleem et al., 2003).

Process validation, as seen above, is involved with a wide range of activities in the drug development and manufacturing process. At one end of the spectrum, that of product development, the final clinical trials of a new drug on human subjects can be viewed, on an abstract level, as a validation of the medical action of the drug, i.e. ensuring that the drug ‘does what it purports to do’. At the other end of the spectrum, the regular stability studies can be viewed as validation of the storage conditions of the drug. In-between these two points comes a wide variety of activities as described above. In fact, validation is a form of quality assurance (QA), which is a quality-related concept based on the premise that it is not possible to inspect quality into a product but rather quality has to be built into it (Aleem et al., 2003).

3.3.1 Stages in process validation

When the FDA requires process validation to be performed, it does not specify how it should be carried out. Over time, industry has developed certain concepts and methodologies to fulfil the FDA requirement. Validation has been broken down into a number of successive and systematic steps known as installation qualification (IQ), operation qualification (OQ), performance qualification (PQ) and process validation (PV). Looking at them from a functional point of view, each step encompasses more functionality than the preceding one as in Figure 3.2 (see page 53).

3.3.1.1 Installation qualification (IQ)

The purpose of IQ as shown in Figure 3.2 (see page 53) is to ensure that the facility in which the process will take place is suitable for the process, the environment in the facility is suitable, the utilities and services that the equipment requires meet these requirements and that the equipment itself is installed correctly (Aleem et al., 2003).
3.3.1.2 Operation Qualification (OQ)

The purpose of OQ as shown in Figure 3.2 is to ensure that the equipment operates as specified. This may involve testing of individual components such as pumps, fans and motors, in general, to check motor speed and direction of rotation. Also, the controls of the machine are tested, such as switches, alarms (by simulating an alarm condition) and different control instruments, to ensure that the machine responds accordingly and in the specified range. A very important activity here is that of calibration of measuring instruments. This is often treated as a separate activity and sometimes as part of IQ. Calibration is usually carried out by more specialised personnel, and as a discipline, it has developed independently of validation as it is utilised in many other industries and services. The purpose of calibration is to ensure the accuracy of the measuring instruments (Aleem et al., 2003).

Figure 3.2: Validation stages, a functional view

![Validation stages diagram]

Source: Aleem et al., 2003.

3.3.1.3 Performance Qualification (PQ)

The purpose of PQ as shown in Figure 3.2 is to check the performance of the equipment as a whole after testing its individual components and controls. It is at this stage that the product is introduced. The purpose here is to ensure that the equipment produces the product to the
required specifications. Here, several tests will be performed to cover the different operating conditions of the equipment and different ranges of the critical parameters. In particular, the FDA calls for testing the ‘worst case’ conditions of the process, which it describes as those ‘which pose the greatest chance of process or product failure when compared to ideal conditions. However, during normal operation, when validation is over, good record keeping of operation and maintenance tasks will continuously give an accurate view of the performance of the equipment. Such records may include data and maintenance logs. In particular, applying concepts such as reliability centred maintenance can be especially beneficial in such cases (Aleem et al., 2003).

3.3.1.4 Process Validation (PV)

PV is yet another level of functionality above PQ which in turn is above OQ as shown in Figure 3.2 (see page 53). PV is concerned with the overall process, not just the section of the activity associated with the equipment. This may involve the handling of material, loading it into the equipment, the performance of the equipment (PQ), handling of the product, cleaning of the equipment between batches of different formulations and microbiological challenge (Aleem et al., 2003).

A major purpose of the validation activity is to ensure consistency of the process, to limit its variability and keep it within control. It is thus imperative that the process be monitored closely after the validation work is over. This is done by keeping records of the critical and relevant process variables and operation parameters, and maintenance logs for the equipment. The purpose is for any deviation of the process from its validated state to be detected early. In some cases a deliberate change to the process is done as a modification for some technical or economic reason. In both cases, whether the change is inadvertent or intended, a revalidation may be necessary (Aleem et al., 2003).

3.4 Quality assurance in the pharmaceutical industry (QA)

The role of the QA unit has become critical since the increased reliance on non-quality control (QC) personnel for quality related activities such as in-process control and customer complaint coordination. The regulations essentially expect the QA function to provide an independent policy type role to monitor the entire production process from purchasing of materials to distribution and use of the product. The function should also be proactive by
evaluating data on processes, materials and suppliers and recommending changes that will improve efficiency and consistency (Willig & Stoker, 1997).

3.4.1 Change control and deviations

Change control procedure is possibly the most important Standard Operating Procedure (SOP) in a plant operation. It is also one of the broadest ranging and most complex. Consequently the management of the process must be delegated to someone with the necessary knowledge and skills to understand and manage this complexity. In larger facilities there may be separate change control procedures for different types of change. However QA should confirm that each meets the needs of the operation and evaluation of change control should be part of the QA plant audit (Willig & Stoker, 1997).

Providing mechanisms for ongoing process optimisation and ensure a continuing state of process control, a formal change control system should be established to evaluate and approve proposed changes to specifications, test procedures, raw materials, facilities, support systems, equipment (including computer hardware), processing steps, packaging materials, and computer software. The change-control program should include procedures to (Food and Drug Administration, 1998):

- Prevent unauthorised modifications to a validated system;
- Evaluate proposed changes against development and technology transfer documents;
- Identify and evaluate all proposed changes to assess their potential effects on the API process and determine if, and to what extent, revalidation is needed;
- Ensure that all documents affected by changes are promptly revised;
- Determine the impact of changes on the critical chemical and physical attributes of the API (e.g., impurity profiles, stability, and particle size).

Proposals for changes should be drafted, reviewed, and approved by the appropriate organisational units, and reviewed and approved by the quality control unit (Food and Drug Administration, 1998).

3.5 The maintenance qualification for pharmaceuticals

Maintenance qualification, as stated by Brown & McCabe (2005), provides documentary evidence of the maintenance controls in place to maintain cGMP and identifies the optimum
maintenance policies required for cost-effective and efficient operations. By eliminating unnecessary or non-value-adding maintenance routines and by focussing resources on those equipment items with the greatest impact on business performance can enhance compliance and reduce maintenance costs and unplanned downtime as indicated in Figure 3.3.

**Figure 3.3: Maintenance qualification**

![Maintenance Qualification Diagram](attachment:maintenance_diagram.png)

**Source:** Brown & McCabe, 2005.

### 3.5.1 Methodology for maintenance qualification

A key requirement of the methodology is to channel effort only onto critical equipment. This is determined by assessing whether the equipment or system is GMP-critical and by further assessing the business risk of failure. The maintenance controls in place to ensure the continued compliance of GMP-critical equipment are reviewed and documented. Maintenance controls for other equipment items are assessed to identify opportunities to improve reliability and make efficiency savings (Brown & McCabe, 2005).

### 3.5.2 Pre-screening

With a large number of equipment items to consider, a pre-screening assessment is used to improve the overall efficiency of the process. Pre-screening uses the concept of 'positive exclusion' to identify noncritical items and, thereby, reduce the load on the subsequent
criticality analysis. The assessment tests all equipment items against two criteria, namely, risk and consequence by using a few simple questions. A pre-screening assessment can substantially reduce the numbers of items to be assessed during criticality analysis (Brown & McCabe, 2005).

3.5.3 Impact assessment

Following pre-screening, GMP criticality is determined by a system impact assessment. Systems are divided into direct, indirect or non-impact systems which are defined as follows (Brown & McCabe, 2005):

a) **Direct impact system**
   This is where a system that is expected to have a direct impact on product quality, via product contact or direct influence on quality.

b) **Indirect impact system**
   This is where a system that is not expected to have a direct impact on product quality, but typically supports a direct impact system.

c) **Non-impact system**
   This is where a system will not have any impact, either directly or indirectly, on product quality.

The impact assessment process is divided into two main activities. The first identifies the system boundaries and evaluates the impact of the system on the product quality. The second evaluates the criticality of the components within each direct impact system with respect to their role in assuring product quality (Brown & McCabe, 2005).

3.6 Environmental Health and Safety in the maintenance environment (EHS)

Maintenance units should clearly understand and comply with EHS requirements for their areas of responsibility. The operations and processes supported by the maintenance unit, which embrace maintenance basic, good and best practices, can vary significantly. Primary responsibility for the EHS aspects of maintenance work resides with maintenance managers and supervisors. Maintenance activities can be high risk with respect to EHS concerns. Maintenance managers and supervisors should ensure that the risks are understood in advance of an activity and then provide equipment and procedures to provide employee protection (ISPE, 2009).
Maintenance tasks that are performed due to EHS mandates, help to ensure ongoing protection and legal compliance for personnel, environment, and property. Failure to complete EHS required maintenance tasks can expose employees or the environment to hazards or put the facility in legal difficulties or both (ISPE, 2009).

3.7 Summary

In this chapter the expectations of the FDA in the pharmaceutical industry was discussed and the partnership with the International Society for Pharmaceutical Engineering (ISPE) was highlighted. The ISPE guideline acts as a guide for the pharmaceutical industry engineering which covers all aspects of maintenance basic, good and best practices. This chapter also highlights the requirements of process validation and the stages thereof when performing engineering practices. The chapter also explains how the QA department forms part of the controlling body where change controls and deviations plays an important part to prevent unauthorised modifications to a validated system.

This chapter achieved the research question RQ3 research objective RO3 which was to explore the good engineering practice guidelines for the pharmaceutical industry. The roles that process validation, quality assurance, change controls and deviations play with equipment qualification are also identified in this chapter which has achieved research objective RO4 which was to understand the regulatory controls that influence the maintenance management systems in the pharmaceutical industry. In the next chapter, an integrated maintenance management model will be developed for My Pharmaceuticals to address the research question RQ5 and research objective RO5.
Chapter 4

Developing the Integrated Maintenance Management System Model

4.1 Introduction

In Chapter 2, a literature study was conducted to identify the best maintenances practices for maintenance management systems within organisations. A preliminary study was also conducted to indentify the main problems of the maintenance management system problems at My Pharmaceuticals which was explained in Chapter 2. The results in Chapter 2 were to address research questions RQ1 and RQ2 and research objectives RO1 and RO2 which were to identify best practices from the literature about maintenance management systems within organisations and to investigate the main problems in the maintenance management system being experienced at My Pharmaceuticals respectively. Chapter 3 presented a literature study on guidelines of pharmaceutical good engineering practice and the regulatory controls that influence the maintenance management systems in the pharmaceutical industry to address research questions RQ3 and RO3 and research objectives RQ4 and RO4 respectively.

In this chapter the theory on generic maintenance management models will be discussed in Section 4.2. It will include a proposed approach to the maintenance management system and the strategic levels of a maintenance management system framework identified in Section 4.3. An integrated maintenance management system model will be developed for My Pharmaceuticals in Section 4.4, which will address research question RQ5 and research objective RO5 by combining the theory on the generic maintenance management models and the results of the research questions RQ1 to RQ4 and research objectives RO1 to RO4. There will be referencing made to previous chapters in this chapter where an abstract will be brought forward to be explained.

4.2 The maintenance management framework (model)

The maintenance management process can be divided into two parts namely; the definition of the strategy and the strategy implementation. The first part, definition of the maintenance strategy, requires the definition of the maintenance objectives as an input, which should be derived directly from the business plan. This initial part of the maintenance management process conditions the success of maintenance in an organisation and determines the
effectiveness of the subsequent implementation of maintenance plans, schedules, controls and improvements (Crespo Marquez et al., 2009). In the case of maintenance, effectiveness can represent the overall company satisfaction with the capacity and condition of its assets or with the reduction of the overall company costs obtained because production capacity is available when needed. Effectiveness concentrates then on the correctness of the process and whether the process produces the required result (Crespo Marquez et al., 2009).

The second part of the process, the implementation of the selected strategy, has a different significance level. The ability to deal with the maintenance management implementation problem, for instance, the ability to ensure proper skill levels, proper work preparation, suitable tools and schedule fulfillment, will allow the company to minimise the maintenance direct cost such as labour and other maintenance required resources. In this part of the process the efficiency of management is dealt with, which should be less important. Efficiency is acting or producing with minimum waste, expense, or unnecessary effort. Efficiency is then understood as providing the same or better maintenance for the same cost (Crespo Marquez et al., 2009).

Figure 4.1 presents a generic model proposed for maintenance management for built and in-use assets and consists of eight sequential management building blocks. The first three building blocks condition maintenance effectiveness, the fourth and fifth ensure maintenance efficiency, blocks six and seven are devoted to maintenance and assets life cycle cost assessment of assets. Finally, block number eight ensures continuous maintenance management improvement (Crespo Marquez et al., 2009).

Figure 4.1: Proposed generic model for maintenance management.

Source: Crespo Marquez et al., 2009.
4.3 A proposed approach to maintenance management system

A major consideration, as explained by Crespo Marquez & Gupta, (2006), data, policies, techniques and tools affect the effective execution of maintenance, particularly in a modern technologically endowed factory. In such instances, an integrated, rather than the conventional “silo” style approach to maintenance management (MM) would play a pivotal role. However, much difficulty in the practice of MM arises from the mix up between the actions and the tools designed to enable them.

This issue often remains unresolved by practitioners and unaddressed by researchers. To help resolve this, it is important to describe the essentials of an effective maintenance process and a corresponding framework to enable this process to yield the desired results. Although it could also be said that a given process has a structure, the proposed framework is considered as the distinct technological support to the process and the process consists of the set of various tasks that one must accomplish each day to manage maintenance. It is suggested that MM must be aligned with actions at three levels of business activities, namely, strategic, tactical, and operational as shown in Figure 4.2 (see page 62) (Crespo Marquez & Gupta, 2006).

4.3.1 Strategic levels of the maintenance management system framework (model)

Actions at the strategic level will transform business priorities into maintenance priorities. To meet these priorities, this process will help craft mid-to-long-term strategies to address current potential gaps in equipment maintenance performance. As a result, a generic maintenance plan will be obtained at this level (Crespo Marquez & Gupta, 2006). Transformation of business priorities into maintenance priorities is done by establishing critical targets in current operations. Detailed analysis creates measures of such items as the incidence of the plant equipment breakdowns as these would impact the plant’s operational targets by criticality analysis. MM would then develop a course of strategic actions to address specific issues for the critical items. Other actions would focus on the acquisition of the requisite skills and technologies, for instance, condition monitoring technologies for the micro-level improvement of maintenance effectiveness and efficiency (Crespo Marquez & Gupta, 2006).
4.3.2 Tactical levels of the maintenance management system framework (model)

Actions at the tactical level would determine the correct assignment of maintenance resources, such as skills, materials and test equipment to fulfill the maintenance plan. As a result, a detailed program would materialise with all tasks specified and resources assigned. Moreover, during the process of detailed maintenance requirements planning and scheduling, this level of activity must develop a competency to discriminate among a variety of resource options that may be assigned to execute a maintenance task at a certain asset, location and time. Such action would spell out the tactical maintenance policies (Crespo Marquez & Gupta, 2006).

4.3.3 Operational levels of the maintenance management system framework (model)

Actions at the operational level would ensure that the maintenance tasks are carried out by skilled technicians, in the time scheduled, following the correct procedures, and using the proper tools. As a result, work would be done and data would be recorded in the information system. Procedures at the operational level would be needed for preventive works, equipment repairs, and troubleshooting with a high degree of attention (Crespo Marquez & Gupta, 2006).

As shown in Figure 4.2, these three courses of action and the related processes going on in the organisation are clearly interrelated.

**Figure 4.2: Maintenance process, course of action and feedback operating at the three levels of business activities**

Source: Crespo Marquez & Gupta, 2006.
4.4 Developing the integrated maintenance management system model for My Pharmaceuticals

All benchmarks are interconnected and interdependent when measured against known benchmarks of best practices. This is why an organisation must have a defined maintenance and reliability process in order to implement best practices. Tailoring of a best practice to meet a need in an environment is essential for an effective implementation (Gulati, 2009). As systems become more complicated and require new technologies and methodologies, more sophisticated maintenance models and control policies are needed to solve the maintenance problems (Cho & Parlar, 1991). Figure 4.3 to Figure 4.5 (see pages 64, 68 and 74) displays how an integrated maintenance management model was developed for My Pharmaceuticals and is explained below in the following sub-sections.

4.4.1 Maintenance policy

The maintenance policy should include all aspects of the maintenance management system process. It is stated in Section 2.1 in Chapter 2 that to develop an appropriate maintenance management system, maintenance must be considered holistically. Factors that describe the interrelations and interactions between the different systems as well as factors that describe the general organisational structure should be addressed (Panayiotou et al., 2009). Section 2.3 in Chapter 2 states that the maintenance policy describes, in broad terms, the direction in which the maintenance management team wants to steer the maintenance organisation (Coetzee, 1997). This policy should address every block (element) on the maintenance cycle diagram, in this case the model, and it must state the company’s stand on each of these fundamental issues. This policy document is typically drawn up and subsequently annually revised by the maintenance management team (Coetzee, 1997). It is therefore important that when developing this model that the maintenance policy be the first step and should get priority as it should define the maintenance strategy for the company as shown in Figure 4.3 (see page 64).

4.4.2 Steering committee – senior management

One of the main problems identified by the preliminary study is problem P5 in Section 2.15.2.4 in Chapter 2 that states that there is no senior management involvement and buy in. It
is stated in Section 2.9 in Chapter 2 that the first step toward a formal maintainability process is to develop maintainability awareness at the corporate level. Management should become familiar with maintainability objectives, methods, and concepts at a tactical level. After gaining a basic understanding of maintainability and its impact on the project, the management team can then establish its relationship to overall business objectives (Meier & Russell, 2000). The steering committee block is thus placed under the maintenance policy block in the model as shown in Figure 4.3 as the maintenance policy will guide the steering committee on the maintenance strategy.

Figure 4.3: Developing the integrated maintenance management system model at the tactical level for My Pharmaceuticals

Source: Authors own construction

4.4.3 Maintenance objectives

This part of the model involves the objectives of the maintenance management system at My Pharmaceuticals. It encompasses the integration of the different departments that have an impact on the Engineering department and the strategy that the company should take to fulfil its maintenance obligations. This forms part of the tactical level actions mentioned in Section 4.3.2 in this chapter.

It is stated in Section 2.4 in Chapter 2 that the maintenance management team should, on least an annual basis, maintain and update the maintenance department’s objectives. These should be based on, and should be in line with the framework as defined in the maintenance policy (Coetzee, 1997). Objectives should be developed by first doing an analysis of how well the
maintenance organisation is already performing in terms of the management team’s direction, as set out in the policy document (Coetzee, 1997). This is shown as well in Figure 4.3 (see page 64).

4.4.4 Multi skilled engineering staff with pharmaceutical regulatory training.

A main problem that was identified by the preliminary study was problem P8 in Section 2.15.2.7 in Chapter 2 that states there is a lack of training of engineering staff with the latest technology in process equipment. It is stated in Section 2.12 in Chapter 2 that an organisation constitutes the combining of resources in such a manner as to fulfil some specific need. This forms part of the tactical level actions mentioned earlier in Section 4.3.2 (see page 62) of this chapter. Organisations involve a group of individuals of varying levels of expertise combined into a social structure of some type to accomplish one or more functions within the maintenance structure. Organisational maintenance structures vary with the functions to be performed and the results depend on the established goals and objectives, the resources available, the communications and working relationships of the individual participants, personnel motivation and many other factors (Blanchard et al., 1995).

There is also no understanding of the importance of maintenance and the periodically reviewing of equipment that the Validation department performs, which the preliminary study revealed in problem P2 stated in Section 2.15.2.2 in Chapter 2. It is stated in Section 3.2.8 in Chapter 3 that it is important to document the roles and responsibilities of the maintenance staff as they might impact the quality of a drug (ISPE, 1998). The importance for this stated in Section 3.3 of the same chapter is that process validation is a comprehensive activity that comprises, among other things, a well defined and well-designed set of tests and inspections on the process at large. These include the facility, the equipment and the procedures, to verify its conformance to preset specifications and conditions which assure its ability to produce the final product to the desired quality characteristics (ISPE, 1998).

Compulsory training in the above will ensure that the engineering staff at My Pharmaceuticals will have an understanding of the regulations and what compliance is needed in the pharmaceutical industry, as well as being multi-skilled in process equipment. This is confirmed in Section 2.12 in Chapter 2 where it states that a well-developed training program based on job task analysis and maintenance skills assessment can provide the solution to the inadequate availability of maintenance skills. The training must be focused to produce results
as quickly as possible and must also meet the organisations long term goals. Maintenance training, when developed and implemented properly can help organisations save money, increase productivity, product quality and improve employee morale (Gulati, 2009). This block is incorporated in Figure 4.3 (see page 64).

4.4.5 Compliance

Compliance includes the validation and quality assurance aspects of the pharmaceutical industry regulated by, amongst other regulatory bodies, the Food and Drug Administration (FDA) and the World Health Organisation (WHO). It is stated in Section 3.1 in Chapter 3 that the Food and Drug Administration (FDA) expects appropriate current good manufacturing practices (cGMPs) to be applied to all steps of an active pharmaceutical ingredient (API) manufacturing process, beginning with the use of starting materials. Such practices include the validation of processes determined to impact the quality and purity of the API. The agency recognises that the stringency of cGMPs in API production. The extent of written instructions, in-process controls, sampling, testing, monitoring and documentation, should increase as the process proceeds from early steps to final synthesis and purification stages (Food and Drug Administration, 1998).

Compliance can be effectively achieved when the engineering staff are trained in all aspects of pharmaceutical regulations as the model proposes so that there is an understanding of what is required. A link between compliance and the maintenance identification and qualification process as pointed out in the model in Figure 4.4 (see page 68) is proposed. This is to ensure that when engineering, validation and quality assurance qualify new equipment, they work hand in hand to perform the installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) as stated in Section 3.3.1 in Chapter 3 which forms part of the strategic level actions mentioned in Section 4.3.1 of this chapter (see page 61). To have this in the model will contribute to the combating of problem P2 in Section 2.15.2.2 in Chapter 2 that identifies that there is no understanding of the importance of maintenance and periodical review of equipment by the validation department.

4.4.6 Validation

Process validation is a key process within the pharmaceutical process and is included in the model under compliance in Figure 4.4 (see page 68). It is stated in Section 3.3 in Chapter 3
that process validation is a comprehensive activity that comprises, among other things, a well defined and well-designed set of tests and inspections on the process at large, including the facility, the equipment and the procedures, to verify its conformance to the preset specifications and conditions in order to assure its ability to produce the final product to the desired quality characteristics (Aleem et al., 2003).

There is also a link in the model between validation and the maintenance history process. This is included as part of validations review of the current equipment maintenance history to ensure that all the maintenance performed over a certain period has been done according to regulation. This will help solve problem P9 in Section 2.15.2.8 in Chapter 2 that states there is a lack of understanding of equipment that is validated and there is no clear instruction of when change controls and deviations are needed. The link is bidirectional as stated in Section 3.3 in Chapter 3. Process validation interfaces and interacts with many other different activities related to the construction and operation of the facility and the process. This interaction involves a flow of data and documents that in many cases may be bidirectional (Aleem et al., 2003).

4.4.7 Quality assurance (QA)

The QA department is the driver in compliance within the pharmaceutical industry and is included in the model next to validation in Figure 4.4 (see page 68). It is stated in Section 3.4 in Chapter 3 that the QA function should be proactive by evaluating data on processes, materials and suppliers and by recommending changes that will improve efficiency and consistency (Willig & Stoker, 1997). In the model there is a link between QA and the maintenance execution process under maintenance identification and qualification. The link is included as there needs to be a relationship between QA and maintenance execution on change controls, deviations and maintenance standard operating procedures (SOP). It is stated in Section 3.4 in Chapter 3 that in larger facilities, there may be separate change control procedures for different types of change. However QA should confirm that each change meets the needs of the operation and evaluation of change control should be part of the QA plant audit (Willig & Stoker, 1997).

It is also noted in Section 3.3 in Chapter 3 that any deviation of the process from its validated state must be detected early. In some cases a deliberate change to the process is done as a
modification for some technical or economic reason. In both cases, whether the change is inadvertent or intended, a revalidation may be necessary (Aleem et al., 2003). This is important when equipment has to be maintained in its validated state and any changes or deviations from that will involve the change control and deviation process. However, when a part is installed, there should be a predetermination as to whether the part is suitable for its application. In Section 3.2.6 in Chapter 3 it states that this includes establishing criteria to determine whether a replacement part is identical or if it requires additional evaluation or possibly change control prior to its application. Criteria should include defined roles to assess and implement part and material replacements. The Maintenance Baseline Practices approach is to establish criteria to identify spare parts and material application as “like for like” (ISPE, 1998).

Figure 4.4: Developing the integrated maintenance management system model at the strategic level for My Pharmaceuticals

Source: Authors own construction
4.4.8 Maintenance identification and qualification

This part of the model is where the integration between maintenance planning and production planning is proposed is shown in Figure 4.4 (see page 68). Maintenance execution and maintenance history analysis are also presented here. These form part of the strategic level actions mentioned in Section 4.3.1 of this chapter (see page 61). These processes under the maintenance identification and qualification should be guided by the International Society for Pharmaceutical Engineering (ISPE) guidelines and maintenance best practices. Section 2.5 in Chapter 2 explains that, despite the need to improve on processes as times change, best practice is considered by some as a business buzzword used to describe the process of developing and following a standard way of doing activities that any organisation can use or implement to obtain better results (Gulati, 2009).

It is highlighted in Section 3.5 in Chapter 3 that maintenance qualification provides documentary evidence of the maintenance controls in place to maintain cGMP and identifies the optimum maintenance policies required for cost-effective and efficient operations. Eliminating unnecessary or non-value-adding maintenance routines and focussing resources on those equipment items with the greatest impact on business performance can enhance compliance and reduce maintenance costs and unplanned downtime (Brown & McCabe, 2005).

4.4.9 Production planning

The production system as shown in Figure 4.4 (see page 68) has to operate according to the production scheduling. This satisfies demands and should be as profitable as possible. Demands describe items and their quantity that should be produced and the time when the product must be ready. Some production demands in the pharmaceutical industry have hard deadlines so the demand quantity must be ready at a given time.

Section 2.9.2.3 in Chapter 2 indicates that in many cases production units need to be shut down for maintenance and this may lead to tensions between the production and maintenance departments of a company. On the one hand, the production department needs maintenance for the long-term well-being of its equipment but on the other hand it needs to shut down in periods that could well be used for production (Budai et al., 2006).
4.4.10 Integration between production and maintenance planning

One of the main problems identified by the preliminary study discussed in Section 2.15.2.1 in Chapter 2 is problem P1 that states that there is a lack of maintenance and production planning integration. The International Society for Pharmaceutical Engineering (ISPE) guide states in Section 3.2.5 in Chapter 3 that the maintenance activities performed by the operating departments and the maintenance activities performed by the maintenance unit should be clearly defined. Methods used and record keeping in the pharmaceutical industry should be harmonised between operations and maintenance (ISPE, 2009).

Opportunistic maintenance is proposed for the integration between production and maintenance planning to “harmonise” the process as indicated in Figure 4.4 (see page 68). Section 2.9.2.3 in Chapter 2 states that this opportunistic maintenance concept mainly requires considering the integration of the maintenance planning into the production strategy planning in order to develop opportunistic maintenance tasks synchronised with production. More generally, define an opportunity as being a moment (i) at which the units to be maintained are less needed for their function than normally, (ii) that occurs occasionally and (iii) that is difficult to predict in advance. These opportunities appear not only in the case of failure of other elements, but also at an interruption or stoppage of production (Levrat et al., 2008).

Opportunistic maintenance is often criticised for not being ‘plannable’ long in advance and therefore no work preparation is possible. Moreover the length of the finite horizons considered is often much shorter than the lifespan of a component. But it is admitted that opportunistic maintenance can help save set-up costs and guarantee expected performances for the system (Levrat et al., 2008).

4.4.11 Maintenance planning and scheduling

This part of the model presents the maintenance planning and scheduling process of My Pharmaceuticals also indicated in Figure 4.4 (see page 68). The scheduling part should incorporate the opportunistic maintenance proposed in the previous sub-section so that the schedules are aligned to the opportunities presented by production as stated in Section 2.9.2.3 in Chapter 2 that this equivalence mainly requires considering the integration of the
maintenance and the production strategy planning for developing opportunistic maintenance tasks to preserve conjointly the performances of the product production equipment (Levrat et al., 2008).

Part of this maintenance planning is the management of the current computerised maintenance management system (CMMS) within the engineering department. The preliminary study identified problem P6 which is discussed in Section 2.15.2.5 in Chapter 2 that there are two CMMS databases serving one engineering department. The model proposes that there should be one CMMS database as stated in Section 3.2.9 in Chapter 3 that the maintenance good practice would be to have all maintenance and related work performed under a single maintenance program at a site. To ensure that equipment history is preserved, only one system should be used to document performed maintenance and repair activity on equipment. The recommended approach is to have a single system that the operations and maintenance departments share (ISPE, 2009).

The model proposes that the spare parts management be managed by the CMMS as well. Problem P7, discussed in Section 2.15.2.6 in Chapter 2, identified by the preliminary study states that there is no proper spares management system within the company. The inventory is managed by a finance system which does not take into consideration inventory reports. There is no integration between this finance system and the CMMS. This causes a problem with having a complete maintenance costing and budgeting on maintenance activities. It is stated by Gulati (2009) in Section 2.10.1 in Chapter 2 that achieving a high level of inventory accuracy is a critical factor in the success of store room operations. Accurate inventory is defined as the actual quantity and types of parts, in the right location in the storeroom, matching exactly what is shown on the inventory in the computerised maintenance management system (CMMS). All these elements encompass the strategic level actions mentioned in Section 4.3.1 (see page 61) of this chapter.

4.4.12 Maintenance execution

This part of the model flows from the maintenance planning and scheduling indicated in Figure 4.5 (see page 74). It describes the types of maintenance execution that My Pharmaceuticals is currently performing and proposes the maintenance the company should perform. Although the company is performing preventative and corrective maintenance, the
preliminary study identifies problems P3 and P4 in Section 2.15.2.3 in Chapter 2 that the company does not practice predictive and reliability centred maintenance (RCM).

It is stated in Section 2.7.3 in Chapter 2 that predictive type of maintenance often refers to a condition-monitoring preventative-maintenance program where direct monitoring methods are used to determine the exact status of equipment for predicting possible degradation and to highlight areas where maintenance is desired. The objective is to predict when failures will occur and to take preventative measures accordingly. Various test methods, like vibration signature analysis, thermography and tribology are used (Blanchard et al., 1995). It is also stated in ISPE guidelines in Section 3.2.1 in Chapter 3 that the pharmaceutical industry should be using more condition-driven maintenance programs based on operating data, derived from predictive maintenance (PdM) technologies, rather than performing maintenance on calendar basis. PdM practices are mature and have been in use in other industries for years (ISPE, 2009).

Section 2.7.4 in Chapter 2 shows that the RCM methodology deals with some key issues not dealt with by other maintenance programs. It recognises that all equipment in a facility is not of equal importance to either the process or to facility safety. It recognises that equipment design and operation differ and that some equipment will have a higher probability to undergo failures from different degradation mechanisms than others. Systematic evaluation of a facility’s equipment and resources will show how to best mate the two and result in a high degree of facility reliability and cost-effectiveness. This is highly reliant on predictive maintenance. It also recognises, however, that maintenance activities on equipment that is inexpensive and unimportant to facility reliability, may best be left to a reactive maintenance approach (Methods Apparel Consultancy India, 2001). Maintenance execution forms part of the operational level actions as stated in Section 4.3.3 (see page 62) of this chapter.

4.4.13 Maintenance history

Maintenance performed on equipment whether it is preventative, corrective, RCM or predictive all form part of the history of the equipment. This history tells a story of the problem areas of the equipment and when analysed properly, can help to identify maintenance improvements. Section 2.9.4 in Chapter 2 states that analysis of maintenance history of the high maintenance equipment is to identify specific repetitive failures. Engineering discipline should be applied to these to determine how equipment or instrumentation might be modified
to reduce premature equipment failures, frequency of repetitive failures and the general level of required maintenance (Kister & Hawkins, 2006).

One of the problems identified by the preliminary study is P10 in Section 2.15.2.9 in Chapter 2 is that My Pharmaceuticals does not perform proper value-adding analysis on maintenance data. The model proposes that My Pharmaceuticals uses the failure mode, effects and criticality analyses (FMECA) method as indicated in Figure 4.5 (see page 74) as this forms part of the operational level actions mentioned in Section 4.3.3 (see page 62) of this chapter. Section 2.9.5 in Chapter 2 states that FMECA is a design technique systematically to identify and investigate potential system (product or process) weaknesses. It consists of a methodology for examining all the ways in which a system failure can occur, potential effects of failure on system performance and safety and the seriousness of these effects. The FMECA consists of two distinct analyses, namely, the failure mode and effect analysis (FMEA). These are then extended to analyse failure mode critically, called critical analysis (CA) (Blanchard et al., 1995).

There are many methods of failure analysis. The most common is the tabular method. Fault-tree analysis is another form. The point is that a method must be selected to fit the subject project, organisation and other initiatives (Lamb, 1995). The first step involves defining the system in the functional terms. System functionality is clearly delineated using a symbolic representation such as functional flow diagram. The next step is to identify the manner in which the system element fails to accomplish its function, which is called a failure mode (Blanchard et al., 1995).

It is important to determine the causes of failure. This involves analysing the process or product in order to delineate the cause(s) responsible for the occurrence of any particular failure. Once this is achieved, the effects of the failure can be determined. When conducting a FMECA, it is important to consider the effects of failures on the next higher-level functional entity along with the impact on the overall system (Blanchard et al., 1995). Lastly it is important to rate the severity of a failure mode. This task is to rank the consequences of each failure according to its category (Lamb, 1995).
4.4.14 Optimisation and self audits

This link in the model to the maintenance identification and qualification block as shown in Figure 4.5 proposes that the engineering department perform self-audits to optimise the processes of production and maintenance planning integration, maintenance planning and scheduling, maintenance execution and maintenance history. This is to keep them in line within maintenance standard operating procedures (SOP) as stated in Section 3.2.2 in Chapter 3 that the maintenance program should outline the policies for self audits and assessments (ISPE, 2009).

It is also stated in Section 2.13 in Chapter 2 that a formal audit of the department should be done at least on an annual basis. This includes both hard and soft audits. The hard audit
consists of a proper inspection of the plant, using a well-defined checklist and scoring mechanism. The soft audit on the other hand audits the ability of the department’s management and technical systems to ensure long-term achievements of the results required by the policy and objectives. If the department does not start measuring the performance of the maintenance function, through a proper audit, performance improvements cannot be realised as it is only through the knowledge of present performance levels afforded by the auditing process, that insight can be developed regarding the future directions for improvement (Coetzee, 1997).

4.4.15 Maintenance policy re-evaluation

This link in the model to the maintenance policy as shown in Figure 4.5 (see page 74) proposes that the maintenance objectives which include having multi-skilled staff, being compliant to validation and quality assurance and the process of maintenance identification and qualification be re-evaluated to ensure continuous improvement as stated in Section 3.2.2 in Chapter 3 that the maintenance program should also include management processes and controls, e.g., incorporating new system and associated equipment, supervision and overview of the processes and activities and authority to approve and make changes (ISPE, 2009). This links back to the tactical level actions mentioned in Section 4.3.2 of this chapter (see page 62).

4.4.16 Complete proposed integrated maintenance management system model

Figure 4.6 (see page 76) proposes the complete maintenance management model that can be used within My Pharmaceuticals taking into consideration the problems identified in the preliminary study and the best maintenance practices literature study in Chapter 2, the pharmaceutical maintenance best practices in Chapter 3 and the generic maintenance models presented in Chapter 4. To identify if this model can be used in the company, it will be presented to a sample of employees in the various departments, namely, Engineering, Validation, Quality Assurance and Production.
4.5 Conclusions

In this chapter the theory of generic maintenance management models was explained. It was determined that an integrated, rather than the conventional “silo” style approach to maintenance management (MM) would play a pivotal role. This chapter also highlighted that there is sometimes confusion on maintenance practice actions and the tools that put them into action. It is important, therefore, that an effective maintenance process has a corresponding framework to enable this process to yield the desired results. The concepts of maintenance and MM are briefly reviewed and then used to develop a framework to set the various functions within MM. A clear perspective of the three levels of business activities, operational, tactical and strategic is maintained in positioning these functions within the organisation.
This initial part of the maintenance management process conditions the success of maintenance in an organisation and determines the effectiveness of the subsequent implementation of the maintenance plans, schedules, controls and improvements. Effectiveness shows how well a department or function meets its goals or company needs and is often discussed in terms of the quality of the service provided, viewed from the customer’s perspective. This chapter has answered research question RQs and research objective ROs which was to develop an integrated maintenance management system model for My Pharmaceuticals. The proposed model will now be evaluated in an empirical study in Chapter 6 as part of the research methodology that will be discussed in the next chapter.
Chapter 5

Research and Design Methodology

5.1 Introduction

In Chapter 4, a proposed integrated maintenance management system model was developed for My Pharmaceuticals which addressed research question RQs and research objective ROs. In order to verify the findings in the literature study and to investigate if the proposed maintenance management system model could be used to improve the current maintenance management system at My Pharmaceuticals, an empirical study was conducted.

The methodology used will be addressed in this chapter where Section 5.2 will give the definition of research and Section 5.3 will address the types of research. The sub-sections in Section 5.4 explain the sample design, the data collection methods, the data analysis and describe what the reliability and validity of the data means.

5.2 Definition of research

Research is the systematic process of collecting and analysing information (data) in order to increase understanding of the phenomenon about which there is a concern or interest (Leedy & Omrod, 2001). Although research projects vary in complexity and duration, research typically has eight distinct characteristics (Leedy & Omrod, 2001):

- Research originates with a question or problem;
- Research requires a clear articulation of a goal;
- Research follows a specific plan or procedure;
- Research usually divides the principle problem into more manageable sub problems;
- Research is guided by the specific research problem, question or hypothesis;
- Research accepts certain critical assumptions;
- Research requires the collection and interpretation of data in an attempt to resolve the problem that initiated the research;
- Research is, by its nature, cyclical or more exactly, helical.
5.3 Types of research

The different types of research can be classified according to (Collis & Hussey, 2003):

- The purpose or the reason why the research is conducted;
- The process or method of data collection and analysis;
- The logic of the research;
- The outcome of the research where a particular problem needs to be solved or just making a general contribution to knowledge.

There are three different ways in which types of research have been distinguished namely (Blanche & Durrheim, 1999):

- Exploratory, descriptive and explanatory research;
- Applied and basic research;
- Quantitative and qualitative research.

5.3.1 Exploratory, descriptive and explanatory research

Distinction focuses on the goals of a research. Exploratory studies are used to make preliminary investigations into relatively unknown areas of research (Blanche & Durrheim, 1999). The techniques that are used in this type of research are case studies, observations and historical analysis which can provide qualitative and quantitative data. The main characteristic of this type of research is that it is very flexible with very few constraints on the nature of activities employed or the type of data that is collected (Collis & Hussey, 2003).

Descriptive research is research in which a specific situation is studied either to see if it gives rise to any general theories or to see if existing general theories are borne out by the specific situation (Goddard & Melville, 2001). Descriptive studies aim to describe phenomena whereas exploratory studies generate speculative insights, new questions and hypotheses. Descriptive studies aim to describe phenomena accurately either through narrative type descriptions, classifications or by measuring relationships (Blanche & Durrheim, 1999). Explanatory studies aim to provide causal explanations of phenomena. Experimental and quasi-experimental designs are used to determine whether one variable causes another (Blanche & Durrheim, 1999).
5.3.2 Applied and basic research

The findings derived from basic research are typically used to advance the fundamental knowledge of the social world. Knowledge of the world exists as general theories about how the world operates and basic research is used to refute or support these theories (Blanche & Durrheim, 1999). The findings derived from applied research, in contrast, have a practical application. Applied research aims to contribute towards practical issues of problem solving decision making policy analysis and community development (Blanche & Durrheim, 1999).

5.3.3 Quantitative and qualitative research

The distinction between quantitative and qualitative research marks a series of differences in approaches to research. Quantitative and qualitative researchers base their conclusions on different kinds of information and employ different techniques of data analysis (Blanche & Durrheim, 1999). Quantitative research is used to answer questions about relationships between measured variables with the purpose of explaining, predicting and controlling phenomena. This approach is sometimes called the traditional, experimental or positivist approach (Leedy & Ormrod, 2001).

Qualitative research believes that the researcher’s ability to interpret and make sense of what is seen as critical for an understanding of any social phenomenon. Qualitative research is typically used to answer questions about the complex nature of phenomena, often with the purpose of describing and understanding the phenomena from the participants’ point of view (Leedy & Ormrod, 2001).

5.4. The method of research applied for this study

The research approach applied in this study is both exploratory and descriptive, in that the research focused on a specific management process in form of a case study, in order to provide a detailed description of this process. The descriptive aspect of the research incorporated perspectives drawn from both the participants in the study and those drawn by the researcher from relevant literature.
The method applied in this study was conducted in a manner that ensures that the study will satisfactorily answer the research questions. The method followed was the academic literature study which laid the foundation of the research using books, the internet and journals.

5.4.1 Literature study

The literature that was presented in Chapter 2 reveals the elements of best maintenance management systems and the importance it plays within organisations. It is also important for this study to reveal what best engineering guidelines are there for the pharmaceutical industry which are presented in Chapter 3. Part of Chapter 4 presents literature on generic maintenance management system models that will guide the researcher in developing this proposed integrated maintenance management system model for My Pharmaceuticals.

5.4.2 Preliminary study

In order to understand the main maintenance management system problems at My Pharmaceuticals it was imperative to conduct a preliminary study which was presented to the different departments in the company. The preliminary study proposed to identify the main problems surrounding the maintenance management elements established in Chapter 2 and from the practical experience of the researcher in the industry. The preliminary study for this research used a simple random sampling method in order to identify the main maintenance management system problems within the company.

In selecting such a random sample, the researcher can assume that the characteristics of the sample approximate the characteristics of the total population (Leedy & Ormrod, 2001). The questions are opened-ended which allows the respondents to express their opinion thus giving the researcher a full picture of the problems. Open or instructed questions can be used in a preliminary survey or to get a feel for the subject (Goddard & Melville, 2001). There are ten main problems that were identified which are discussed at the end of Chapter 2.

5.4.3 Development of the proposed integrated maintenance management system model

The proposed integrated maintenance management system model was developed in Chapter 4. The model was developed by taking into account the literature presented in Chapter 2, the main problems identified by the preliminary study, the literature in Chapter 3 and the generic
maintenance models literature in Chapter 4. To determine if this model is applicable to solve the maintenance management system problems within the company, it is presented in the empirical study.

5.4.4 Empirical Study

The empirical study was conducted using questionnaires that were distributed to staff in the engineering, production, validation and quality assurance departments within My Pharmaceuticals. These questionnaires (Annexure 2) were hand delivered to a sample of 43 participants. The ten main problems in the maintenance management system that were identified in Chapter 2 with the preliminary study are presented in Section B in the main study. Section C1 presents the proposed integrated maintenance management system model as an annexure with statements relating to the model. Section C2 presents open-ended questions relating to the model. The questionnaires will be used to determine:

- If the bigger sample of employees in the different departments namely, Production, Engineering, Validation and Quality Assurance (QA) at My Pharmaceuticals, feels that the ten main maintenance management system problems identified by the preliminary study are a reality in the company.
- If the employees feel that the proposed integrated maintenance management model developed by the researcher will help solve the maintenance management system problems and help streamline the maintenance process.
- If there are any problems that can be identified if this model is to be implemented in the company.

5.4.4.1 Sample design

Sampling involves decisions about which people, settings, events, behaviours and social processes to observe. Exactly what will be sampled in a particular study is influenced by the unit of analysis. The main concern in sampling is representativeness. The aim is to select a sample that will be representative of the population about which the researcher aims to draw conclusions. Representative samples are especially important in descriptive surveys that are used to estimate accurately the properties of the population (Blanche & Durrheim, 1999).
In stratified random sampling some researchers have prior information regarding certain characteristics of the population’s composition and they want the selection of sample items to reflect this (Goddard & Melville, 2001). The members of a particular stratum will thus be more alike or homogeneous than the population at large. In other words, the variation within any particular stratum will be smaller than the variation among the respective data. It may be unwise to ignore the differences among such clearly discernible populations, so it is important to include them when a random sample is drawn (Welman & Kruger, 2001).

This evaluation of the proposed integrated maintenance management system model for this research will use a type of stratified random sampling method. The company has a large population within the different departments but only the maintenance artisan, maintenance managers, maintenance planners, maintenance senior manager, production planners, production team and group leaders, production and operation senior managers, quality assurance managers and the validation managers are directly involved and have an influence with the company’s maintenance management system. Table 5.1 depicts the targeted sample and the positions and departments that they are in.

Table 5.1: Sample targeted

<table>
<thead>
<tr>
<th>Position</th>
<th>Department</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>Engineering</td>
<td>12</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>Engineering</td>
<td>7</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>Engineering</td>
<td>2</td>
</tr>
<tr>
<td>Production Planner</td>
<td>Production</td>
<td>4</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>Production</td>
<td>8</td>
</tr>
<tr>
<td>Production/Operations Snr. Manager</td>
<td>Production</td>
<td>3</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>Engineering</td>
<td>1</td>
</tr>
<tr>
<td>QA Manager</td>
<td>QA</td>
<td>2</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>Validation</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>43</strong></td>
</tr>
</tbody>
</table>

In a phenomenological paradigm, also known as a qualitative paradigm, a smaller sample is examined with the understanding of human behaviour from the participant’s own frame of reference being the main concern. A case study may consist of as little as one participant (Collis & Hussey, 2003). Interviews and open-ended questions are often used to gather the information needed in the study. Reliability is normally low and validity high in this
paradigm. This paradigm is concerned with generating theories and generally produces qualitative data. The phenomenological paradigm generalises from one setting to another. The nature and importance of the variables are assessed by the qualitative paradigm (Collis & Hussey, 2003).

In a positivistic paradigm, also known as a quantitative paradigm, a larger sample size is utilised in comparison with the phenomenological paradigm. The data generated tends to be quantitative, and involves working with numbers, and is highly specific and precise. This paradigm is used when testing relationships between variables and uses hypothesis testing to assist in determining these relationships. Reliability is high and validity low in this paradigm. This paradigm generalises from the sample to the population (Collis & Hussey, 2003).

5.4.4.2 Data collection methods

Data is the basic material with which researchers work. Data comes from observation and can take the form of numbers (numeric or quantitative data) or language (qualitative data). To draw valid conclusions from a research study, it is essential that the researcher has sound data to analyse and interpret (Blanche & Durrheim, 1999). The most common instruments that are used for this purpose are tests, interviews and questionnaires (Goddard & Melville, 2001). The collection method that was used for the preliminary study and the main study was a questionnaire.

a) The questionnaire

A questionnaire can be defined as a group of written questions used to gather information from the respondents and is regarded as one of the commonest tools for gathering data in the social sciences (Blanche & Durrheim, 1999). Open or instructed questions can be used in a preliminary survey or to get a feel for the subject as mentioned earlier as respondents answer questions in their own words. Closed or structured questions are used in large scale data collection (Goddard & Melville, 2001).

The questionnaire used in this research has been formatted according to the five-point Likert Scale that ranges from (1) Strongly Disagree to (5) Strongly Agree. A rating by a Likert Scale is more useful when a behaviour, attitude or other phenomenon of interest needs to be evaluated on a continuum of, say, “inadequate” to “excellent,”
“never” to “always,” or “strongly disagree” to “strongly agree” (Leedy & Ormrod, 2001:197). The advantages of the Likert Scale are flexibility, economy, ease of composition and the fact that it is possible to obtain summaries of data from clusters of items.

Goddard and Melville (2001) suggest that a good questionnaire:

- Is complete, i.e. gets all the data needed;
- Is short, i.e. does not abuse the respondents time or concentration;
- Asks only relevant questions;
- Gives clear instructions;
- Has precise, unambiguous and understandable questions;
- Has objective questions, i.e. does not suggest answers;
- Starts with general questions;
- Use mostly closed questions.

The questionnaire was divided into four sections. Section A is about the biographical information of the respondent, Section B is the confirmation of the ten main maintenance management problems identified by the preliminary study, Section C1 presents statements on the proposed integrated maintenance management system model and while Section C2 poses open-ended questions on the proposed model. Annexure 2 indicates the types of questions that are included in the chosen data collection method.

In the covering letter and accompanying questionnaire (Annexure 2), the aim of the research was briefly explained and the respondent was also assured that the content of the questionnaire would be regarded as strictly confidential as indicated in Annexure 2. The covering letter was sent out attached to the questionnaire to the participants at My Pharmaceuticals.

b) Pretesting the questionnaire

The completed questionnaire was presented to five staff members in the Engineering department to establish if they would have any difficulties in answering the questions. Problematic questions would then be eliminated so that there were no difficulties in
recording of the data. The feedback was received and amendments were made to the questionnaire.

5.4.4.3 Data analysis

Data analysis procedures can be divided into quantitative and qualitative techniques. Quantitative techniques employ a variety of statistical analyses to make sense of data, whereas qualitative techniques begin by identifying themes in the data and the relationships between these themes (Blanche & Durrheim, 1999). The researcher analysed the data with help of a statistician using Microsoft Excel. The data was captured and analysed per statement. This is explained in more detail in Chapter 6. Statistical methods, such as the Cronbach Alpha and T test, could not be utilised in this study due to the small populations in each groups so only qualitative analysis could be performed.

5.4.4.4 Reliability and validity

The term validity means that the measurements are correct, i.e. the instrument measures what is intended to measure and that it measures this correctly (Goddard & Melville, 2001). Validity of a measurement instrument is the extent to which the instrument measures what it is supposed to measure. It takes different forms, each of which is important in different situations (Leedy & Ormrod, 2001):

- **Face validity** is the extent to which, on the surface, an instrument looks like it is measuring a particular characteristic;

- **Content validity** is the extent to which a measurement instrument is a representative sample of the content area being measured;

- **Criterion validity** is the extent to which the results of an assessment instrument correlate with another, presumably related measure;

- **Constructive validity** is the extent to which an instrument measures a characteristic that cannot be directly observed but must instead be inferred from patterns in people’s behavior.

The term reliability means that measurements made are consistent, i.e. if the same experiment is performed under the same conditions, the same measurements will be obtained (Goddard &
Melville, 2001). Leedy and Ormrod (2001) state that the following are forms of reliability that are frequently of interest in research studies:

- **Interrater reliability** is the extent to which two or more individuals evaluating the same product or performance give identical judgments;
- **Internal consistency reliability** is the extent to which all the items within a single instrument yield similar results;
- **Equivalent forms reliability** is the extent to which two different versions of the same instrument (e.g. "Form A" and "Form B" of a scholastic aptitude test) yield similar results;
- **Test-retest reliability** is the extent to which the same instrument yields the same result on two different occasions.

### 5.5 Summary

In this chapter the research methodology being followed for this research was described in depth. This chapter described the purpose of the research, the research approach and how the empirical study was conducted. The data collected by means of questionnaires will be analysed and discussed in greater detail in Chapter 6 where research question RQ6 and research objective RO6 will be addressed.
Chapter 6

Research Findings

6.1 Introduction

In Chapter 5 the research methodology was discussed. In this chapter an analysis and interpretation of data obtained from the empirical study will be discussed. Research question RQ6 and research objective RO6 will be addressed in this chapter, which is to identify if the proposed integrated maintenance management system model, which was developed in Chapter 4, can be evaluated. A survey, by means of distributing questionnaires, will be conducted to investigate the opinions of the respondents at My Pharmaceuticals. The data obtained from these questionnaires will be used to analyse empirical results.

This chapter will include information pertaining to the research findings such as the analysis of the empirical results in Section 6.2, the response rate, how the questionnaires was constructed, the biographical data of the questionnaire, the data obtained for the ten main maintenance management system problems that were identified earlier in the preliminary study in Chapter 2 and the data obtained on the proposed integrated maintenance management system model for My Pharmaceuticals follow in Section 6.2.

6.2 Analysis of the empirical results

The respondents that participated in the research were employees from My Pharmaceuticals located in Port Elizabeth, South Africa. The analysis will cover two issues. The first issue is the confirmation of the problems identified in the preliminary study conducted and explained in Chapter 2 and the second issue is to identify if the proposed integrated maintenance management system model will work within the company.

6.2.1 Response rate

The questionnaire was presented to a selected target within key positions of My Pharmaceuticals. Since the maintenance management system is being looked at holistically, it was important to obtain feedback from the different departments on which plant maintenance has an influence. The departments that were targeted were Production, Validation, Quality
Assurance (QA) and Engineering. A total of 43 employees were targeted and 35 responded which produced an 81 percent response rate. Table 6.1 presents which positions were targeted as well as the response rate from each department.

**Table 6.1: Sample response rate**

<table>
<thead>
<tr>
<th>Position</th>
<th>Department</th>
<th>Issued</th>
<th>Received</th>
<th>Response rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>Engineering</td>
<td>12</td>
<td>8</td>
<td>67%</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>Engineering</td>
<td>7</td>
<td>6</td>
<td>86%</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>Engineering</td>
<td>2</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Production Planner</td>
<td>Production</td>
<td>4</td>
<td>3</td>
<td>75%</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>Production</td>
<td>8</td>
<td>8</td>
<td>100%</td>
</tr>
<tr>
<td>Production/Operations Sr. Manager</td>
<td>Production</td>
<td>3</td>
<td>2</td>
<td>67%</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>Engineering</td>
<td>1</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td>QA Manager</td>
<td>QA</td>
<td>2</td>
<td>2</td>
<td>100%</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>Validation</td>
<td>4</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>43</strong></td>
<td><strong>35</strong></td>
<td><strong>81%</strong></td>
</tr>
</tbody>
</table>

6.2.2 Main study questionnaire

The questionnaire (Annexure 2) that was distributed to the employees consisted of 3 sections from Section A to Section C. Section A is the biographical information. Section B statements are designed on the Likert Scale model and covers the preliminary study. The purpose of presenting the preliminary study main problem statements here is to obtain confirmation that the problems are valid as the proposed model incorporated these problems. Section C1 statements are also designed on the Likert Scale model and covers the proposed model developed in Chapter 4. Section C2 has the open-ended questions whereby the respondents were asked their own opinion on the problems and improvements they see with the proposed integrated maintenance management model. In order to analyse the Likert Scale responses a decision was taken to group all the “strongly agree” and “agree” responses together. The same was done with the “strongly disagree” and “disagree” data.

**6.2.2.1 Section A: Biographical data**

The biographical information was analysed according to years of service in the company, the department the respondent is currently working in, the current position and years of service in
the current position. Annexure 3 presents a table that gives a summary of the biographical information. This will be explained in detail and presented by Chart 6.1 to 6.4.

Chart 6.1 shows that most of the respondents have been in the company long enough to understand the programmes and systems being used in the company. It can be seen that 43 percent of the respondents have served the company between five and ten years and 20 percent have eleven and more years of service. This affirms that the sampled respondents are reasonably familiar with and have been involved with the company programmes and processes long enough to make informed judgments. There are 37 percent respondents that have less than five years service within the company.

**Chart 6.1: Number of respondents according to length of service.**

Chart 6.2 shows that majority of the respondents are from the Engineering and the Production departments which are 46 and 37 percent respectively. This is a true reflection as these are the two biggest departments in terms of employees. Only four of the Validation department employees were targeted as they have a direct influence in the maintenance reviews and only two of the Quality Assurance (QA) employees were targeted, as they have a direct influence in the maintenance change controls, deviations and standard operating procedures (SOP) processes.

**Chart 6.2: Number of respondents by department.**
Chart 6.3 indicates the positions of the respondents. The twelve maintenance artisans that were targeted are artisans that work directly with the processing equipment in all the facilities. Only eight of these artisans responded which makes up 23 percent of the total sample. There are seven maintenance managers in the facility with one senior maintenance manager. The one senior manager including six maintenance managers responded to the questionnaire. The planning office has three maintenance planners of which one is the position of the researcher while only one of the remaining two responded to the questionnaire.

Production has three operations managers for the whole site of which two managed to respond to the questionnaire. There are also only four production planners for the site where three responded to the survey. Production has eight team/group leaders that perform functions as team leaders on the production floor and they all responded. There are only two QA managers that deal directly with the engineering department with regard to change controls and deviations on maintenance aspects. Both of these managers that were targeted responded to the questionnaire. Lastly there are only four validation managers that evaluate the maintenance procedures within the whole site. All of them responded to the questionnaire.

Chart 6.3: Number of respondents by position

The majority of the respondents are with the company for 5 years or more as indicated earlier in Chart 6.1, but Chart 6.4 indicates that majority are in their positions for less than 5 years. It could indicate that the respondents receive promotion frequently as they do not stay long in their positions, but the contrary to this effect is that they posses different experiences which further affirm that the sampled respondents are able to give a holistic opinion.
6.2.2.2 Section B: Preliminary study problem statements

The preliminary study that was performed in Section 2.15.2 in Chapter 2 identified 10 main problems. Opinions on these problems are asked in the main study in Section B of the questionnaire to obtain a response from the bigger sample. All the “agree” or “strongly agree” responses were combined and the same was done with “disagree” and “strongly disagree” as mentioned earlier in order to make the analysis more meaningful. Annexure 4 presents a table that depicts a summary of the overall responses on the main problems identified in the preliminary study. Annexure 5 splits these responses per department. This will be explained in detail in the following figures as Figure 6.1 to Figure 6.10 presents the responses by the different departments while the following tables, Table 6.2 to Table 6.11, presents the responses by the relevant positions. The problem number (P1 to P10) with the description of the problem statement will be presented for each explanation.

Problem P1: States that there is a lack of maintenance and production planning integration.

There is an overwhelming response from the Engineering, Validation and QA department that agrees that this is a problem within the company as shown in Figure 6.1 (see page 92). There is a concern that the Production department is not fully convinced that this is a problem and the concern is highlighted in Table 6.2 (see page 92) that shows that 3 of the 8 team/group leaders in production disagree while 2 are neutral towards this problem giving a total of 5 out of 8. The reason for this can be that the Production department is achieving their targets every month so there is no or hardly any emphasis on trying to integrate the planning with the Engineering department. The equipment is high tech and fairly new so the breakdowns are not
as frequent, but when the age of the equipment increases, proper planning integration will be needed.

**Figure 6.1: Response to P1 per department**

**Table 6.2: Response to P1 per position**

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
<th>Neutral (n=1)</th>
<th>Strongly agree / Agree (n=2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>25% (n=2)</td>
<td>12% (n=1)</td>
<td>63% (n=5)</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>17% (n=1)</td>
<td>0%</td>
<td>83% (n=5)</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>100% (n=1)</td>
<td>0%</td>
</tr>
<tr>
<td>Production Planner</td>
<td>33% (n=1)</td>
<td>0%</td>
<td>67% (n=2)</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>38% (n=3)</td>
<td>24% (n=2)</td>
<td>38% (n=3)</td>
</tr>
<tr>
<td>Production/Operations Sr. Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>25% (n=1)</td>
<td>75% (n=3)</td>
</tr>
</tbody>
</table>

**Problem P2**: States that there is no understanding between Engineering, Process Validation and Production on the importance of maintenance and periodically validation reviews.

Figure 6.2 for problem P2, indicates that the Production department’s response is that 46 percent agree, 8 percent are neutral and 46 percent disagree, while the other departments have a majority response that agrees with this problem. This proves that the Production department again does not fully agree that this is a problem as 2 of the 3 production planners as well as 4 of the 8 production team/group leaders disagree and feel that they do understand the importance of maintenance and periodic validation reviews, as shown in Table 6.3. Although the Engineering department has an 81 percent response rate that this is a problem that exists in the company, there is a concern that the engineering senior manager is neutral on this problem shown in Table 6.3, which indicates that he might not be aware that this problem exists.

**Figure 6.2: Response to P2 per department**

**Table 6.3: Response to P2 per position**

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
<th>Neutral (n=1)</th>
<th>Strongly agree / Agree (n=2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=8)</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>17% (n=1)</td>
<td>17% (n=1)</td>
<td>66% (n=4)</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>Production Planner</td>
<td>67% (n=2)</td>
<td>0%</td>
<td>33% (n=1)</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>50% (n=4)</td>
<td>12% (n=1)</td>
<td>38% (n=3)</td>
</tr>
<tr>
<td>Production/Operations Sr. Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>100% (n=1)</td>
<td>0%</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=4)</td>
</tr>
</tbody>
</table>
**Problem P3**: States that predictive maintenance is not being practised within the company.

Figure 6.3 for problem P3, indicates that the only department that has a high percentage in agreeing with this problem is the Engineering department as the response is that 63 percent agree, 12 percent are neutral and 25 percent disagree. Predictive maintenance is an engineering function so it is understandable that the other departments do not fully agree or understand that this problem exists. Table 6.4 shows that 4 of the 8 maintenance artisans agree, 4 of the 6 maintenance managers agree, the 1 maintenance planner and the 1 senior manager also agrees.

![Figure 6.3: Response to P3 per department](image)

**Table 6.4: Response to P3 per position**

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
<th>Neutral</th>
<th>Strongly agree / Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>38% (n=3)</td>
<td>12%</td>
<td>50% (n=4)</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>17% (n=1)</td>
<td>17%</td>
<td>66% (n=4)</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>Production Planner</td>
<td>67% (n=2)</td>
<td>33%</td>
<td>9%</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>25% (n=2)</td>
<td>12%</td>
<td>63% (n=5)</td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
<td>100%</td>
<td>9%</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0%</td>
<td>50%</td>
<td>50% (n=1)</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>25% (n=1)</td>
<td>25%</td>
<td>50% (n=2)</td>
</tr>
</tbody>
</table>

**Problem P4**: States that reliability centred maintenance (RCM) is not being practised within the company.

Figure 6.4 (see page 94) for problem P4, indicates that there is an uncertainty within the other departments except in the Engineering department as the response is that 69 percent agree, 25 percent are neutral and 6 percent disagree. Here again RCM is an engineering function, therefore the uncertainty is with the other departments.

Table 6.5 (see page 94) indicates that not all the maintenance artisans agree as 4 of the 8 agree, 3 are neutral and 1 disagrees. This might be a contributing factor to training within the pharmaceutical industry maintenance that the maintenance artisans do not fully understand the importance of RCM in the pharmaceutical environment. The response from the maintenance managers’ shows in Table 6.5 (see page 94) that 5 of the 6 of them do agree while 1 is neutral, the 1 maintenance planner and the one senior manager agree that RCM is not being practised within the company.
**Problem P5**: States that there is overall poor senior management interaction and buy in on maintenance policies.

Figure 6.5 for problem P5, indicates that the Engineering department has the majority respondents that agree that this is a problem within the company. The other departments are mostly uncertain of this problem which could indicate that they are not aware this problem exists or that it does not affect them.

Table 6.6 indicates that the 1 maintenance senior manager agrees and 1 of the 2 production/operations senior manager also agrees where the other 1 production/operations senior manager is neutral. This is a positive sign from top management that they agree that there is an overall poor senior management interaction and buy in on maintenance policies. Top management should be the driving force behind company polices.
**Problem P6:** States that there are 2 CMMS databases for one central engineering department.

Figure 6.6 for problem P6, indicates that the Validation department has the highest percentage that agrees that this is a problem with a response of 75 percent that agree and 25 percent that are neutral. This is understandable as the equipment maintenance data from the two CMMS is reviewed yearly by the Validation department to identify any discrepancies and having two CMMS causes an issue where equipment maintenance task, for example, is different on the two CMMS especially for the same type of equipment housed in the different units.

There is also a large number of respondents that are neutral from the other departments including the Engineering department. This reason for this is, as shown in Table 6.7 where only 1 maintenance artisan agrees, 6 are neutral and 1 disagrees, that they are the end users and they are allocated to a specific unit that has one CMMS servicing it, so they do not need to work on the other CMMS in the other unit and are not exposed to the constraints of having two CMMS for one site. The maintenance employees that should have a problem with this are the maintenance managers and maintenance planners as they have to work on both CMMSs to obtain consolidated reports for all the sites. This is proven in Table 6.7 as the 1 maintenance planner agrees and 5 of the 6 maintenance managers agree with 1 being neutral. The maintenance senior manager agrees as well.

**Problem P7:** States that there is no proper spares management system.

Figure 6.7 (see page 96) for problem P7, indicates that there is a general neutral response to this problem from all the departments, but the reason for the Production department having a 46 percent response to agreeing with this problem could indicate the experience they have.
when breakdowns occur and part of the delay is waiting for spares. The reason for the QA department having a 50 percent response to agreeing with this problem could indicate the experience they have on the feedback that they receive from production reports on breakdowns which take a long time to repair as they are waiting for engineering to obtain spares.

Equipment spares management is controlled by the Engineering department and the maintenance artisans and maintenance managers deal directly with the spares and majority of them agree that there is no proper spares management in place. Table 6.8 shows that 4 of the 8 maintenance artisans agree, 2 are neutral and 2 disagree, 3 of the 6 maintenance managers agree, 1 is neutral and 2 disagree and the 1 maintenance senior manager agrees that there is no proper spares management in place. There is a concern that the 1 maintenance planner, as shown in Table 6.8, disagrees that proper spares management is a problem. This could indicate that the maintenance planner is settled in the current spare management process is not aware that it can be improved.

Figure 6.7: Response to P7 per department

<table>
<thead>
<tr>
<th></th>
<th>Strongly disagree / Disagree</th>
<th>Neutral</th>
<th>Strongly agree / Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>25% (n=2) 25% (n=2)</td>
<td>50% (n=4)</td>
<td></td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>33% (n=2) 17% (n=1)</td>
<td>50% (n=3)</td>
<td></td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>100% (n=1)</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Production Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>25% (n=2) 50% (n=4)</td>
<td>25% (n=2)</td>
<td></td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
<td>50% (n=1)</td>
<td>50% (n=1)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0% 50% (n=1)</td>
<td>50% (n=1)</td>
<td></td>
</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>75% (n=3)</td>
<td>25% (n=1)</td>
</tr>
</tbody>
</table>

Table 6.8: Response to P7 per position

Problem P8: States that there is a lack of training of engineering staff in the latest technology of process equipment.

Figure 6.8 (see page 97) for problem P8, indicates that there is an overwhelming response from all the departments and from all the positions as shown in Table 6.9 (see page 97) that agree that there is a lack of training of engineering staff in the latest technology of process equipment. In the pharmaceutical industry, process equipment is critical and the design is hi-tech so there is a need for this type of training.
The high response to agreeing that this is a problem from the Production and the QA departments might be from their experience at looking at the overall equipment effectiveness (OEE) reports that include equipment failure as the reason for not reaching targets. The Validation department’s high response to agreeing to this problem might come from when they find faults on equipment performance and functioning when doing their yearly reviews. The Engineering department confirms this by also having a high response rate to agreeing that this is a problem.

**Problem P9:** States that there is a lack of understanding of equipment that is validated and no clear process as to when change controls and deviations are needed.

Figure 6.9 (see page 98) for problem P9, indicates that all the departments agree that there is a problem understanding change control and deviation. The change controls and deviation process is critical to the pharmaceutical industry on equipment that is validated to know what changes can or cannot be made to the equipment.

Table 6.10 (see page 98) indicates that 7 of the 8 maintenance artisans agree and 1 disagrees while all the maintenance managers agree with this problem. They are the front line engineering staff that deals directly with the maintenance of the validated equipment and when they do repairs, there is an uncertainty about when a change control or deviation needs to be created. The 1 maintenance senior manager is neutral on this problem which indicates that he could be unaware that this problem exists.
Problem P10: States that there is no value adding maintenance analysis performed on maintenance data.

Figure 6.10 for problem P10, indicates there is a high response from the Engineering, Validation and QA departments that agrees that this is a problem. This indicates that the departments do understand the value of maintenance analysis on equipment maintenance data and that it should be practised within the company.

The maintenance analysis should be used as a tool for the engineering management team so it understands that the Production department does not fully agree with this problem. It is clear from Table 6.11 that all the maintenance managers agree to this problem as they understand that the analysis can be used as a proactive tool for equipment maintenance. The 1 maintenance senior manager is neutral on this problem which proves that there is no drive to get proper value adding analysis on maintenance data.

Table 6.10: Response to P9 per position

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
<th>Neutral</th>
<th>Strongly agree / Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>12% (n=1)</td>
<td>0%</td>
<td>88% (n=7)</td>
</tr>
<tr>
<td>Maintenance Manager</td>
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</tr>
<tr>
<td>Maintenance Planner</td>
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<td>0%</td>
</tr>
<tr>
<td>Production Planner</td>
<td>33% (n=1)</td>
<td>0%</td>
<td>67% (n=2)</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>25% (n=2)</td>
<td>12% (n=1)</td>
<td>63% (n=3)</td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>100% (n=1)</td>
<td>0%</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0%</td>
<td>0%</td>
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<tr>
<td>Validation Manager</td>
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</table>

Table 6.11: Response to P10 per position

<table>
<thead>
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<th>Strongly agree / Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
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<td>57% (n=3)</td>
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</tr>
<tr>
<td>Maintenance Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=6)</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>100% (n=1)</td>
<td>0%</td>
</tr>
<tr>
<td>Production Planner</td>
<td>33% (n=1)</td>
<td>67% (n=2)</td>
<td>0%</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>25% (n=2)</td>
<td>12% (n=1)</td>
<td>63% (n=3)</td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
<td>50% (n=1)</td>
<td>50% (n=1)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>100% (n=1)</td>
<td>0%</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>25% (n=1)</td>
<td>75% (n=1)</td>
</tr>
</tbody>
</table>
6.2.2.3 Summary for research findings in Section B

In the selected sample there is a good response from all the departments and from all the positions within the company that agree that these main problems are setbacks within the company as can be seen in previous figures, Figure 6.1 to Figure 6.10. It can also be seen in the figures that some of the problems that the Engineering department experiences are not entirely experienced by the other departments. This is understandable as some of these problems are engineering specific. There is a concern however that some management and senior management are neutral on some of these main problems.

Studying the previous tables, Table 6.2 to Table 6.11, which presents the positions responses, there is a feeling that the Production department is not as convinced as the Engineering, Validation and QA departments that these problems exist especially on problems P1 and P2 which states that there is no proper planning integration between the 2 departments and that there is no understanding between the Production department, the Engineering department and the Validation department on the importance of maintenance and process validation. In the next section the statements on the proposed integrated maintenance model will be investigated.

6.2.2.4 Section C1: Proposed Integrated Maintenance Management System Model

An integrated maintenance management system model was developed for My Pharmaceuticals in Chapter 4 as shown in Figure 6.11 (see page 100). This model was developed with the help of the generic maintenance management models literature presented in Chapter 4 and from the ten main problems identified from the preliminary study as well as the best maintenance practices in Chapters 2 and the best pharmaceutical maintenance practices and regulatory controls literature in Chapter 3.
The statements in Annexure 2 Section C1 describe what the model proposes and were presented to the sample. Annexure 6 presents a table that summarises the respondents’ opinions on these statements. Annexure 7 splits these responses per departments and is presented in a table format. This will be explained in detail and presented by the following figures, Figure 6.12 to Figure 6.28 and following tables, Table 6.12 to Table 6.28. The statement number (S1 to S17) with the description of the statement that the model proposes will be presented for each explanation.

**Statement S1:** It is important to have a steering committee to develop maintainability objectives for the maintenance policy of the company.

Figure 6.12 (see page 102) for statement S1, indicates that there is an overwhelming response from all the departments in agreeing that this is an important element at the tactical level to have for the maintenance management system that the model proposes. Table 6.12 shows that
all the positions agree, except for 1 maintenance artisan who is neutral. This indicates that the artisan is uncertain if a steering committee can help with the maintenance objectives. This could indicate that this artisan has become complacent with performing maintenance in the current way at the company.

Figure 6.12: Response to S1 per department

Table 6.12: Response to S1 per position

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
<th>Neutral</th>
<th>Strongly agree / Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>0%</td>
<td>12% (n=1)</td>
<td>88% (n=7)</td>
</tr>
<tr>
<td>Maintenance Manager</td>
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<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>0%</td>
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<tr>
<td>Production Planner</td>
<td>0%</td>
<td>0%</td>
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<tr>
<td>Production Team/Group Leader</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=6)</td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=4)</td>
</tr>
</tbody>
</table>

Statement S2: Having a steering committee will encourage senior management involvement in the maintenance management system objectives of the company.

Figure 6.13 (see page 102) for statement S2, indicates that there is an overwhelming response from all the departments in agreeing that this is an important element to have for the maintenance management system that the model proposes. All the respondents agree with this statement that the model proposes except for 1 maintenance manager and 1 production team/group leader that are neutral as shown in Table 6.13 (see page 102), as this indicates that they are not sure whether having a steering committee will encourage senior management involvement. This could indicate that the 1 maintenance manager has no confidence in the current senior management within the company and feels that they would not be interested in being part of the steering committee. This could also be the case for the 1 production team/group leader who is neutral.
Statement S3: One of the main parts of the maintenance management system objectives in the company is to have multi-skilled Engineering personnel that understand the pharmaceutical industry dynamics.

Figure 6.14 for statement S3, indicates that there is an overwhelming response from all the departments in agreeing that having multi-skilled engineering personnel, that the tactical level of the model proposes as part of the maintenance management system objectives, is important for the company. All the respondents agree with this statement that the model proposes except for 1 maintenance manager who is neutral as shown in Table 6.14. This indicates that this maintenance manager is uncertain if this element of the proposed model is important. This could indicate that this maintenance manager believes that the current maintenance personnel’s skills are sufficient for this company.

Statement S4: One of the main parts of the maintenance management system objectives of the company, being in the pharmaceutical industry, is to be compliant to Validation and Quality Assurance requirements.
Figure 6.15 for statement S4, indicates that there is a good response from all the departments in agreeing that this is an important strategic level element to have for the maintenance management system that the model proposes. The respondents that are uncertain are the 1 maintenance artisan and the 1 production team/group leader who are neutral as shown in Table 6.15. This could indicate that these two respondents do not understand the implications of process validation and quality requirements in the pharmaceutical industry.

Figure 6.15: Response to S4 per department

Table 6.15: Response to S4 per position

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
<th>Neutral</th>
<th>Strongly agree / Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
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<td>Maintenance Manager</td>
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<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Production Planner</td>
<td>0%</td>
<td>0%</td>
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<tr>
<td>Production Team/Group Leader</td>
<td>0%</td>
<td>12%</td>
<td>88%</td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
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</tr>
<tr>
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<tr>
<td>QA Manager</td>
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</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
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</tr>
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</table>

Statement S5: The International Society for Pharmaceutical Industry (ISPE) guide with a combination of Maintenance Best Practices should be used as a guide in the maintenance approach and qualification for the company in the proposed model.

Figure 6.16 (see page 104) for statement S5, indicates that there is an overall good response from all the departments in agreeing that this is an important element to have in the maintenance management system of the company that the model proposes. Most of the respondents agree with this statement that the model proposes.

A concern from the Engineering department is that 1 maintenance artisan, 1 maintenance manager, the 1 maintenance senior manager and the 1 maintenance planner are neutral to this statement as shown in Table 6.16 (see page 104). This indicates that they are not aware of the ISPE guideline and maintenance best practices that can be used in the company’s maintenance approach and maintenance qualification as the model proposes. There is 1 production team/group leader and 1 production/operations senior that are also neutral to this statement, but this should not be a concern as the International Society for Pharmaceutical
Engineering (ISPE) guideline and maintenance approach is more applicable for the Engineering department.

**Statement S6:** Maintenance execution should include RCM which focuses resources on those equipment items with the greatest impact on business performance can enhance compliance and reduce maintenance costs and unplanned downtime.

Figure 6.17 for statement S6, indicates that almost all of the responses from the different departments agree that this is an important operational level element to have for the maintenance management system for the company that the model proposes. Table 6.17 shows that there is an uncertainty from 1 maintenance artisan, 1 production team/group leader and the 2 validation managers that are neutral with this statement. This could indicate that these respondents are uncertain what reliability centred maintenance (RCM) entails.

**Table 6.16: Response to S5 per position**

<table>
<thead>
<tr>
<th>Position</th>
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</tr>
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<td>12% (n=1)</td>
<td>88% (n=7)</td>
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<tr>
<td>Maintenance Manager</td>
<td>0%</td>
<td>17% (n=1)</td>
<td>100% (n=5)</td>
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<tr>
<td>Maintenance Planner</td>
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<td>100% (n=1)</td>
<td>0%</td>
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<tr>
<td>Production Planner</td>
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<td>100% (n=3)</td>
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<tr>
<td>Production Team/Group Leader</td>
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<td>13% (n=1)</td>
<td>88% (n=7)</td>
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<tr>
<td>Production/Operations Sr Manager</td>
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<td>50% (n=1)</td>
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<tr>
<td>Maintenance Senior Manager</td>
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<td>100% (n=1)</td>
<td>0%</td>
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<tr>
<td>QA Manager</td>
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<td>Validation Manager</td>
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</table>

**Table 6.17: Response to S6 per position**

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<tr>
<td>Maintenance Manager</td>
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<td>0%</td>
<td>100% (n=6)</td>
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<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
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<tr>
<td>Production Planner</td>
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<td>Production Team/Group Leader</td>
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<td>13% (n=1)</td>
<td>88% (n=7)</td>
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<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
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<tr>
<td>Maintenance Senior Manager</td>
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<td></td>
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</tr>
<tr>
<td>Validation Manager</td>
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<td>50% (n=2)</td>
<td>50% (n=2)</td>
</tr>
</tbody>
</table>
Statement S7: Process validation must integrate with engineering in verifying equipment maintenance to the specifications and conditions in order to assure its ability to produce the final product to the desired quality characteristics.

Figure 6.18 for statement S7, indicates that there is an overall positive response from the different departments that agree that this is an important process to have for the maintenance management system for the company that the model proposes. Table 6.18 shows that all the quality assurance and validation managers agree with this process that the model proposes as process validation plays a critical part in the pharmaceutical industry.

All the other departments respondents agree as well except for 1 maintenance manager and 1 production team/group leader that are neutral which indicates that they do not understand the importance of process validation and are uncertain whether it should be integrated with engineering.

Figure 6.18: Response to S7 per department

Table 6.18: Response to S7 per position

<table>
<thead>
<tr>
<th>Position</th>
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<th>Strongly agree / Agree</th>
</tr>
</thead>
<tbody>
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<td>0%</td>
<td>88% (n=7)</td>
</tr>
<tr>
<td>Maintenance Manager</td>
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<td>17% (n=1)</td>
<td>83% (n=5)</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
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<td>Production Planner</td>
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<td>0%</td>
<td>100% (n=3)</td>
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<td>Production Team/Group Leader</td>
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<td>12% (n=1)</td>
<td>88% (n=7)</td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
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<tr>
<td>QA Manager</td>
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</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=4)</td>
</tr>
</tbody>
</table>

Statement S8: Quality assurance (QA) must integrate with engineering with regard to change controls and deviations to prevent unauthorised modifications to maintenance tasks and equipment that are validated.

Figure 6.19 (see page 106) for statement S8, indicates that there is a strong response from all the different departments that agree that this is an important element to have for the maintenance management system for the company that the model proposes. Table 6.19 (see page 106) shows that all the quality assurance, validation managers and production staff agree with this process that the model proposes as quality assurance plays a critical part in the
pharmaceutical industry. There are two engineering respondents that are neutral with this statement, a maintenance artisan and a maintenance manager. This could indicate that they do not understand the impact of QA on the process equipment in the pharmaceutical industry.

**Figure 6.19: Response to S8 per department**

**Table 6.19: Response to S8 per position**

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
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<th>Strongly agree / Agree</th>
</tr>
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<tbody>
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<td>Maintenance Artisan</td>
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<td>0%</td>
<td>88% (n=7)</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>0%</td>
<td>17% (n=1)</td>
<td>83% (n=5)</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>Production Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=3)</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=6)</td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
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<td>100% (n=2)</td>
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<tr>
<td>Maintenance Senior Manager</td>
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<td>QA Manager</td>
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</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=4)</td>
</tr>
</tbody>
</table>

**Statement S9:** Integration with production planning and engineering maintenance planning will encourage a good maintenance plan which can result in considerable cost savings to the company.

Figure 6.20 for statement S9, indicates that all the respondents from the Production, Engineering, Validation and the Quality Assurance (QA) departments agree with this statement. This is a positive sign which indicates that all the role players understand that there is a need for production and maintenance planning integration that the model proposes.

**Figure 6.20: Response to S9 per department**

**Table 6.20: Response to S9 per position**

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
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<th>Strongly agree / Agree</th>
</tr>
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<td>Maintenance Manager</td>
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<tr>
<td>Maintenance Planner</td>
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<td>0%</td>
<td>100% (n=1)</td>
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<td>Production Planner</td>
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<tr>
<td>Production Team/Group Leader</td>
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<td>Production/Operations Sr Manager</td>
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<tr>
<td>Validation Manager</td>
<td>0%</td>
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<td>100% (n=4)</td>
</tr>
</tbody>
</table>

**Statement S10:** Opportunistic maintenance, which is about maintenance tasks that are planned and performed at the stoppages planned by the production department, such as
cleaning, shift, batch or tool changes, can be integrated between production planning and engineering maintenance planning.

Figure 6.21 for statement S10, indicates that there is a good response from all the different departments that agree that this is an important type of maintenance to have for the maintenance management system for the company that the model proposes. All the department’s respondents agree except for the Engineering department as 69 percent agree, 25 percent are neutral and 6 percent disagree.

Table 6.21 indicates that 4 maintenance artisans are neutral and 1 maintenance manager disagrees. This could indicate that the maintenance artisans were never exposed to opportunistic maintenance and are therefore uncertain if it can be implemented as the model proposes. The 1 maintenance manager that disagrees with this type of maintenance could have had an unsuccessful experience with the Production department in getting equipment for maintenance during a planned stoppage, but this could have been attempted with the operators of the equipment instead of with the production and maintenance planning departments as the model proposes.

**Statement S11:** Management of the spare parts in the company should be managed by the current computerised maintenance management system (CMMS).

Figure 6.22 (see page 108) for statement S11, indicates that there is a majority of the respondents from all the different departments that agree that the spare parts should be managed by the current CMMS of the company as the model proposes. Table 6.22 indicates
that there is a maintenance artisan and a maintenance manager from the Engineering department that are neutral to this statement. This could indicate that they are uncertain if the current CMMS can successfully manage the spare parts. Table 6.22 also indicates that 1 of the production team/group leaders, 1 of the senior production/operations managers, 1 of the QA managers and 2 of the validation managers are neutral with this statement. This could indicate that they are uncertain if a CMMS can accommodate a spares module.

**Figure 6.22: Response to S11 per department**

**Table 6.22: Response to S11 per position**

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
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<tr>
<td>Maintenance artisan</td>
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<td>17% (n=1)</td>
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<td>Production Planner</td>
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<tr>
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<td>50% (n=1)</td>
<td>50% (n=1)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0%</td>
<td>50% (n=1)</td>
<td>50% (n=1)</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>50% (n=2)</td>
<td>50% (n=2)</td>
</tr>
</tbody>
</table>

**Statement S12:** The maintenance planning and scheduling should be managed by one (1) computerised maintenance management system (CMMS) for the whole site.

Figure 6.23 (see page 109) for statement S12, indicates that there is an overwhelming response from the Production and Engineering departments that agree that there should be 1 CMMS for the whole site as the model proposes. Table 6.23 (see page 109) indicates that from the Engineering department, there is 1 maintenance artisan that is neutral.

The reason for this could be that since the artisans are working in one unit they get to work on one CMMS anyway. Table 6.23 also shows that 2 of the production planners and 2 of the validation managers are neutral with this proposal. This could simply be because the CMMS is an engineering tool and the constraints are mostly felt by the Engineering department.
Statement S13: Maintenance history on equipment, which is the primary tool of reliability engineering in evaluation and analysis, is used to direct necessary reviewing of maintenance tasks.

Figure 6.24 for statement S13, indicates a 100 percent response from the Validation and QA departments on this statement that the model proposes. Table 6.24 indicates 1 maintenance artisan that is neutral and 1 maintenance manager that disagrees. This could indicate that this maintenance artisan is not involved with the reviewing of maintenance tasks and is therefore uncertain that the maintenance history on equipment can be used for this. The reason why the 1 maintenance manager disagrees with this could be that that maintenance history on equipment is currently not being utilised. Table 6.24 also indicates that the 1 senior production/operations manager is neutral on this statement. This could simply be because the reviewing of maintenance tasks on equipment is an engineering function.
**Statement S14:** Engineering should perform failure mode, effects and criticality analyses (FMECA) on equipment to improve and optimise maintenance identification and qualification.

Figure 6.25 for statement S14, indicates that all the departments have an overwhelming response to agree with the model that proposes FMECA on equipment to improve and optimise maintenance identification and qualification. Table 6.25 indicates that the 1 senior production/operations manager and the 1 validation manager are neutral on this proposal. This could indicate that they are unaware that this type of analysis can be performed on equipment.

**Table 6.25: Response to S14 per position**

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
<th>Neutral</th>
<th>Strongly agree / Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=8)</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=6)</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>Production Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=3)</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=8)</td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
<td>50% (n=1)</td>
<td>50% (n=1)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>25% (n=1)</td>
<td>75% (n=3)</td>
</tr>
</tbody>
</table>

**Statement S15:** Engineering self-audits will help keep the maintenance identification and qualification in line.

Figure 6.26 (see page 111) for statement S15, indicates that all the departments have an overwhelming response to agree with the model that proposes engineering self audits on the processes and equipment. Table 6.26 (see page 111) indicates that there is 1 maintenance artisan and 1 maintenance manager that are neutral with this statement. This could be that these positions are unaware of the value that self-audits can add to the maintenance identification and qualification of equipment.
Statement S16: The maintenance policy is an overall relationship of management awareness, maintainability objectives, methods, and concepts.

Figure 6.27 for statement S16, indicates that all the departments have an overwhelming response to agree with the model that presents the maintenance policy as an overall relationship of management awareness, maintainability objectives, methods, and concepts. Table 6.27 indicates that 1 maintenance artisan, 2 maintenance managers and the 1 maintenance senior manager are neutral with this statement. It is understandable that the 1 maintenance artisan and the 1 maintenance manager are neutral as they normally execute maintenance strategies and are not always involved with maintenance policies. There is a concern that the 1 maintenance senior manager is uncertain about the maintenance policy as it is at this level that the maintenance policies are driven.

Statement S17: This proposed integrated maintenance management system model will help streamline the maintenance management system within the company.
Figure 6.28 for statement S17, indicates that all the departments agree convincingly that this proposed integrated maintenance management system model will help streamline the maintenance system within the company. Table 6.28 indicates that there is only 1 maintenance artisan and 1 maintenance manager that are uncertain that the model will be effective. This could indicate that these respondents would like to see the model implemented before giving their opinion.

**Figure 6.28: Response to S17 per department**

![Figure 6.28: Response to S17 per department](image)

**Table 6.28: Response to S17 per position**

<table>
<thead>
<tr>
<th>Position</th>
<th>Strongly disagree / Disagree</th>
<th>Neutral</th>
<th>Strongly agree / Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Artisan</td>
<td>0%</td>
<td>12% (n=1)</td>
<td>88% (n=7)</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>0%</td>
<td>17% (n=1)</td>
<td>83% (n=5)</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>Production Planner</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=3)</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=8)</td>
</tr>
<tr>
<td>Production/Operations Sr Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=1)</td>
</tr>
<tr>
<td>QA Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=2)</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>0%</td>
<td>0%</td>
<td>100% (n=4)</td>
</tr>
</tbody>
</table>

**6.2.2.5 Summary for research findings in Section C1**

In the selected sample there is an overwhelming response from all the departments and from all the positions within the company that agree with the statements that the proposed model presented in Figure 6.11 (see page 100) proposes to the company. A positive result is that senior management is in favour of having a steering committee for the development of the maintenance objectives in the company as shown in Table 6.12 (see page 101) and they also agree that this will encourage more senior management involvement as shown in Table 6.13 (see page 102).

The respondents are in favour of having the artisans be multi-skilled and be familiar with the pharmaceutical regulations as shown in Figure 6.14 (see page 102), however there is a concern that some engineering respondents are not familiar with the International Society for Pharmaceutical Engineering (ISPE) guide as shown in Table 6.16 (see page 104). It is also shown that the respondents from all the departments understand the importance of working in the pharmaceutical industry as they agree that there should be integration between all the departments as shown in Figure 6.15 (see page 103), Figure 6.18 (see page 105) and Figure
6.19 (see page 106). Reliability Centred Maintenance (RCM) seems to be unfamiliar to some of the respondents as in Figure 6.17 (see page 104).

The respondents in the Production and Engineering departments are in favour of having the spares managed by the current computerised maintenance management system (CMMS), since they are involved with the spares, they understand the benefits that can be achieved by having this module. All the departments understand the importance of doing analysis on maintenance history as shown in Figure 6.24 (see page 109) and Figure 6.25 (see page 110) as this will lead to proactive maintenance and decrease breakdowns. Figure 6.28 and Table 6.28 (see page 112) convincingly concludes that all the respondents agree to what the model proposes as it will help streamline the maintenance management system within the company.

6.2.2.6 Section C2: Respondents’ opinions

This is the section whereby the respondents were asked their opinion on the following open ended questions:

1. What problems do you foresee with implementing this proposed integrated maintenance management system model for the company
2. What improvements can be identified with this proposed integrated maintenance management system model for the company?

Table 6.29 (see page 114) and Table 6.30 (see page 115) are summaries all of the respondents’ opinions on these open ended questions. Annexure 8 gives a list of the problems that were received from the respondents that gave their opinion on the two open ended questions.

The findings in Table 6.29 are related to the respondents’ opinion on what they might foresee if this proposed integrated model had to be implemented in the company. Table 6.29 summarises the similar problems and the ones that stand out. These problems will be evaluated below.
Table 6.29: Respondents opinion to open ended question 1

<table>
<thead>
<tr>
<th>What problems do you foresee with implementing this proposed integrated maintenance management system model for the company?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Artisans to be trained to understand on RCM that the model proposes</td>
</tr>
<tr>
<td>2. Multi-skilling will take too long and staff will lose focus</td>
</tr>
<tr>
<td>3. Buy in from all the departments</td>
</tr>
<tr>
<td>4. Management might force this model on the Artisans and they will do nothing but put pressure on Artisans</td>
</tr>
<tr>
<td>5. Biggest problem with an integrated system is running effective communication between the role players</td>
</tr>
<tr>
<td>6. Engineering tends to see itself as an individual entity as opposed to an integrated whole. The mindsets need to be changed to adopt a wider view taking in QA and regulations expectations</td>
</tr>
<tr>
<td>7. No system is bullet proof. Once put into practice one will identify if the system is doing what it was intended for.</td>
</tr>
<tr>
<td>8. Too many links, if one links fails then the system fails</td>
</tr>
<tr>
<td>9. The proposed model needs to sufficiently differentiate the approach to the various types of maintenance</td>
</tr>
</tbody>
</table>

Table 6.29 indicates that the respondents feel that the artisans need to be trained on reliability centred maintenance (RCM) so that when this model is implemented there is a clear understanding of what is needed. The respondents also feel that multi-skilling will take too long to perform and the staff will lose focus. The respondents feel that there needs to be a buy-in from all the departments for this model to work and for it to be communicated to all. This is understandable as this proposed model encompasses aspects from all the departments’ processes and procedures to be successful.

The respondents feel that this model will force more work for the artisans where the maintenance managers will do nothing. This could indicate that there are conflict issues between the maintenance managers and artisans that need to be identified. This could also mean that the engineering staff are not clear what their job descriptions are. The respondents feel that the Engineering department sees itself as a separate entity and the mindsets of the engineering team need to change for this model to be implemented. This could indicate that when there are equipment breakdowns, there is a tendency that the Production and Engineering department blame each other for time loss or when equipment is needed for maintenance and Production cannot accommodate. There is this feeling of ‘them and us’. Some respondents feel that only once the proposed model is implemented can the problem areas be identified.

Some respondents feel that there is too many links on the model and if one link fails then the system fails. This could indicate that the respondents are not familiar with the integration process and are not currently experiencing it within the company. The respondents also feel that the model needs to elaborate more on the processes it proposes, especially on the
different types of maintenance. This could indicate that the respondents do not understand that there is theory that accompanies the proposed model, which will discuss what the model proposes in more detail.

The findings in table 6.30 are related to the respondent’s opinion on the improvements that can be identified with this proposed integrated maintenance management system model for the company. The table summarises the similar problems and the ones that stand out. These problems will be evaluated below.

**Table 6.30: Respondents opinion to open ended question 2**

<table>
<thead>
<tr>
<th>What improvements can be identified with this proposed integrated maintenance management system model for the company?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. More transparency that is needed between production and maintenance</td>
</tr>
<tr>
<td>2. Consider having a good representation of artisans in the steering committee</td>
</tr>
<tr>
<td>3. Proper maintenance and spares availability</td>
</tr>
<tr>
<td>4. An integrated preventative maintenance program on all machines will help to avoid major breakdowns</td>
</tr>
<tr>
<td>5. Improvements in maintenance system lead to improve uptimes which helps with cost reduction and improved gains</td>
</tr>
<tr>
<td>6. Optimised maintenance and production planning integration</td>
</tr>
<tr>
<td>7. Integration of all departments will work towards a common goal</td>
</tr>
<tr>
<td>8. Decentralised unit owners reporting into a centralised policy framework having the knowledge and skills of equipment in specific areas.</td>
</tr>
<tr>
<td>9. RCA and FMCEA’s are key in solving re-occurring problems</td>
</tr>
<tr>
<td>10. Helpful in organising the maintenance program in a systematic manner.</td>
</tr>
<tr>
<td>11. Maintenance and calibration will be done on time - Overtime will be reduced as work can be planned during the week. Maintenance can be done properly as enough time will be available.</td>
</tr>
</tbody>
</table>

Table 6.30 indicates that the respondents feel that the proposed model will encourage transparency that is needed between production and maintenance and optimise the integration between the two departments so that they work towards a common goal. This simply confirms that there is a problem with no maintenance and production planning integration within the company. Some respondents feel that the steering committee proposed in the model should have good representation of artisans.

Some respondents feel that the integrated preventative maintenance system that the model proposes will help avoid major breakdowns and lead to improvement in cost reduction and improved gains. This indicates that the respondents affirm the problem that there is no proper maintenance management system currently in place in the company and this proposed model with help streamline the maintenance management system. The respondents feel that, since the model proposes that the different departments integrate with each other into one maintenance management system for the company, this will encourage sharing of skills and
knowledge of equipment in specific areas. This indicates that the respondents feel there is no sharing of knowledge and skills within the company.

They also believe that RCA and FMCEA are key strategies in solving re-occurring problems that the model proposes. The respondents have an overall belief that if this proposed model is implemented then maintenance and calibration will be done on time and overtime will be reduced as work can be planned and equipment availability will increase.

6.2.2.7 Summary for research findings in Section C2

Table 6.29 (see page 114) displays the respondent’s opinion of the main problems that they felt was important if this proposed model is to be implemented in the company. Selected themes were highlighted. These problems could be categorised into two themes namely, maintenance training and maintenance strategy.

Multi-skilling the artisans could be a problem as there seems to be training constraints within the company. Some artisans do not understand the concept of reliability centred maintenance (RCM) as some respondents mentioned that the artisan should understand this for the model to be in place. There is also a problem that the respondents feel that the types of maintenance that the model proposes should be explained to the artisans. These problems fall under the theme of maintenance skills and training.

The respondents felt that there needs to be buy-in from all the departments and effective communication between the departments on how this model works before it can be implemented. There is a need for the mindsets of the Engineering department to change as the respondents feel the Engineering department works as a separate entity from other departments and also within its own department. It was noted that the artisans feel that they will be given more work to do by the maintenance managers with this model in place and that the managers will do hardly any work. Some respondents felt that the model had too many links and if one link failed the model would fail. These problems fall under the theme of maintenance strategy and identification.

Table 6.30 (see page 115) displays the respondent’s opinion on what improvements they could support if this proposed integrated maintenance management system model were implemented in the company. Some respondents feel that the steering committee proposed in the model ought to have good representation of artisans. This could indicate that the artisans
in the company feel that the maintenance management team are making all the rules and decisions and the artisans are not being consulted in maintenance decisions. Some of the improvements that stand out are that the communication between the Production and Engineering planning departments would be more transparent and the integration would be optimised. There would be a proper spares and maintenance system that would lead to improved uptimes of equipment which will help with cost reduction and improve gains. The model will improve skills and knowledge sharing as the staff in the different units will be encouraged to work to a common goal.

6.3 Conclusions

The idea of presenting the proposed integrated maintenance management system model to a sample of respondents in the company is to find out if the model would work for the company and to identify any problems in its implementation. The results of this will be used to improve the current proposed model so that a more relevant model can be implemented in the company. There is an overwhelming response that the respondents agree to the statements that the model proposes and that the model brings definite solutions to the problems in the maintenance management system that were identified in the preliminary study in Chapter 2 within the company.

Section B of the main study questionnaire presented the ten main maintenance management system problems at My Pharmaceuticals. There was a good response, especially from the Engineering department, that these problems exist within the company. It was identified that management and senior management are not aware that some of these problems exist and that the Production department does not feel that some of these problems are experienced within the company.

Section C1 presented the proposed integrated maintenance management system model and statements on what the model proposed to the sample of respondents. There was a positive response from all the respondents especially from the management and senior management that they are in favour of this model. The model will have good support from this commitment and it will help drive the process. All the statements (S1 to S17) have a very good response rate. It was identified that some of the respondents were unfamiliar with reliability centred maintenance (RCM).
The current proposed model identifies RCM as part of the maintenance execution for the company and this will have to be explained or taught to the staff as part of the initial implementation of the model. It is, however, important to update the model so that if there are new maintenance staff or staff that need refresher training, the model will help identify the training needed for the type of maintenance that the company is using. It is therefore noted that the current proposed model will be updated to include that training must be included for this type of maintenance and this will be presented in the improved proposed model.

It was identified that some of the engineering personnel are not familiar with the International Society for Pharmaceutical Engineering (ISPE) guidelines that the model proposes for the engineering team and with which all maintenance personnel should be familiar. This could indicate that ISPE guidelines are not being communicated to all the engineering personnel. In the current proposed model, the ISPE guideline is stipulated for the maintenance identification and qualification. This means that if this model is successfully implemented, the problem of familiarising the artisans with this guideline will be solved. It is therefore noted that this part of the current proposed model does not need to be changed or improved.

Opportunistic maintenance seems to be an unfamiliar concept to some of the maintenance artisans. This could indicate that they were never exposed to this type of maintenance strategy. There is also a maintenance manager who does not agree that this type of maintenance will work. This could indicate that he had a bad experience trying to obtain equipment from production for maintenance. The current proposed model presents the opportunistic maintenance strategy for the Production and Maintenance Planning department and part of the implementation of this model will have to be explained or taught to the staff as part of the initial implementation of the model.

The model must be updated so that if there are new maintenance staff or staff that need refresher training, the model will help identify the training needed. This unified concept requires considering the integration of the maintenance planning into the production strategy planning in order to develop opportunistic maintenance tasks synchronised with production. It is therefore noted that the current proposed model will be improved to include that training is required for this type of strategy integration and this will be presented in an improved proposed model.

Section C2 presented two open-ended questions on the model. The first question asked the respondent’s opinion on the problems that might be incurred if the model was to be
implemented in the company. The general feeling was that a main problem would be the training and understanding of the concepts of the types of maintenance that the model proposes. The respondents felt that there needs to be buy-in from all the departments and effective communication between the departments how this model works, before it can be implemented.

The second question asks the respondent’s opinion on what improvements they could identify if this current, proposed integrated maintenance management system model were implemented in the company. Section 6.2.2.7 highlights that there some positive results on the improvements the model would bring if implemented, but one point stands out. Some respondents feel that the steering committee proposed in the model should have a good representation of artisans. It could indicate that the artisans in the company feel that the maintenance management team are making all the rules and decisions and the artisans are not being consulted in maintenance, which could also indicate that it would help the steering committee understand what is happening on the shop floor when the maintenance policies and objectives are drawn up. The researcher recommends that this is a valid point to improve the current maintenance management system and it should be implemented in the improved, proposed model.

Figure 6.29 (see page 120) proposes an improved proposed integrated maintenance system model that can be implemented at My Pharmaceuticals. This updated model incorporates the improvements suggested by the analysis conducted in this Chapter. The model has been updated to include the two improvements that are indicated in Figure 6.29 (see page 120) as improvement 1 and improvement 2. Firstly that the steering committee should include selected artisans (improvement 1) to join the steering meetings so that there can be representation from the shop floor. Secondly, as part of the prerequisite that the engineering staff need to be multi-skilled and to be trained in all aspects of the pharmaceutical industry regulations, they need to be trained in the reliability centred maintenance (RCM) type of maintenance and be trained to understand the unified concept of opportunistic maintenance tasks (improvement 2) synchronised with production and maintenance planning that the model proposes.
In this chapter, the researcher presented and analysed the research questionnaire (Annexure 2). An improved, proposed integrated maintenance management system model was presented, in Figure 6.29 from the results of the survey. In the next chapter, the researcher will present the summary of the research findings which are based on the empirical survey. Recommendations and additional research opportunities will also be presented in the final chapter.
Chapter 7

Conclusions and Recommendations

7.1 Introduction

In Chapter 2, a literature study was conducted to identify the best maintenances practices for maintenance management systems. A preliminary study was conducted and explained also in this chapter. Chapter 3 presented a literature study on pharmaceutical best engineering guidelines to identify the regulations that have an influence on maintenance in the pharmaceutical industry. Chapter 4 presented a literature study on generic maintenance management system models on which the proposed integrated maintenance management system model for the company was based. This proposed model was developed in Chapter 4. The research methodology for this research study was indentified in Chapter 5. In Chapter 6, a critical analysis of findings and interpretation of the results of the empirical study was conducted. An improved proposed integrated maintenance management system model was presented at the end of Chapter 6.

In this chapter, the research questions will be discussed to determine whether the research conducted, effectively answers the questions to these problems in a summary in Section 7.2. There are some recommendations in Section 7.3 that My Pharmaceuticals can consider which will be discussed. The limitations of the research will be discussed in Section 7.4 and the opportunity for future research will be discussed in Section 7.5.

7.2 Summary of the research

In order to address the main research question of this research study, several research questions were identified and investigated. Summaries of these investigations of these questions are explained below.

7.2.1 Main research question RQm

The main research question of the research was stated as, “Can an integrated maintenance management system model be developed for the pharmaceutical industry in South Africa?” In
order to suggest solutions to this main problem, six research questions (RQ₁ to RQ₆) were identified and investigated as follows:

- RQ₁ identified and investigated the literature study on best maintenance management practices elements within organisations;
- RQ₂ identified and investigated the main maintenance management system problems for a company within the pharmaceutical industry;
- RQ₃ identified and investigated the best engineering guides that the maintenance management systems in the pharmaceutical industry should follow;
- RQ₄ identified and investigated the regulatory controls that influence the maintenance management systems in the pharmaceutical industry;
- RQ₅ identified and investigated the possibility of developing an integrated maintenance management system model for a company within the pharmaceutical industry;
- RQ₆ identified and investigated the possibility of evaluating an integrated maintenance management system model for a company within the pharmaceutical industry.

7.2.2 Research question RQ₁

The first research question was stated as, “What best practices does the literature identify about maintenance management systems within organisations?” In Chapter 2, a literature study was conducted which focused on the elements of best maintenance management practices. It was important to obtain a holistic view on what makes up a maintenance management system within an organisation. This included the importance of maintenance policies and objectives and how they are developed.

Then the maintenance management process which includes work identification, work planning, work scheduling, work execution, history recording and analysis of the data was discussed. Part of this maintenance management system includes, the need for spares management and its importance, the need for computerised maintenance management systems (CMMS), staffing the organisation for maintainability and maintenance audits. These were highlighted in Chapter 2.
7.2.3 Research question RQ\textsubscript{2}

The second research question was stated as, “What main problems is My Pharmaceuticals experiencing with its current maintenance management system?” In order to identify these main problems, it was important to perform a preliminary study. The preliminary study consisted of open-ended questions (Annexure 1) about the elements of maintenance management systems that were identified in the literature study in Chapter 2. The preliminary study results which identified ten main problems with the company’s maintenance management system were presented in Table 2.1 in Chapter 2 (see page 40). These problems were identified as problem P1 to problem P10.

7.2.4 Research question RQ\textsubscript{3}

The third research question was stated as, “What good engineering practice guidelines are there for pharmaceutical organisations?” In Chapter 3, literature on good engineering practice guidelines was presented for the pharmaceutical industry. One of the aspects was highlighted in Chapter 3 was that the pharmaceutical companies use the International Society of Pharmaceutical Engineering (ISPE) guide as tool for good engineering practice. Some of these good engineering practice guidelines included systems maintenance strategies, maintenance plans, spare parts and materials, maintenance documents, roles and responsibilities and the use of CMMS in the pharmaceutical industry.

7.2.5 Research question RQ\textsubscript{4}

The fourth research question was stated as, “What regulatory controls have an influence on maintenance management systems in the pharmaceutical industry?” In Chapter 3, the stages of validation, the role of quality assurance (QA) and the concept of deviations and change controls that play a role in the pharmaceutical industry, were described.

Process validation has four stages when installing new equipment. These are required by the Food and Drug Administration (FDA). These four stages are known as installation qualification (IQ), operation qualification (OQ), performance qualification (PQ) and process validation (PV). The Engineering department must accept these qualifications as they influence the process when maintenance is determined for equipment. It is therefore important
to include this process when developing a maintenance management system for the pharmaceutical industry.

The QA department’s role is important as it plays as an independent policy type role. This department is proactive by evaluating data on processes, materials and suppliers and by recommending changes that will improve efficiency and consistency. Standard operating procedures (SOP) for the Engineering department are assessed by the QA department and changes to equipment are controlled by change control and deviations procedures. It is therefore also important to include this process when developing a maintenance management system for the pharmaceutical industry.

Maintenance qualification provides documentary evidence of the maintenance controls in place to maintain current good manufacturing practices (cGMP) and identifies the optimum maintenance policies required for cost-effective and efficient operations. This process proposes to eliminate unnecessary or non-value-adding maintenance routines and focus resources on those equipment items with the greatest impact on business performance. This can enhance compliance and reduce maintenance costs and unplanned downtime. This should be included in a maintenance management system where equipment can be pre-screened on criticality before maintenance and resources are linked to it.

7.2.6 Research question RQ5

The fifth research question was stated as, “Can an integrated maintenance management system model be developed for My Pharmaceuticals?”. In order to identify how maintenance models are developed, a literature study on generic maintenance models was presented in Chapter 4. It is suggested by the literature study that an integrated, rather than the conventional “silo” style approach to maintenance management (MM) would play a pivotal role in organisations. It is also discovered that MM must be aligned with actions at three levels of business activities which are, strategic levels, tactical levels and operational levels. These were used as a base to develop a proposed integrated maintenance management system model for My Pharmaceuticals in Chapter 4.

The proposed model incorporates elements of the literature study in Chapter 2 on the best practices in maintenance management systems. It was also important to address the main problems that My Pharmaceuticals is experiencing with regard to their maintenance management system in the proposed model, so a preliminary study was conducted and
explained in Chapter 2 to identify these main problems. There are ten main problems of the maintenance management system that were identified and incorporated into the proposed model. To have this proposed model applicable to the pharmaceutical industry, it was also important to identify the best engineering guidelines and regulatory controls that have an influence in the maintenance management system. This was achieved in Chapter 3 and incorporated in the proposed model.

7.2.7 Research question RQ6

The sixth research question was stated as, “Can an integrated maintenance management system model be evaluated for the pharmaceutical industry?”. In order to evaluate if this proposed, integrated maintenance management system model will help improve the current maintenance management system at My Pharmaceuticals, an empirical study was conducted using a sample from all the relevant departments and positions at the company that have an impact on the maintenance management system.

The ten main problems in the maintenance management system that were identified in the preliminary study was presented in the questionnaire (Annexure 2 - Section B) in the main study. This was to determine if the respondents agreed that these were the main problems that was incorporated in the proposed model. The questionnaire (Annexure 2 – Section C) also included statements and open-ended questions on the proposed integrated model that incorporated elements from the literature studies that were conducted in Chapters 2 and 3. The results of the responses from the questionnaires were discussed and evaluated in Chapter 6.

In Chapter 6, the proposed, integrated model was evaluated and the results of the analysis allowed the researcher to re-evaluate the current, proposed integrated maintenance management system model and present an improved proposed integrated maintenance management system model that can be presented to the pharmaceutical industry displayed in Figure 7.1 (see page 126).
Figure 7.1: Improved proposed integrated maintenance management system model

7.3 Recommendations

It is clear from the empirical study that this improved proposed integrated maintenance management system model can be implemented within the company as this will solve the main problem which was stated as, “Can an integrated maintenance management system model be developed for the pharmaceutical industry in South Africa?”. There are several recommendations that the researcher recommends should take place for this improved proposed integrated model to be implemented successfully. They are discussed below.

a) It is recommended that the company start focusing on establishing a steering committee that includes senior management from all the departments (QA, Validation and Production). They should meet once a month to decide on the maintenance objectives and to solve any problem areas in the maintenance system as described in Section 2.6 in Chapter 2. It is mentioned there that the first step towards a formal
maintainability process is to develop maintainability awareness at corporate level where management should become familiar with maintainability objectives, methods, and concepts and after gaining a basic understanding of maintainability and its impact on the project. The management team can then establish its relationship to overall business objectives. (Meier & Russell, 2000)

The steering committee should also have members that have expertise on the shop floor. This was identified by the open-ended questions that were analysed in Section 6.2.2.7 of the empirical study in Chapter 6 (see page 116). Once these members feel part of the decisions made in the maintenance objectives, the buy-in of this concept from the all the departments is encouraged.

b) It is recommended that the company should have a training development program for the artisans so that they can be trained in the latest expertise in pharmaceutical process equipment. All the relevant departments agree that this should be in place as identified in Table 6.14 (see page 102) in the empirical study in Chapter 6. This development program should also include training in all facets of the pharmaceutical industry to understand the regulations. This is encouraged by the ISPE guide in section 3.2.8 in Chapter 3 that states it is important to document roles and responsibilities of the maintenance staff, to the extent that they might impact the quality of a drug and the regulations specifically state that assignment of responsibility for maintenance and maintenance scheduling shall be included in the written procedures for maintenance (ISPE, 1998).

c) The ISPE guideline is stipulated in the maintenance identification and qualification part of the improved proposed integrated model, but is also recommended that this guide be made more available to the Engineering team for reference purposes. The aim of this guide, as stated in the introduction in Chapter 3, is to provide engineers and other professionals, within the pharmaceutical industry, with baseline information on the design, construction and commissioning of new and renovated facilities, equipment and systems to achieve regulatory compliance (Tunnicliffe, 2003).

d) It is recommended that the company’s maintenance and production planning should integrate to propose opportunistic maintenance as confirmed in Figure 6.20 and Table
6.20 (see page 106) in the empirical study performed in Chapter 6 that 100 percent of
the respondents feel that the integration with production planning and engineering
maintenance planning will promote a good maintenance plan which can result in
considerable cost savings to the company.

This will encourage opportunistic maintenance as stated in Section 2.9.2.3 in Chapter 2
that opportunistic maintenance can help save set-up costs and guarantee the expected
performances for the system (Levrat et al., 2008). This will also create a culture of
gaining access to equipment when there are tool changes, product changes and shift
changes and this will alleviate the stress of trying to obtain the equipment over a
shutdown period. The improved proposed integrated model proposes that the
maintenance staff receive training on what opportunistic maintenance is and how it
can be implemented.

e) It is recommended that the company should invest in the material module of the
current CMMS. This will help the Engineering team manage spares more effectively
and accurately. This is confirmed by Figure 6.22 and Table 6.22 (see page 108) in the
empirical study performed in Chapter 6, which the majority of the engineering team
agree that the management of spare parts in the company should be managed by the
current computerised maintenance management system (CMMS). In section 2.10.1 in
Chapter 2 is stated that accurate inventory is defined as the actual quantity and types
of parts in the right location in the storeroom matching exactly what is shown on the
inventory system in the computerised maintenance management system (CMMS)
(Gulati, 2009).

f) It is recommended that the company should merge the two CMMS databases into one.
This will streamline the asset management process and create a standard within the
whole site. Apart from the need of CMMSs as described in Section 2.11 in Chapter 2
maintenance managers are provided with information in a form that allows for more
effective control of their department’s activities (Labib, 2004). To ensure that
equipment history is preserved, only one system should be used to document
performed maintenance and repair activity on equipment. The recommended approach
is to have a single system that the operations and maintenance departments share
(ISPE, 2009).
7.4 Limitations of the study

The following limitations were identified with this research study:

- The sample size was small due to the small groups in each department that had an influence in the maintenance management system of the company;
- Statistical methods, such as the Cronbach Alpha and T test, could not be utilised in this study due to the small populations in each group so only qualitative analysis could be performed;
- This research study was performed on one manufacturing plant in Port Elizabeth.

7.5 Future research

A number of related issues could be addressed by further research. Some of these research issues are outlined below:

- Future research can be performed by applying this model in other pharmaceutical companies in the pharmaceutical industry in order to obtain a bigger sample size so that quantitative statistical analysis of the model can be evaluated;
- An in-depth research could be conducted on the strategy of opportunistic maintenance and impact it has on cost savings and minimising unplanned breakdowns for the process equipment in the pharmaceutical industry;
- An in-depth research could be conducted on the overall equipment effectiveness (OEE) of the process equipment in the pharmaceutical industry incorporating the improved proposed integrated maintenance management system model.

7.6 Summary

The main objective of this research summary was to develop an integrated maintenance management system model for the pharmaceutical industry. The deliverables to achieve this included:

- A literature study on maintenance management system best practices;
- A preliminary study that had to be conducted in a pharmaceutical company to identify the main maintenance management system problems;
• A literature study on pharmaceutical industry good engineering practice guidelines and regulatory controls that have an influence on the maintenance management systems;

• A development of a proposed integrated maintenance management system model for the pharmaceutical company;

• Presenting this proposed integrated model to a sample in the pharmaceutical company with a questionnaire, evaluating the results and developing the current proposed integrated maintenance system model to an improved proposed integrated maintenance management system model.

The contributions to this study concluded that an integrated maintenance management system model for the pharmaceutical industry can be developed. Recommendations were made to areas where improvements are needed for this model to be implemented successfully and opportunities for further research were also outlined in this chapter.
References


Dear Sir / Madam,

I am an MBA student at the Nelson Mandela Metropolitan University (NMMU) currently completing my final year. As part of my course, research needs to be conducted in the form a treatise to be submitted to fulfil the requirements of the MBA course. The aim of this research is to investigate the main problems of the maintenance management system being practiced at the company and to develop an integrated maintenance model that can be used within the company.

This questionnaire will be used to collect data for this research. The questionnaire will remain anonymous hence your name will not be recorded therefore ensuring your confidentiality. The questions will be asked on a one-on-one basis therefore you may feel free to ask for clarity at any point.

Thank you for your co-operation.

Yours sincerely,

Kribban Coopoosamy

Engineering Maintenance Planner (Systems).

Supervisor – Prof Andre Calitz – NMMU Business School
Preliminary Study Questionnaire.

Section A - Preliminary Questions

Please write down your own opinion with regards to these sections indicated below. Please print when you write, keep it sort and be clear.

1. In your opinion what are the main problems, if any, in trying to have production machines/equipment available for maintenance?

________________________________________________________________________________________________________________________________________

2. In your opinion does the company perform the following types of maintenance and if yes, what problems, if any, do you think the company experiences with performing these types of maintenance?

a) On maintenance that is not scheduled (Corrective Maintenance)?

________________________________________________________________________________________________________________________________________

b) On maintenance that is scheduled (Planned Maintenance)?

________________________________________________________________________________________________________________________________________

c) On maintenance that is performed by condition based (Predictive Maintenance)?

________________________________________________________________________________________________________________________________________

d) On maintenance that prioritises between critical and non critical equipment (Reliability Centered Maintenance)?

________________________________________________________________________________________________________________________________________

3. What are the problems, if any, which the company faces with spare parts identification, classification and reporting?
4. What are the constraints, if any, are there with the current computerised maintenance management system (CMMS) within the company?

5. In your opinion what are the problems, if any, with the engineering staff with regard to the engineering structures, competency and training?

6. What are the main constraints, if any, of performing maintenance on equipment that are validated being in a pharmaceutical industry?

7. In your opinion are there any other problems with the maintenance management system at the company that affects the overall equipment effectiveness (OEE), which is not covered in the above questions?
Dear Sir / Madam,

I am an MBA student at the Nelson Mandela Metropolitan University (NMMU) currently completing my final year. As part of my course, research needs to be conducted in the form a treatise to be submitted to fulfill the requirements of the MBA course. The aim of this research is to investigate the main problems of the maintenance management system being practiced at the company and to develop an integrated maintenance management system model that can be used within the company.

A pilot study was performed to identify the main maintenance management system problems within the company which is stated in Section B. Attached is a proposed maintenance management system model (Attachment 1) for the company where these problems are addressed and a questionnaire in Section C that will be used to collect data on this model for the research.

The questionnaire will remain anonymous hence your name will not be recorded therefore ensuring your confidentiality. The questions will be asked on a one-on-one basis therefore you may feel free to ask for clarity at any point.

Thank you for your co-operation.

Yours sincerely,

Kribban Coopoosamy

Engineering Maintenance Planner (Systems).

Supervisor – Prof Andre Calitz – NMMU Business School
**Questionnaires**

Please provide the following information regarding your work situation by marking an X in the appropriate box. Sections A, B, C1 and C2 must be completed.

**Section A - Biographical Information**

1. What is your current length of service in years within the company?

<table>
<thead>
<tr>
<th>Length of Service</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5</td>
<td>1</td>
</tr>
<tr>
<td>5-10</td>
<td>2</td>
</tr>
<tr>
<td>11-15</td>
<td>3</td>
</tr>
<tr>
<td>16-20</td>
<td>4</td>
</tr>
<tr>
<td>More than 20</td>
<td>5</td>
</tr>
</tbody>
</table>

2. In which department are you currently in?

<table>
<thead>
<tr>
<th>Department</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production</td>
<td>1</td>
</tr>
<tr>
<td>Engineering</td>
<td>2</td>
</tr>
<tr>
<td>Validation</td>
<td>3</td>
</tr>
<tr>
<td>Quality Assurance (QA)</td>
<td>4</td>
</tr>
</tbody>
</table>

3. What is your current position in the company?

<table>
<thead>
<tr>
<th>Position</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Operator</td>
<td>1</td>
</tr>
<tr>
<td>Machine Setter</td>
<td>2</td>
</tr>
<tr>
<td>Maintenance Artisan</td>
<td>3</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>4</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>5</td>
</tr>
<tr>
<td>Production Planner</td>
<td>6</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>7</td>
</tr>
<tr>
<td>Production/Operations Senior Manager</td>
<td>8</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>9</td>
</tr>
<tr>
<td>Quality Assurance Manager</td>
<td>10</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>11</td>
</tr>
</tbody>
</table>

4. How many years have you spent in your current position?

<table>
<thead>
<tr>
<th>Years</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5</td>
<td>1</td>
</tr>
<tr>
<td>5-10</td>
<td>2</td>
</tr>
<tr>
<td>11-15</td>
<td>3</td>
</tr>
<tr>
<td>16-20</td>
<td>4</td>
</tr>
<tr>
<td>More than 20</td>
<td>5</td>
</tr>
</tbody>
</table>
Section B – Preliminary Study Results

Below are the main problems that were identified with the company’s current maintenance management system performed in a pilot study. In your own opinion please indicate whether you strongly disagree, disagree, are neutral, agree or strongly agree with these statements.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Main Problems Statements</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>There is a lack of maintenance and production planning integration.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>P2</td>
<td>There is no understanding between Engineering, Process Validation and Production on the importance of maintenance and periodically validation reviews.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>P3</td>
<td>Predictive maintenance is not being practiced within the company.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>P4</td>
<td>Reliability Centered Maintenance is not being practiced within the company.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>P5</td>
<td>Overall poor senior management interaction and buy in on maintenance policies.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>P6</td>
<td>There are 2 CMMS databases for one central engineering department.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>P7</td>
<td>There is no proper spares management system.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>P8</td>
<td>There is a lack of training of Engineering Staff with the latest technology in process equipment.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>P9</td>
<td>There is a lack of understanding of equipment that are validated and no clear process of when change controls and deviations are needed.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>P10</td>
<td>There is no value adding maintenance analysis performed on maintenance data.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Section C1 - Proposed Maintenance Management System Model

On the last page of this questionnaire is a proposed integrated maintenance management system model for the company being in the pharmaceutical industry (Attachment 1). Please study the model in detail and in your own opinion please indicate whether you strongly disagree, disagree, are neutral, agree or strongly agree with the statements that the model proposes.
<table>
<thead>
<tr>
<th>No.</th>
<th>Statements</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>It is important to have a steering committee to develop maintainability objectives for the maintenance policy of the company. (Problems P5, P2)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S2</td>
<td>Having a steering committee will encourage senior management involvement in the maintenance management system objectives of the company. (Problem P5)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S3</td>
<td>One of the main parts of the maintenance management system objectives of the company is to have multi-skilled Engineering personnel that understand the pharmaceutical industry dynamics. (Problem P8)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S4</td>
<td>One of the main parts of the maintenance management system objectives of the company, being in the pharmaceutical industry, is to be compliant to Validation and Quality Assurance requirements. (Problem P9,P2)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S5</td>
<td>The International Society for Pharmaceutical Industry (ISPE) guide with a combination of Maintenance Best Practices should be used as a guide in the maintenance approach and qualification for the company in the proposed model. (Problem P3,P4)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S6</td>
<td>Maintenance execution should include RCM which focuses resources on those equipment items with the greatest impact on business performance can enhance compliance and reduce maintenance costs and unplanned downtime. (Problem P4)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S7</td>
<td>Process validation must integrate with engineering in verifying equipment maintenance to the specifications and conditions in order to assure its ability to produce the final product to the desired quality characteristics. (Problem P2)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S8</td>
<td>Quality assurance (QA) must integrate with engineering with regard to change controls and deviations to prevent unauthorised modifications to maintenance tasks and equipment that are validated. (Problem P9)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S9</td>
<td>Integration with production planning and engineering maintenance planning will encourage a good maintenance plan which can result in considerable cost savings to the company. (Problem P1)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S10</td>
<td>Opportunistic maintenance, which is about maintenance tasks that are planned and performed at the stoppages planned by the production department, such as cleaning, shift, batch or tool changes, can be integrated between production planning and engineering maintenance planning. (Problem P1)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S11</td>
<td>Management of the spare parts in the company should be managed by the current computerised maintenance management system (CMMS). (Problem P7)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S12</td>
<td>The maintenance planning and scheduling should be managed by one (1) computerised maintenance management system (CMMS) for the whole site. (Problem P6)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S13</td>
<td>Maintenance history on equipment, which is the primary tool of reliability engineering in evaluation and analysis, is used to direct necessary reviewing of maintenance tasks. (Problem P10)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S14</td>
<td>Engineering should perform failure mode, effects and criticality analyses (FMECA) on equipment to improve and optimise maintenance identification and qualification. (Problem P10)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S15</td>
<td>Engineering self audits will help keep the maintenance identification and qualification in line. (Problem P2)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S16</td>
<td>The maintenance policy is an overall relationship of management awareness, maintainability objectives, methods, and concepts. (Combination of all problems)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>S17</td>
<td>This proposed integrated maintenance management system model will help streamline the maintenance management system within the company. (Combination of all problems)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Section C2: Respondents Opinion

In your own words please answer the following questions relating to the integrated maintenance management model presented in Annexure 1.

1. What problems do you foresee with implementing this proposed integrated maintenance management system model for the company?

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

2. What improvements can be identified with this proposed integrated maintenance management system model for the company?

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

Thank you for your cooperation.
**ANNEXURE 3: MAIN STUDY OVERALL BIOGRAPHICAL DATA**

<table>
<thead>
<tr>
<th>What is your current length of service in years within the company?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Years</td>
<td>Number of responses</td>
</tr>
<tr>
<td>Less than 5 years</td>
<td>13</td>
</tr>
<tr>
<td>5 - 10 years</td>
<td>15</td>
</tr>
<tr>
<td>11 - 15 years</td>
<td>1</td>
</tr>
<tr>
<td>16 - 20 years</td>
<td>2</td>
</tr>
<tr>
<td>More than 20 years</td>
<td>4</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>35</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In which department are you currently in?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Department</td>
<td>Number of responses</td>
</tr>
<tr>
<td>Production</td>
<td>13</td>
</tr>
<tr>
<td>Engineering</td>
<td>16</td>
</tr>
<tr>
<td>Validation</td>
<td>4</td>
</tr>
<tr>
<td>Quality Assurance (QA)</td>
<td>2</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>35</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What is your current position in the company?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Position</td>
<td>Number of responses</td>
</tr>
<tr>
<td>Maintenance Artisan</td>
<td>8</td>
</tr>
<tr>
<td>Maintenance Manager</td>
<td>6</td>
</tr>
<tr>
<td>Maintenance Planner</td>
<td>1</td>
</tr>
<tr>
<td>Production Planner</td>
<td>3</td>
</tr>
<tr>
<td>Production Team/Group Leader</td>
<td>8</td>
</tr>
<tr>
<td>Production/Operations Senior Manager</td>
<td>2</td>
</tr>
<tr>
<td>Maintenance Senior Manager</td>
<td>1</td>
</tr>
<tr>
<td>QA Manager</td>
<td>2</td>
</tr>
<tr>
<td>Validation Manager</td>
<td>4</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>35</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How many years have you spent in your current position?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Years</td>
<td>Number of responses</td>
</tr>
<tr>
<td>Less than 5 years</td>
<td>26</td>
</tr>
<tr>
<td>5 - 10 years</td>
<td>8</td>
</tr>
<tr>
<td>11 - 15 years</td>
<td>0</td>
</tr>
<tr>
<td>16 - 20 years</td>
<td>0</td>
</tr>
<tr>
<td>More than 20 years</td>
<td>1</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
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# ANNEXURE 4: MAIN STUDY OVERALL RESPONSE TO MAIN PROBLEMS

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<tr>
<td>P1</td>
<td>There is a lack of maintenance and production planning integration.</td>
<td>20%</td>
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<td>66%</td>
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<tr>
<td>P2</td>
<td>There is no understanding between Engineering, Process Validation and Production on the importance of maintenance and periodically validation reviews.</td>
<td>20%</td>
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<tr>
<td>P3</td>
<td>Predictive maintenance is not being practiced within the company.</td>
<td>26%</td>
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<td>P4</td>
<td>Reliability Centered Maintenance is not being practiced within the company.</td>
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<tr>
<td>P5</td>
<td>Overall poor senior management interaction and buy in on maintenance policies.</td>
<td>12%</td>
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<td>P6</td>
<td>There are 2 CMMS databases for one central engineering department.</td>
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<td>P7</td>
<td>There is no proper spares management system.</td>
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<tr>
<td>P8</td>
<td>There is a lack of training of Engineering Staff with the latest technology in process equipment.</td>
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<td>P9</td>
<td>There is a lack of understanding of equipment that are validated and no clear process of when change controls and deviations are needed.</td>
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<td>P10</td>
<td>There is no value adding maintenance analysis performed on maintenance data.</td>
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### ANNEXURE 5: OVERALL DEPARTMENTAL RESPONSE TO THE MAIN PROBLEMS PRESENTED IN THE MAIN STUDY

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## ANNEXURE 6: MAIN STUDY OVERALL RESPONSE TO THE PROPOSED INTEGRATED MAINTENANCE MANAGEMENT SYSTEM MODEL

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<th>Statements no.</th>
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<th>Neutral</th>
<th>Strongly agree / Agree</th>
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<td>S1</td>
<td>It is important to have a steering committee to develop maintainability objectives for the maintenance policy of the company. (Problems P5, P2)</td>
<td>0%</td>
<td>3%</td>
<td>97%</td>
</tr>
<tr>
<td>S2</td>
<td>Having a steering committee will encourage senior management involvement in the maintenance management system objectives of the company. (Problem P5)</td>
<td>0%</td>
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<td>94%</td>
</tr>
<tr>
<td>S3</td>
<td>One of the main parts of the maintenance management system objectives in the company is to have multi-skilled Engineering personnel that understand the pharmaceutical industry dynamics. (Problem P8)</td>
<td>0%</td>
<td>3%</td>
<td>97%</td>
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<tr>
<td>S4</td>
<td>One of the main parts of the maintenance management system objectives of the company, being in the pharmaceutical industry, is to be compliant to Validation and Quality Assurance requirements. (Problem P9,P2)</td>
<td>0%</td>
<td>6%</td>
<td>94%</td>
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<tr>
<td>S5</td>
<td>The International Society for Pharmaceutical Industry (ISPE) guide with a combination of Maintenance Best Practices should be used as a guide in the maintenance approach and qualification for the company in the proposed model. (Problem P3,P4)</td>
<td>0%</td>
<td>20%</td>
<td>80%</td>
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<tr>
<td>S6</td>
<td>Maintenance execution should include RCM which focuses resources on those equipment items with the greatest impact on business performance can enhance compliance and reduce maintenance costs and unplanned downtime. (Problem P4)</td>
<td>0%</td>
<td>11%</td>
<td>89%</td>
</tr>
<tr>
<td>S7</td>
<td>Process validation must integrate with engineering in verifying equipment maintenance to the specifications and conditions in order to assure its ability to produce the final product to the desired quality characteristics. (Problem P2)</td>
<td>3%</td>
<td>6%</td>
<td>91%</td>
</tr>
<tr>
<td>S8</td>
<td>Quality assurance (QA) must integrate with engineering with regard to change controls and deviations to prevent unauthorised modifications to maintenance tasks and equipment that are validated. (Problem P9)</td>
<td>3%</td>
<td>3%</td>
<td>94%</td>
</tr>
<tr>
<td>S9</td>
<td>Integration with production planning and engineering maintenance planning will encourage a good maintenance plan which can result in considerable cost savings to the company. (Problem P1)</td>
<td>0%</td>
<td>0%</td>
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<tr>
<td>S10</td>
<td>Opportunistic maintenance, which is about maintenance tasks that are planned and performed at the stoppages planned by the production department, such as cleaning, shift, batch or tool changes, can be integrated between production planning and engineering maintenance planning. (Problem P1)</td>
<td>3%</td>
<td>11%</td>
<td>86%</td>
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<tr>
<td>S11</td>
<td>Management of the spare parts in the company should be managed by the current computerised maintenance management system (CMMS). (Problem P7)</td>
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<tr>
<td>S12</td>
<td>The maintenance planning and scheduling should be managed by one (1) computerised maintenance management system (CMMS) for the whole site. (Problem P6)</td>
<td>0%</td>
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<tr>
<td>S13</td>
<td>Maintenance history on equipment, which is the primary tool of reliability engineering in evaluation and analysis, is used to direct necessary reviewing of maintenance tasks. (Problem P10)</td>
<td>6%</td>
<td>6%</td>
<td>88%</td>
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<tr>
<td>S14</td>
<td>Engineering should perform failure mode, effects and criticality analyses (FMECA) on equipment to improve and optimise maintenance identification and qualification. (Problem P10)</td>
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<td>S15</td>
<td>Engineering self audits will help keep the maintenance identification and qualification in line. (Problem P2)</td>
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<tr>
<td>S16</td>
<td>The maintenance policy is an overall relationship of management awareness, maintainability objectives, methods, and concepts. (Combination of all problems)</td>
<td>0%</td>
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<td>89%</td>
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<tr>
<td>S17</td>
<td>This proposed integrated maintenance management system model will help streamline the maintenance management system within the company. (Combination of all problems)</td>
<td>0%</td>
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ANNEXURE 7: MAIN STUDY OVERALL DEPARTMENTAL RESPONSE TO THE PROPOSED INTEGRATED MAINTENANCE MANAGEMENT SYSTEM MODEL

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## ANNEXURE 8: MAIN STUDY OVERALL RESPONSE TO THE RESPONDENTS

### OPINION ON THE TWO OPEN ENDED QUESTIONS

<table>
<thead>
<tr>
<th>What problems do you foresee with implementing this proposed integrated maintenance management system model for the company?</th>
<th>What improvements can be identified with this proposed integrated maintenance management system model for the company?</th>
</tr>
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<tbody>
<tr>
<td>1. Specialist Artisans in the different departments needed.</td>
<td>1. There needs to be commitment from all</td>
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<tr>
<td>2. Artisans to be trained to understand on RCM that the model proposes</td>
<td>2. More transparency that is needed between production and maintenance</td>
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<td>3. Practical experience needed for Artisans</td>
<td>3. Consider having a good representation of technicians and artisans in the steering committee</td>
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<tr>
<td>4. Buy in from Production in the long term</td>
<td>4. Validation to agree with the maintenance changes</td>
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<td>5. Multi-skilling will take too long and staff will loose focus</td>
<td>5. More commitment from all</td>
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<td>6. Lack of interest, skills and knowledge to make it happen</td>
<td>6. Proper maintenance and spares availability</td>
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<tr>
<td>7. Buy in from all the departments</td>
<td>7. An Integrated preventative maintenance program on all machines will help to avoid major breakdowns</td>
</tr>
<tr>
<td>8. Management might force this model on the Artisans and they will do nothing but put pressure</td>
<td>8. Engineering self audits will also help with the development of cost saving machine modifications</td>
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<tr>
<td>9. Biggest problem with an integrated system is running effective communication between the role players</td>
<td>9. Improvements in maintenance system lead to improve uptimes which helps with cost reduction and improved gains</td>
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<tr>
<td>10. Engineering tens to see itself as an individual entity as opposed to an integrated whole. The mindsets need to be changed to adopt a wider view taking in QA and regulations expectations</td>
<td>10. Optimised maintenance and production planning integration</td>
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<td>11. Lack of buy-in from top management.</td>
<td>11. Proper spares management system</td>
</tr>
<tr>
<td>12. Buy-in from top management and follow through by the Engineers and Group Leaders</td>
<td>12. Change controls to be built in the system so that QA and Validation approve these changes within the system and not on a separate system</td>
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<tr>
<td>13. No system is bullet proof. Once put into practice one will identify if the system is doing what it was intended for.</td>
<td>13. Integration between process validation, quality assurance and production planning</td>
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<tr>
<td>14. Processing and controlling of deviations and change controls. There must be a time frame so as not to slow down the production process.</td>
<td>14. Costs. Prevention is better than cure.</td>
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<tr>
<td>15. Maintenance history should be first step in maintenance identification and qualification (FMCEA) should be in place at all times</td>
<td>15. Management of spares parts - in many cases the line stands waiting for parts.</td>
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<tr>
<td>16. The centralised approach runs the risk of bureaucratic style management.</td>
<td>16. Integration of all departments will work towards a common goal</td>
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<td>17. The current custodians will possibly reject the change</td>
<td>17. Decentralised unit owners reporting into a centralised policy framework having the knowledge and skills of equipment in specific areas.</td>
</tr>
<tr>
<td>18. Too many links, if one links fails then the system fails</td>
<td>18. The strategy needs to be identified will all before implementing this model.</td>
</tr>
<tr>
<td>19. Buy in from external stakeholders (not engineering) such as management, QA due to lack of interest in improvement initiatives related to Maintenance of production machinery.</td>
<td>19. Team integration between Engineering and Production for smoother running of equipment.</td>
</tr>
<tr>
<td>20. Initial implementation of the system, getting the engineering staff to understand it</td>
<td>20. Tie in with Production - only actual maintenance staff</td>
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<tr>
<td>21. Market properly to get the buy in.</td>
<td>21. A streamlined system as a result of this integrated maintenance management system.</td>
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<tr>
<td>22. Sustainability, Top Management support. Getting the different departments to share the one vision</td>
<td>22. Downtime will be minimised, production optimised and equipment will last longer.</td>
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<tr>
<td>23. Buy in from all departments</td>
<td>23. RCA and FMEA's are key in solving re-occurring problems</td>
</tr>
<tr>
<td>24. The proposed model also does not explicitly indicate how the historical data will be incorporated before commissioning new equipment and the maintenance department role in the selection of new equipment.</td>
<td>24. Helpful in organising the maintenance program in a systematic manner.</td>
</tr>
<tr>
<td>25. Buy-in from all the managers</td>
<td>25. Better understanding.</td>
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<tr>
<td>26. to create consistence and balance between production and engineering on conflicting objectives</td>
<td>26. Improve communication. Ensure focus in business goals and objectives. Reduce risk of the business and increase profitability</td>
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<tr>
<td>27. Ownership of the process</td>
<td>27. Define the role of steering committee</td>
</tr>
<tr>
<td>28. Buy in with all the departments</td>
<td>28. Maintenance and calibration will be done on time - Overtime will be reduced as work can be planned during the week. Maintenance can be done properly as enough time will be available.</td>
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<tr>
<td>29. Buy in</td>
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<td>30. Production planning must be done per machine per day for the following month,</td>
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<tr>
<td>31. The proposed model needs to sufficiently differentiate the approach to the various types of maintenance</td>
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