IMPLEMENTING LEAN MANUFACTURING TO IMPROVE PRODUCTION EFFICIENCY IN THE MANUFACTURING OPERATIONS AT THE ASPEN GENERAL FACILITY.

By

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Promoter: Prof. K. Pieterse
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DECLARATION

This treatise is submitted in partial fulfilment of the requirements for the
degree of Master's in Business Administration, in the Faculty of Business and
Economic Sciences at the Nelson Mandela Metropolitan University. The work
has not been previously accepted in substance for any degree and is not
being concurrently submitted in candidature for any other degree. The
research contained in this document is a result of my own independent work
and investigation, except where otherwise stated. All sources consulted are
acknowledged and referenced.

_________________
Signed: L. B. Jozaffe

_________________
Date
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1.1 Introduction
What is world class? Anand Sharma, author of *The Perfect Engine* (2002) describes world class manufacturing as a concept that is easy to understand (Sharma, 2005).

According to Anand Sharma, everyone knows what world class means, don’t they? If you are world class, you are among the best in the world at what you do. That is all there is to it. Unfortunately for manufacturers, there is no universally accepted dictionary definition. Everyone has a different interpretation of world class manufacturing" (Sharma, 2005).

South African producers are constantly facing competition from foreign organisations in their domestic markets. The adverse effects of this competition stem, in part, from the low levels of productivity which characterise South African industry and which is well documented by the National Productivity Institute of South Africa. The concept of continuous improvement offers a proven methodology for increasing the effectiveness and efficiency of production processes.

Given the situation that faces South African producers, it would seem appropriate to investigate how the concept of continuous improvement can be applied to a specific South African manufacturing organisation, like the Aspen Pharmacare General Facility, in order to improve its effectiveness and efficiency.

Womack and Jones (1996:10) summarises Lean Manufacturing in five principles;

- Precisely specify *value* by specific product
- Identify the *value stream* for each product
- Make the defined value *flow* without interruptions
- Let the customer *pull* value from the manufacturer/producer
- Constantly pursue *perfection*. 
Manufacturers or producers of pharmaceuticals in South Africa were, until recently, isolated from the more demanding markets internationally and continued with outdated forms of organisation for production. As a result of globalisation and trade liberalisation, this head-in-the-sand attitude is no longer viable. The new principles of production – Lean Production/Manufacturing – are in sharp contrast to the inherited patterns of mass production (Faull, 1998).

The organisation of production has become flexible and the boundaries between “skilled” and “unskilled” employees have diminished in South Africa. A key success factor will be to develop an organisation that focuses on learning and continuous improvement, involving all of the labour force rather than just the “skilled” engineers and managers, particularly in the pharmaceutical industry, where the margins for error are relatively small (Womack & Jones, 1996).

What then prevents South African pharmaceutical manufacturers, like Aspen Pharmacare, from becoming Lean or world class and how can such practices be maintained with a focus on continuous improvement? This study will essentially examine the potential stumbling blocks that prevent pharmaceutical companies, like Aspen Pharmacare from achieving world class manufacturing standards and the factors that could potentially influence the implementation of a successful and sustainable Lean, world class organisation.

1.2 The Research Problem
The problem addressed in this research study focuses on the need to improve the effectiveness and efficiency of the production processes in the manufacturing organisation under consideration utilising the concept or principles of Lean Manufacturing Systems.

1.3 The Sub-problems
The main research problem is too complex for effective resolution. The division of the main problem statement into smaller units will facilitate a comprehensive resolution of the main problem (Leedy & Ormrod, 2001:56). These smaller units are called sub-problems and have been defined as follows:
• The first sub-problem is to determine whether the organisation under consideration has the basic characteristics in place in order to implement Lean Manufacturing Systems.
• The second sub-problem is to identify the techniques included in the concept of continuous improvement and to determine if these were implemented and understood, in a systematic or appropriate manner.
• The third sub-problem is to determine whether the implementation of the Lean Manufacturing Systems was effective in order to facilitate efficient and improved productivity along with continuous improvement.

1.4 Delimitation of the Research
This study will not include any of the competitors contained within the pharmaceutical industry, for which Aspen Pharmacare competes in terms of market share.

The study will be limited to the Aspen Group Operations, with particular reference or emphasis on the potential capabilities of the manufacturing operations situated in Port Elizabeth, South Africa.

The study will be limited to employees who function within the manufacturing operations environment and will include all levels of employees contained within the organisational structure of the business. This will include, but not be limited to, employees from the shop floor to the senior management.

1.5 Prior Research
The concept of Lean manufacturing application started out when Toyota applied the methodology to their manufacturing operations in Japan. Toyota was performing exceptionally well in the 1970’s and 1980’s when the rest of the world was struggling. The concept of world class has endured and the most important value is the visionary leadership that showed an unrelenting and constant focus on seven critical factors that have defined Lean Manufacturing organisations.
These critical factors include:

- An absolute focus on satisfying the customer daily, in three specific areas:
  - Increasing responsiveness in everything that the organisation does.
  - reliability
  - Implicit quality standards in all that is performed.
- Motivating and treating employees in a similar capacity as the organisational assets.
- Constant innovation in the products and services that the organisation provides – first to market and end-to-end solutions.
- Providing seamless synchronisation throughout the value chain, in order to achieve line of sight from the moment contact is made with the customer.
- Sustaining a culture of continuous improvement – doing more with less; eliminating waste; reducing the product lead time.
- Strategic agility to adapt to the market conditions and flexibility.
- To achieve growth in the top and bottom line and to reduce trade working capital. It is important to realise a multiple of the industry average. (Sharma, 2005).

In the South African pharmaceutical environment, established organisations like Aspen Pharmacare are required to evaluate their past activities and new entrants to ensure that they are able to meet the challenges of global competition. International experience has suggested that in meeting this challenge, organisations will be affected by their:

- Position – the sector within which it operates, the market position and the strengths and weaknesses of the science and technology infrastructure in South Africa.
- Path – its core competencies and the trajectory of its past operations.
- Processes – the way in which it has structured its operations and its links to other organisations.
The reorientation process must address three specific areas:

- The market segments to be targeted.
- The organisations’ relationship with other firms in the supply chain.
- The organisation of production within the business.


Richard Schonberger (2001:vii) argues that no company is built to last. After sixteen years of prosperity, nearly 75 per cent of the world’s most admired manufacturing organisations have slipped badly from their peaks in 1995. Schonberger (2001:viii) has found that by the critical standards of Lean production and World Class Manufacturing – shedding inventories – General Motors, General Electric, Toyota and other world class leaders have stopped improving.

Schonberger (2001:ix) asserts that the inclination of industry leaders to engage in stock hyping to gain a quick fix from the dot-com explosion has distracted attention from the “basics” of world class excellence.

1.6 Definition of Key Concepts

- **World Class Manufacturing**: the use of production or manufacturing techniques that aim to maximise productivity, create flexibility and facilitates a culture of continuous improvement (Sharma, 2005).
- **Lean Manufacturing**: this technique of manufacturing focuses on the elimination of waste, maximisation of product quality and increased flexibility, inherent in the process (http://www.gemba.com/consulting.cfm?id=201).
- **Productivity**: the ratio of manufacturing output to manufacturing input.
- **Value stream**: a capability provided to a customer at the right time at an appropriate price, as defined in each case by the customer (Womack & Jones, 1996: 311).
• **Flow**: the progressive achievement of tasks along the value stream so that a product proceeds from design to launch, order to delivery and raw material into the hands of the customer with no stoppages, scrap or backflows (Womack & Jones, 1996: 306).

• **Economies of scale**: an advantage that may accrue as a result of high volume production; as the number of production units produced increases, the cost of producing each individual unit decreases (Faull, 1998).

• **Best practices**: the set of activities that are applied in a manufacturing environment that ensures consistent and regular practice by the employees in an organisation (Faull, 1998).

• **Continuous improvement**: the principles of total quality management – the objective is to improve processes while increasing the quality of the production output (Womack & Jones, 1996).

• **Strategy**: the definition of strategy is …"the direction and scope of an organisation over the long term” (Johnson & Scholes, 1997: 10).

• **Value stream mapping**: the identification of all the specific activities occurring along a value stream for a product or a product family (Womack & Jones, 1996: 311).

• **Product family**: a range of related products that can be produced interchangeably in a production process. The term is analogous to “platforms” (Womack & Jones, 1996: 309).

### 1.7 Delimitation and Limitation of the Research

In order to understand the main problem and its sub-problems and to reduce uncertainty, it is necessary to further demarcate the boundaries of the research intended (Leedy & Ormrod, 2001: 60).
1.7.1 Geographical area
The manufacturing industry is the second largest business sector in the Eastern Cape Province in South Africa, while Aspen Pharmacare is the largest manufacturer of pharmaceutical generic products in Africa (http://www.ecprov.co.za). Aspen Pharmacare is situated in Port Elizabeth in the Eastern Cape – this study will therefore be limited to the Nelson Mandela Metropolitan area, specifically – Port Elizabeth.

1.7.2 Industry
The research will focus solely on the Aspen Pharmacare, General Facility manufacturing plant, operating in the pharmaceutical industry.

1.7.3 The Organisation and Size
Formerly known as Lennon Medicines, operating under the South African Druggists group of companies, the organisation became known as Aspen Pharmacare during the late 1990’s. Today, Aspen Pharmacare is the largest producer of pharmaceutical products on the African continent (www.aspenpharma.com). At the General Facility in Port Elizabeth, the focus of this study, the company employs a permanent staff complement of 375 as at June 2006 (Company Records, Group HR, 2006).

1.7.4 The Unit of Analysis and Level within the Organisation
A unit of analysis, according to Hussey and Hussey (1997: 66) is the unit under study and around which the research problem is based, data is collected and subsequently analysed. The unit of analysis in this study will be the employees at the facility, specifically those directly involved in the lean process and application across all the functional participating departments. Contract and casual staff will be excluded from this study.

1.8 Significance of the Research
It is only recently that South African organisations have begun to adopt World Class Manufacturing (WCM) techniques systematically. The progress is most advanced where the leading organisations are forced to change their supply chains and the level of demands of the changing customer. This is more pertinent in organisations where the products are marketed and sold in foreign
markets. These conditions are met more closely in the automotive sector of the South African business environment, although other sectors (often local organisations like brewing), are also demonstrating signs of progress.

Achieving WCM standards is an essential step in organisational restructuring; however, it is only one of a number of challenges facing the South African pharmaceutical industry. The critical step is to develop realistic business strategy in which the firm matches their core competencies with the opportunities in the market (Policy Brief, Enterprise Restructuring: University of Natal, 2005).

In the Aspen Pharmacare business environment, the organisational strategy must identify the key success factors. It is important to realise, specifically in the South African context, that it is from these identified critical factors, that the strategy for continuous improvement in the form of World Class Manufacturing and Lean Production initiatives will be identified.

In conducting the study on the implementation of WCM programmes in the pharmaceutical industry, Aspen will gain a better understanding of the factors that potentially influence the successful implementation of such a programme. Aspen will gain insight into underlying key success factors that could shape the organisation into the future – a Lean Manufacturing organisation operating in the South African pharmaceutical production environment.

1.9 The Research Design

The proposed research for this treatise consists of two components;

- A search and review of the literature on the concept of continuous improvement in manufacturing and the techniques included in the use of this concept – Lean Manufacturing is an example.
- Research at the Aspen Pharmacare General Facility in the form of a practical application of some of the tools in a pilot study conducted in the manufacturing areas.
1.10 Proposed Chapters

1.10.1 Chapter One: Introduction
The first chapter will encompass the description of the general problem area, leading to the more specific problems and the defined sub-problems. The importance of the topic will be discussed as well as a description of the approach, delimitations and the key assumptions of the research treatise.

1.10.2 Chapter Two: The Literature Survey
The second chapter provides a discussion of the concept of continuous improvement and the techniques associated with it. This chapter will attempt to provide an explanation of the research methodology utilised in order to carry out the empirical (practical) research to establish the potential needs for the Aspen Pharmacare General Facility.

1.10.3 Chapter Three: The South African Pharmaceutical Industry
This chapter will briefly describe the South African Pharmaceutical industry and the regulatory environment that governs this industry, with a particular reference to Aspen Pharmacare, General Facility situated in Port Elizabeth. An introduction to the pilot study for the purposes of the research project will be introduced.

1.10.4 Chapter Four: Research Methodology
This chapter will describe how the research has been conducted. The instrument of data collection and the measurement technique will be presented.

1.10.5 Chapter Five: The Findings and Results of the Research.
The results of the data collection will be reported. An analysis of the results will be conducted and an explanation of the conclusions and the implications thereof will be given.
1.10.6 Chapter Six: Summary and Recommendations

The treatise will be summarised and the results of the research conducted will be stressed, especially for any impact arising from these result which may prove to be beneficial.

1.11 Conclusion

This chapter has outlined the format and the methods that the research will employ, with reference to the research problem and its sub-problems. The key terms have been defined and a brief overview of the literature has been compiled, highlighting the need for research in the field of Lean Manufacturing implementation in the pharmaceutical manufacturing industry.

The following chapter provides a discussion of the concept of continuous improvement and the techniques associated with its application.
CHAPTER TWO
WORLD CLASS/LEAN MANUFACTURING– THE TOOLS AND PRINCIPLES

“In layperson terms, being world class or lean infers being able to compete favourably with the best in the world. Whether a firm exports or competes only in its domestic market, the progressive elimination of trade tariffs and export subsidies means that all firms ultimately face world class competitors.”

(Norman Faull, 1998).

2.1 Introduction
Huge and Anderson (1988, ix) state that the philosophy of manufacturing excellence arises out of the global competition sparked by the world class firms of Japan, Germany and other countries. This new mind-set, probably the most significant advance in the twentieth century, is no unusual growth; in large part it is the outgrowth of American ingenuity and industry. The impact of the philosophy of manufacturing excellence is immense. First, the traditional manufacturing function is transformed and the optimum tactics for automating finally appear. Second, all firms functions become affected by and integrated with manufacturing.

Womack and Jones (1996, 10) describe Lean thinking as the constant application of five key principles: precisely specify value by specific product, identify the value stream for each product, make value flow without interruptions, let the customer pull value from the producer and pursue perfection.

Hammer and Champy (1994: 2) believe that in order to achieve world class manufacturing, a business reengineering approach must be applied. Business reengineering means putting aside much of the received wisdom of two hundred years of industrial management. It means forgetting how work was done in the age of the mass market and deciding how it can best be done now. At the heart of business reengineering lies the notion of discontinuous thinking – identifying and abandoning the outdated rules and fundamental assumptions that underlie current business operations.
Brian H. Maskell asks how agile manufacturing differs from lean or world class manufacturing. He argues that the lean or world class manufacturing techniques is being very good at performing the things that can be controlled, while agile manufacturing deals with the things that cannot be controlled. Agile manufacturing is the ability to thrive and prosper in an environment of constant and unpredictable change. Agility is not only to accommodate things, but to relish the opportunities inherent within a turbulent environment (http://www.mmsmag.co.za/print.aspx?id=191).

Jack Harrison, in *Foundry Management and Technology*, describes Six Sigma as nothing less than a phenomenon. From its origins at Motorola Inc. twenty years ago it has grown into a way of life in many organisations. Many organisations today have attributed their success to the Six Sigma approach. Six Sigma is a series of methods used to manage process variations that cause defects defined as unacceptable from the mean (or target) and to work systematically to manage variation in order to eliminate those defects. The objectives of Six Sigma are to achieve world class performance, reliability and to achieve value for customers. It has a profound influence on manufacturing organisations, but the approach has also been adopted in other industries (Harrison, 2006).

Many approaches have thus been adopted as a tool for achieving significant productivity and efficiency improvements in the manufacturing environment. The Pharmaceutical environment is no different in that there are inherent processes or stages of manufacturing in the solids manufacturing operations of the General Facility at Aspen Pharmacare. The manufacturing operation has adopted the Lean approach and what follows is a review of the literature as applied to Lean Manufacturing and the tools associated with an implementation process.

2.2 Achieving Basic Stability – The Starting Point for Lean
Art Smalley is of the opinion that Lean production has dramatically lifted the competitiveness of many manufacturing companies as well as the value they deliver to their customers (Smalley, 2005).
Encouraging news surfaces almost daily, both locally and internationally, about firms embracing significant elements of Lean and driving them into non-production areas of the organisation that include product development, purchasing, supply chain management and engineering. Despite these triumphs and successes, many organisations are stuck in first gear on their initial efforts in implementing Lean systems (Smalley, 2005).

Taiichi Ohno, developed core elements of Lean Manufacturing at the Toyota Motor Corporation in Japan in the period between 1950 and 1955. During this five-year period, Ohno conducted experiments in the machine intensive production shops that he managed. Key concepts such as takt time, process flow, standardised work, single minute exchange of die and basic pull system mechanics were all tested and worked out under his direct supervision (Ohno, 1988).

Basic stability in the simplest sense this implies a general predictability and consistent availability in terms of manpower, machines, materials and methods known as the 4M's. Under each of these basic manufacturing building blocks, manufacturing organisations must establish a consistent and predictable process before getting too far down the road with the latter elements of flow and takt time – because - without fundamental items like machine reliability and availability or the correct skills and aptitudes of the employees in place, one cannot run a production line and achieve perfect flow or pace to takt time, for example, producing to takt time and achieving perfect flow assumes a sufficient level of machine reliability and availability is in place. The same is true for the rest of the 4M's (Smalley, 2005).
2.2.1 The Four Key Elements of Stability

2.2.1.1 Manpower

Basic stability in Lean starts with a well trained workforce. Toyota, in the 1950’s learned some basic techniques about supervision in production and the improvement of the skills and capability of work teams. A good training programme has three specific components for production supervisors;

- **Job instruction**: instructed supervisors how to plan for the correct resources they would need in production, how to break down jobs for instruction and how to teach people safely, correctly and conscientiously.
- **Job relations**: instructed supervisors to treat people as individuals and to solve basic human related problems in production rather than to ignore them.
- **Job methods**: instructed supervisors how to analyse and make simple improvements in their realm or area of control.

Taken together, the above methods assisted supervisors to create a basic routine, discipline and a sense of fairness in the work teams (Smalley, 2005).

Tom Scalf, in *Unleashing the Entrepreneurial Spirit* (2005), adopts the view that Lean Manufacturing should utilise the best base of knowledge any business has – the employees or teams who are engaged in their work. Tom Scalf goes on to say that in order to unleash the entrepreneurial skills of the people, a strong educational system, as well as a strong management effort is required to channel these energies into action. Richard Schonberger (2001: 3) implies that management is the differentiator when leading the workforce in continuous improvement. Industrial organisations who increasingly cultivate success do this with new management techniques that continuously drive out waste and drive down inventories.

Arun Shukla (2006), states that Lean Manufacturing brings change in the way people relate to processes within the organisation. Change can be detrimental in both its magnitude and speed and it can be stressful. This is especially true if the improved productivity resulting from Lean implementation creates a perception that fewer hands will be required at the workplace. Expanded
responsibilities, team ownership of the process and the emphasis on disciplined flexibility that characterise Lean programmes, often lead to resistance. Shukla (2006) maintains that the Lean journey can be seamless and less painful when the management of people’s performance systems is an integral part of the Lean programme. In order to fully grasp the reactive and proactive people management aspect of Lean implementation, it helps to understand the elements that can affect people performance and the drivers that can assist in managing behaviour.

2.2.1.2 Machines
Art Smalley (2005), *In Achieving Basic Stability*, points out that equipment with perfect uptime is not required, however, the customer demand, the capacity of the process and the actual average output must be known. It is only when there is no demonstrated capacity to meet demand that one has a basic machine stability problem. For example, if customer demand is 700 units per shift and the actual output is only 500 units despite having the capacity for 1000 units, then more availability is required.

Tom Dossenbach (2006), in *Implementing Total Productive Maintenance* describes machine maintenance as an approach whereby the employees in the organisation not only identify problems, but to take corrective action to prevent the defects from occurring again. Dossenbach goes on to allude that in moving towards Lean implementation; repairing or fixing a damaged piece of machinery or equipment is a non-value added activity and adds unnecessary cost to the value as perceived by the customer.
2.2.1.3 Materials

In general the goal of Lean Manufacturing is to reduce waste and to shorten the timeline from when an order is received until the time it is produced. This requires the reduction of inventory in the value stream. In the event of basic instability with respect to materials, one may need to increase inventory in the short term.

Not all inventories are waste, only inventory beyond what is required to run a particular process is waste. Inventory often exists as a symptom of a problem inherent in the process. Solving the manufacturing or process problems that exists earns one the right to reduce the inventory (Smalley, 2005).

David Drickhamer (2006), in The Quest for Zero Inventories, interviews Robert Hall in an article published in the Materials Handling Management review, who describes the reduction of inventories and materials as the just-in-time movement of materials. Hall believes that significant opportunities remain for process improvements that go beyond the adoption of the well-known Lean techniques for reducing raw materials, work-in-progress and finished goods inventory. Realising these opportunities requires a significant behavioural and cultural change to take place for most organisations.

2.2.1.4 Methods

Achieving basic stability requires having standard methods in place for manufacturing. The key is the definition of standard. The normal definition is that a standard is a rule or a way to do things. The unintentional side effect is that people are not encouraged to question or change the rule (Smalley, 2005).

The definition of standard at Toyota is slightly different. A standard is a “rule or a basis for comparison”. A standard is nothing more than a tool to measure how we are doing something and refer to when we want to make a change. Lean thinking is about changing the work methods in order to eliminate waste and make improvements (Smalley, 2005).
2.3 The Lean Principles

2.3.1 Lean Thinking versus Muda

*Muda*. It is the one Japanese term that is used very often when implementing Lean Manufacturing. Womack and Jones (1996:15) have interpreted the term from the Japanese language and describe *Muda* as *waste*. In terms of Lean Thinking, *waste* applies to any activity in manufacturing that absorbs resources but does not add value to the final product. Taiichi Ohno (1912 – 1990), identified seven types of waste. In their book, *Lean Thinking*, Womack and Jones (1996: 15) expanded on the seven types of waste to include finished goods and services that do not meet the customer’s requirements as additional forms of *muda*.

This research project argues that Lean Thinking in manufacturing is a suitable improvement methodology to eliminate waste, as it provides a way to specify value, line up value-creating actions in the best sequence, conduct value-creating activities without interruption when needed and performs the activities more effectively. In short, *Lean* Thinking is lean because it provides a way to do more and more with less – less equipment, less human effort, less time and less space, while constantly improving to provide customers with exactly what they want, thus creating capacity to produce more, if the manufacturing capacity is capable to absorb an increased load. Schonberger (2001: 40), in *Let’s Fix It!* defines competitiveness when viewed through the eyes of the customer, as quality, speed, response, flexibility and value. All these indicate that waste is not allowed, while these elements in the Lean approach is constantly improved or revised in order to gain continuous advantage in the global market place.

Drickhamer (2006) indicates that manufacturers do not understand the degree of change necessary to be a truly Lean organisation or culture or doing *Kaizen* regularly in the workplace. In contrast to this mindset, companies like Toyota have taken the approach to address waste as it affects the manufacturing operation as a whole. Lean thinking must start with a conscious attempt to precisely define value in terms of specific products with specific capabilities offered at specific prices through a dialogue with specific customers. The way to do this is to ignore existing assets and technologies and to rethink organisations
on a product-line basis with strong, dedicated product teams (Womack and Jones, 2001: 19).

2.3.2 Value: The First Lean Principle
Womack and Jones (1996: 16) are of the view that the critical starting point for Lean thinking is *value*, with value only being defined by the end customer. According to Womack and Jones value is only meaningful when expressed in terms of a specific product (a food or a service and often both at once) which meets the customer’s needs at a specific price at a specific time.

This value is created by the manufacturer or the organisation. The key however, is to fundamentally change the thinking by focusing on the needs of the customer. This approach radically changes the decision of what specifically the value that is being created is. Schonberger (2001: 8) states that Lean Thinking or world class principles must start with a conscious effort or attempt to precisely define value in terms of specific products and how best to produce these products.

An important aspect about Lean to remember is that it is a manufacturing lifestyle dedicated to the elimination of waste. In theory, manufacturers should not produce more than the customer’s need, since inventory is a form of waste (Campbell, 2006).

Womack and Jones (1996:34) also caution organisations when it comes to the need to rethink the value that the organisation defines. The authors recommend that manufacturers must “talk” to their customers and together, must find new ways to define value along the value stream. The authors suggest that it is vital for the manufacturing organisations to accept the challenge of redefinition, since this is the key to finding more customers. Furthermore, the ability to find more customers and to acquire additional sales rapidly is critical to the success of Lean Thinking. Lean organisations are always, or continuously, freeing up substantial amounts of resources. In lean organisations, the objective is to constantly seek the best economic use of their assets as they pursue new paths and defend their
employees. Defining value critically and deriving improved specifications, often provides the means to the organisational objectives.

Womack and Jones (1996:35) conclude the value discussion by encouraging lean organisations to continually revisit the value question with their product teams. The authors believe that this is the value specification analogue of the kaizen which seeks to continuously improve product development, order-taking and production activities. These factors produce steady results along the value path to perfection.

2.3.2.1 The Target Cost – a final element in the value definition

The most important task in specifying value, once the product is defined, is to determine a target cost based on the amount of resources and effort required to make a product of given specification and capabilities if all the currently visible waste, or muda, is removed from the manufacturing process. Performing this activity is the key to driving out the waste. Womack and Jones (1996: 35) propose that conventional organisations set selling prices based on what they believe the market will bear. Such organisations work backwards to determine acceptable costs to ensure an adequate profit margin.

Lean organisations look at the current bundles of pricing and features being offered to the customers by conventional firms and then ask how much cost they can absorb or take out by the full application of Lean. Lean organisations set targets below the costs borne by competition and as a result, the organisation has choices;

- Reduce prices (another way to increase sales volume and utilise freed-up resources.
- Add features or capabilities to the product (which should also increase sales).
- Add services to the physical product to create additional value (and jobs).
- Expand the distribution and service network (increasing sales, although with a time lag).
- Take profits to underwrite new products (which will increase sales in the longer term).
Womack and Jones (1996:36) conclude the value discussion with the finalisation of the target costs – it must be set for the specific product or product family. The target price becomes the lens for examining every step in the value stream for product development through to production. Constant evaluation of the value stream becomes the key to meeting and challenging the cost target of the value defined product.

2.3.3 The Value Stream: The Second Lean Principle
The value stream is the set of all the specific actions required to produce a specific product (whether a good, a service, or, increasingly, a combination of the two) through the three critical management tasks of any organisation – the problem-solving task running from concept through to detailed design and engineering to product launch, the information management task running from order-taking through detailed scheduled delivery and the physical transformation task proceeding from raw materials to a finished product in the hands of the customer.

Womack and Jones (1996:19) imply that the value stream analysis will almost always show that there are three types of actions occurring along the value stream;

- Many steps will be found to unambiguously create value
- Many other steps will be found to create no value but to be unavoidable with current technologies and production assets.
- Many additional steps will be found to create no value and to be immediately avoidable.

It is important to bear in mind that Lean Thinking must go beyond the organisation, the standard unit of score-keeping in business across the world, to look at the whole – the entire set of activities along entailed in creating and producing a specific product, from concept through to detailed design to actual availability.

Womack and Jones (1996: 21) also point out that in creating Lean organisations, a new way of thinking about the business is apparent, particularly
with reference to all the steps taken together, to produce the final specified product required by the customer.


According to Womack and Jones (1996:37), the objective in creating a value stream map is to define exactly every step in the manufacturing process required to design, order, and make a specific product. This action can be divided into three important steps;

- The process or steps that actually create value as perceived by the customer.
- The steps that add no value, however, they are required in the process of manufacture and cannot be eliminated in the process immediately.
- The steps that do not create value as perceived by the customer and can be eliminated immediately.

The authors believe that once these steps are defined and the third step is removed, the path is clear to focus on the remaining non-value-creating steps through the use of flow, pull and perfecting the techniques as prescribed by lean principles (Womack and Jones, 1996: 38).
2.3.4 Flow: The Third Lean Principle

When the value is accurately defined by the organisation, the value stream mapped for the particular product family and all the wasteful steps are eliminated, Womack and Jones (1996:21) emphasise that the remaining value-creating steps must be made to flow.

The Lean alternative is to redefine the work of functions, departments and organisations so that they can make a positive contribution to value creation and to speak to the real needs of the employees at every point along the value stream so that it is actually in their interest to make value flow. Womack and Jones (1996: 24) confirms this notion by emphasising that this approach not only requires the creation of a lean enterprise for each product but also the rethinking of conventional organisations, function, careers and the development of a lean strategy for the organisation.

Reinertsen and Shaeffer (2005) in an article, The Logic of Lean, describes one of the key approaches to reducing waste is contained in the application of just-in-time (JIT) production. JIT dramatically reduces batch size, which results in proportional reductions in both inventory and cycle time. The authors also describe a second key element of JIT in the creation of flow. Flow occurs, according to Reinersten and Shaeffer, when the value is being added continuously – work products never sit idle and motionless. This flow is based on control systems based on “pull” rather than “push” (Reinersten & Schaeffer, 2005).

The model that Reinersten and Shaeffer present is based on the illustration below:
Diagram 2: Lean enables small lot sizes by reducing set-up time. Small lot sizes directly shorten cycle times, which in turn improve efficiency, and provide the rapid feedback that improves quality. Higher quality leads to further reductions in lot size because it reduces variability and queuing behaviour (Reinersten & Schaeffer, 2005).

2.3.5 Pull: The Fourth Lean Principle
The first visible effects of converting from departments and batches to product teams and flow is that the time required to go from concept to launch, sale to delivery and raw materials to the customer falls dramatically. When flow is introduced, products requiring a significant time to produce are completed within shorter periods. Jamie Flinchbaugh, author and co-founder at the Lean Learning Centre, emphasises that Lean is not born from a bunch of tools. Lean is most successful when born from a way of thinking. It is important to base Lean implementation and application on principles, since this is what leads to sustainable change, because the principles and beliefs determine the behaviour of the teams and the subsequent behaviour determines employee actions. It is these positive actions that drive positive results (Campbell, 2006).

2.3.6 Perfection: The Fifth Lean Principle
As organisations begin to accurately specify value, identify the entire value chain [stream], make the value-creating steps for specific products flow continuously and let customers pull value from the organisation, something very odd begins to happen – it dawns on those involved that there is no end to the
initial improvement. This is the idea of perfection (Womack and Jones, 1996: 25).

The most important spur to perfection, as identified by Womack and Jones (1996: 26), is transparency, the fact that everyone in a Lean system can see everything making it easier to discover better ways at doing the daily things in order to create value for the customer.

2.4 Some Lean Techniques for Implementation

2.4.1 The Kaizen Blitz

According to Schonberger (2001:180), a Kaizen is a continuous improvement in Japanese. Schonberger describes this exercise as a two to five day improvement event. This process does get results and at the same time may get the employees excited about further application of the method. A Kaizen exercise may be a project with a single focus: re-layout of the packaging area for example. More often, the target is an area, such as the packaging area, but with a general goal – to improve the packaging area. External experts or internal facilitators may lead the effort, along with, typically, a mix of direct and indirect labour and technical staff doing the data collection, task breakdown, analysis and the implementation.

According Schonberger (2001:181), Kaizen has been popularised through the efforts of Masaaki Imai and his 1986 book on the particular subject. A closer look at this book demonstrates that Kaizen, in practice, takes in about any idea for improvement. The production cells, visual management, the 5S systems, total quality and training are essential; however, these are excluded from the Kaizen exercise. Kaizen is an intensive attack on the wastes in which a cross-functional team completes study and implementation in just a few days.
Brown, Collins and McCombs (2006), describe KAIZEN as a combination of two words originating from the Japanese culture – good and change. More commonly referred to as “change for the better”, kaizen is a continuous improvement mindset that pursues elimination of waste. The Kaizen breakthrough methodology, as indicated in the diagram above, is a process where a cross-functional team is assembled for a one-week period to measure, analyse, improve and sustain an improvement to a process. It is an intense and focused process that relies on the creativity of the group/team rather than capital investment.

Brown et al suggest that one critical element to the Kaizen methodology is strong and effective leadership on each team. The authors suggest that the methodology works best when someone within the organisation champions the new Kaizen promotion and selects other strong leaders within the organisation to lead the various teams’ breakthrough events. Further, the authors elude to the fact that effective teamwork and positive team performance is critical to the success of the Kaizen intervention; or any other change initiative in continuous improvement.

Diagram 3: Kaizen methodology event schedule (Brown, Collins & McCombs, 2006).
2.4.2 The Value Stream Map and Process Flow Design

2.4.2.1 The Value Stream Map
The value stream map identifies all the current activities or steps in the process, which results in a product or service. For each process step, metrics (time/costs) is added to determine the best improvement possibility for the organisation in terms of time/cost savings. This is known as the leverage point (Womack & Jones, 1996).

Womack and Jones further suggest that in any improvement initiative, it is essential that the organisation identifies and matches the demand and supply, as this process is time consuming and is often identified as the leverage point for improvement.

2.4.2.2 Process Flow Diagram
The process flow diagram is used to do a graphical illustration of the process and to gain an understanding of the information flow in the current state. It identifies all forms of waste in a process.

Mapping symbols are used to draw the map. Mapping questions are employed as a tool, for example, which activities can be eliminated, combined, replaced or improved.

Once the above are combined, to form a visual picture of where the organisation is for the present time (the current state), only then is it able to identify areas for significant improvement. In the research exercise for Aspen Pharmacare, the current and future states will be demonstrated by means of process flow/value stream maps – illustrating the process of the lean implementation (Womack & Jones, 1996).

2.5 Conclusion
The principles of Lean manufacturing, derived from the Toyota Production System, are well documented. However, many organisations appear to struggle to implement Lean manufacturing effectively. According to Ohno (2005), one issue is that Lean implementations are not systemic; they are based on implementing particular techniques in specific areas of the organisation. When Lean was first introduced, many organisations used the Kaizen blitz process, taking particular production lines or departments/processes and converting
these to one-piece flow operations. As a consequence, according to Productivity Europe, it became hard for organisations to see the results of this activity both in the value stream as a whole, or on the bottom line of the organisation.

Paul Quayle implies that it is pointless to implement complex lean projects without the basic stability provided by 5S, standard work methods and teamwork. Any change initiative, or Lean implementations without the basic foundations in place are likely to fail, regardless of the benefits of the theoretical value stream mapping projects (http://search.epnet.com/login.aspx?direct=true&db=buh&an=18077764).

Jamie Flinchbaugh, maintains that leadership is one of the key factors that determine Lean success or failure. Flinchbaugh cites several cases of the “management support myth” where, when deciding whether or not to implement Lean, the management team was “always supportive of the Lean initiative”. Further, Flinchbaugh says that Lean is most successful when the management teams are encouraged to think differently. It is essential that the lean implementation is based on thinking, sound principles and behaviours, as these determine the organisational behaviours; and the organisational behaviour determines the actions (http://search.ebscohost.com/login.aspx?direct=true&db=aph&AN=22066120&site=ehost-live).

The research project seeks to determine the factors that influence the implementation of Lean manufacturing of a particular process in the pharmaceutical industry, specifically, the General Facility situated in Port Elizabeth, where various issues have been tackled aimed at an implementation of Lean principles in a specific value stream/product family within the organisation. The following chapter describes the pharmaceutical industry in South Africa, with a specific reference to the generic pharmaceutical products that the General Facility produces/manufactures at its plant based in Port Elizabeth, as well as the strategic fit and alignment of the Aspen Pharmacare General Facility operations.
CHAPTER THREE
THE GENERIC PHARMACEUTICAL MANUFACTURING INDUSTRY IN SOUTH AFRICA

3.1 Introduction

According to an Mbendi Industry Profile on the pharmaceutical industry, the country has a relatively well-developed pharmaceutical industry, comprising a complex network of pharmaceuticals manufacturers, distributors and dispensers (http://www.mbendi.co.za/indy/chem/phrm/af/sa/p0005.htm).

Over the past few years, the South African health industry has undergone significant change. Given the challenges the country faces, change is likely to continue in the areas of the funding and structure of the industry with a view to providing increased access to healthcare to all of South Africa's people as efficiently and cost-effectively as possible.

Changes which have already occurred are the introduction of the new Pharmacy Act in some sectors, the introduction of free medical care to pregnant women and children under the age of six years and a range of free primary health care services to the general population.

As membership of medical schemes has been declining in recent years, largely because medical aid rates have been increasing more rapidly than inflation, it is likely that more and more employers will contract health care services to Health Maintenance Organisations (HMO's).

There is also likely to be increased an demand for primary health care level drugs such as generic antibiotics and over-the-counter (OTC) drugs, particularly in view of the fact that a number of drugs are due to lose their patent protection.

Over the past few years, there have been a number of mergers and take-overs, as the industry has restructured to meet competitive challenges. Multinational pharmaceutical companies continue to dominate the industry.

Although pharmaceuticals manufacturing in South Africa is somewhat fragmented and there is only limited local production of generic active ingredients, formulation and last step synthesis is common among the local subsidiaries of multinational drug companies.
3.2 An Overview of the Aspen Group

Aspen is Africa’s largest pharmaceutical manufacturer and a major supplier of branded pharmaceutical, healthcare and nutritional products to the Southern African and selected international markets.

- Aspen is acknowledged as one of the largest generics manufacturers in the southern hemisphere. Aspen is the leading supplier of generic medicines to both the private and the public sectors in South Africa.
- Aspen is one of the top 20 generic manufacturers worldwide and South Africa’s number one generic brand.
- Aspen has pharmaceutical manufacturing facilities located at three sites in South Africa. The Group produces a vast range of products including tablets, capsules, liquids, creams and others.
- Aspen produces more than four billion tablets and capsules per annum, equating to some 100 tablets per person per annum across South Africa’s entire population.
- Aspen has an outstanding generic pipeline for the South African market.
- Aspen is vertically integrated into the supply of active pharmaceutical ingredients (APIs) through its joint venture companies in Cape Town, South Africa and Hyderabad, India which are co-owned by Matrix Laboratories of India.

At the General Facility situated in Port Elizabeth, a significant effort in the manufacturing operations is dedicated to improvement initiatives within the facility, in order to continuously achieve first to market generic pharmaceutical medicines, at the best cost, quality, speed and efficacy (http://www.aspenpharma.com).

3.3 Medicines Regulation in South Africa.

Over the last thirty years, South Africa has developed a medicines regulatory authority with internationally recognised standing. Over the past five years, it has been transformed in order to improve its performance and regulatory
processes. The Medicines Control Council (MCC) is a statutory body that was established in terms of the Medicines and Related Substances Control Act, 101 of 1965, to oversee the regulation of medicines in South Africa. It is appointed by the Minister of Health and its main purpose is to safeguard and protect the public through ensuring that all medicines that are sold and used in South Africa are safe, therapeutically effective and consistently meet acceptable standards of quality (http://www.mccza.com).

According to information obtained from the website administered by authorities at the Medicines Control Council (http://www.mccza.com), medicines regulation in South Africa, is administered in the following manner by the relevant authorities as described below;

- The Medicines Control Council applies standards laid down by the Medicines and Related Substances Control Act, (Act 101 of 1965) which governs the manufacture, distribution, sale, and marketing of medicines. The prescribing and dispensing of medicines is controlled through the determination of schedules for various medicines and substances.

- The MCC operates through external experts who are members of Council Committee structures. Most experts evaluate data sets submitted by the pharmaceutical industry for purposes of registration. These evaluators are from various academic institutions, mainly medical and pharmacy schools.

- The office of the Registrar provides administrative and technical support to Council and its activities. The Registrar is also an executive secretary to Council. The Registrar’s office is a Chief Directorate, Medicines Regulatory Affairs, within the Department of Health. There are four Directorates, which are largely responsible for co-ordination and execution of various activities. There is also a Deputy Registrar who performs functions as determined by the Registrar.

- The staff complement of Medicines Regulatory Affairs includes doctors, pharmacists, veterinarians, other scientists and administrative staff. A certain amount of technical evaluation of generic medicines is performed in-house. It is anticipated that this will increase over time as use of generic medicines increases, in line with government policy of improving access to medicines.
The structure of Council and its committees is described below. The skills of Council and its committees are written into law and include expertise in toxicology and medicine safety, clinical pharmacology, biotechnology, pharmaceutics, internal medicine, virology, pharmaceutical chemistry, neonatology, paediatrics, immunology, veterinary science, complementary medicines and law.

The Council has 11 technical committees, with 146 members from various institutions in the country. These include the Clinical Committee, Pharmaceutical and Analytical Committee, Clinical Trials Committee, Scheduling Committee, Veterinary Committee, Pharmacovigilance Committee, Biological Committee, Complementary Medicines Committee, and African Traditional Medicines Committee.

The Council, in considering whether a medicine is suitable for use for its intended purpose, assesses its relative risk against the benefits. The Medicines and Related Substances Control Act 101 of 1965 defines a medicine; as any substance or mixtures of substances used or purporting to be suitable for use of manufacture or sold for use in:

a) Diagnosis, treatment, mitigation, modification, or prevention of a disease, or abnormal physical or mental state, or the symptoms thereof in man, or;

b) Restoring, correcting, or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine.

All medicines for human use are subject to this law, including complementary and complementary biological medicines.

(http://www.mccza.com).

As a result of the regulatory laws governing the industry, the pharmaceutical organisations find it increasingly difficult to implement changes to their manufacturing processes that would achieve significant cost reduction and improved efficiency in manufacturing and packing operations. This is true also for the General Facility Solids manufacturing operations in Port Elizabeth.

This is the challenge then that faces pharmaceutical manufacturers in the industry. The ability to produce high quality generic medicines where the
elimination of waste is determined as a critical success factor in achieving lean manufacturing, while formulating the ability to establish a value stream that impacts positively on the bottom line of the organisation.

3.4 Generic Pharmaceutical Medicines

According to the Pharmaceutical Manufacturer’s Association of South Africa (PMASA), generic medicines have become a myth in that the research based pharmaceutical industry is opposed to the use of generic medicines. Internationally, the industry believes that generic medicines, introduced flowing a period of originator market exclusivity and within an appropriate regulatory policy and processes, generic medicines offer consumers legitimate medicine solutions or choices (http://www.sapma.co.za/article.php?a_id=37).

3.4.1 Patent Protection

There are certain conditions that are essential in the industry since patient and consumer interests are paramount in the market. These patent protection issues include:

- Patent protection to the innovator organisation ensures funds for continued research and development into new medicines. Remember today’s generics are yesterday’s innovative new chemical entities.
- Patent protection is important because it costs up to 1 billion United States (US) dollars to bring a new medicine to the market.
- Of every 5 000 molecules tested and investigated only three will succeed as medicines.
- The failures and product withdrawals have to be paid for by the successful products, when introduced to the market.
- It takes twelve to fourteen years to bring an innovator or original pharmaceutical product to the market. This leaves an average of seven years of exclusive selling time. Often exclusive selling time amounts only to a few months as new, similar pharmaceutical products enter the market from other innovators. These similar products are made possible
only by the fact that the patent granted to the patent holder forces them to share their innovation with the rest of the scientific community - including would-be competitors.

- Patents do not mean monopolies. With the exception of a few blockbuster pharmaceutical products, new products often enter the market with a discount to their nearest competitor.

- New medicines also compete with other health-care interventions, for example surgery and hospitalisation.

(http://www.sapma.co.za/article.php?a_id=37)

3.4.2 The Generic Pharmaceutical Market in South Africa

With respect to generic pharmaceutical usage around the world, the use of these pharmaceuticals has increased over the past twenty years.

- In 1980, in the US, 23 per cent of all volumes manufactured, were generic pharmaceuticals. In 1991 generic volumes rose to 40 per cent. Today generic usage is over 50 per cent.

- In South Africa (SA), 49 per cent of all volumes sold are generic pharmaceuticals. This accounts for 21 per cent of all value yielded, given that the State, which accounts for 70-80 per cent of all sales purchases at steeply discounted prices by comparison to private sector sales.

- Internationally, 20 per cent of all medicines used by value are generic pharmaceuticals.

- In SA, if there were a generic for every medicine used in the private sector, total estimated savings would amount to no more than 4 per cent.

- Present high utilisation of generic pharmaceutical medicine is due mostly to the fact that innovations from Multi-national organisations from the 1960’s, 1970’s and 1980’s are coming off patent.

- Cost containment pressures within all healthcare systems, with particular reference to South Africa, have also increased the utilisation of generics.
• Low generic pharmaceutical medicine usage is often a feature of countries where original drugs are priced low, for example, in countries like Spain and Portugal. This is true also for South Africa, given that the State purchases its medicine at prices that are in line with those of international aid agencies.

• Germany demonstrates the highest generic pharmaceutical medicine penetration.

(http://www.sapma.co.za/article.php?a_id=37)

3.4.3 Pharmaceutical Generic Medicines Quality.

Original drugs have to pass stringent tests to ensure the safety and efficacy of the products before being introduced to the market. Usually, these tests and other analyses are not imposed on generic pharmaceuticals, instead, generic pharmaceuticals must meet the same test standards, however, the approval process is centred on therapeutic equivalence to the innovator product. In South Africa, quality and bioequivalence of the generic product must be proven and consequently approved by the appropriate regulatory authority – safety of the product is assumed.

Pharmaceutical generic products failing Good Manufacturing Practice (GMP) standards are hazardous to the public health for the following reasons;

• Sub standard quality.

• Poor formulations of the product.

• Too little or too much active ingredients contained in the product.

• Microbial contamination.

• Faulty labelling.


To conclude this section on generic pharmaceutical medicine, post-patented generic medicines that are certified to be high quality and bioequivalent copies of the innovator pharmaceutical product, in an acceptable regulatory
environment, like the MCC in South Africa, can offer patients and consumers greater choice. This process in itself, can free up resources for developing other new innovator products (http://www.sapma.co.za/article.php?a_id=37).

3.5 Aspen Pharmacare and the Generic Pharmaceutical Industry.

Aspen is a world leading generic pharmaceutical manufacture situated in South Africa, with its operations based in Port Elizabeth. Aspen remains the generic brand of choice with more South Africans choosing an Aspen generic to any other brand.

Aspen is acknowledged as the pioneer of research and development of generic medicines in South Africa, which continues to enhance its credibility and stature in the generic pharmaceutical industry. The organisation has launched Africa’s first generic anti-retro-viral (ARV) treatment for the HIV/AIDS epidemic in South Africa. The organisation has maintained its generics leadership position by continuous innovation, both in generic pharmaceutical research and manufacturing capability within its operations. This is set to continue as a result of a robust pipeline and continuous efforts to sustain manufacturing efficiency in the manufacturing facilities (www.aspenpharma.com).

Below is a representation of the generic pharmaceutical products launched to the market place in comparison with other pharmaceutical manufacturers.
Aspen Pharmacare’s generic pharmaceutical products market share in South Africa has grown significantly in the last three to five years. The Port Elizabeth plant is the largest on the continent and employs significant expertise in its factory and development laboratories. Aspen’s renowned manufacturing capabilities subscribe to international standards of Good Manufacturing Practices (GMP) and its Pharmaceutical Research Laboratories are International Standards Organisation (ISO) accredited. Aspen manufactures in excess of 400 tons of solid dose pharmaceuticals, which equates to more than two billion tablets annually. In addition, more than three million litres of liquid pharmaceuticals and two hundred tons of pharmaceutical creams and ointments are produced per year.

Below is a snapshot of the generic pharmaceutical market share as at February 2005, latest available (Official site/facilities at Port Elizabeth, February 2005).
In order for the organisation to continue manufacturing generic medicines of the highest quality, at the right price and at the right time for the customer, it becomes increasingly significant for the organisation to continue with its lean manufacturing initiatives, the intention of the research project. Various factors within the South African pharmaceutical industry, or the Healthcare environment, have heightened the urgency to achieve success on the journey towards achieving Lean or world class manufacturing facilities, specifically at the General Facility operations in Port Elizabeth.

3.6 A Pilot Study at the General Facility’s Operations in Port Elizabeth

3.6.1 The Strategic Intent of the General Facility

It has become the objective of the General Facility to develop a low cost focus within a flexible manufacturing environment capable of agility or flexibility in the following manner;

- An ability to handle unpredictable demand patterns.
- To establish shortened manufacturing lead times.
- To engage in disruptive promotional activities while staying true to supporting stringent branding standards.
- To establish quick response times to the Fast Moving Consumable Goods (FMCG) type packaging and artwork changes.
- To maintain its broad product range.
- To establish and maintain effective and efficient production cycles.
- To develop competencies to support the FMCG business.
- To develop low cost capabilities within the manufacturing operations.

Concern about inventories, cycle times and manufacturing costs has been driven by economic need. The Toyota Motor Corporation is generally credited with creating the concept of Lean Manufacturing. The Toyota production system was created as a Kanban, or a Just-in-time system and evolved out of need. This production system was developed to eliminate waste wherever it was found; raw material inventory, work in process, finished product inventories, off-quality materials and scrap. As this system evolved, it began targeting wasted time as much as wasted materials (Ohno, 1988).
Historically, the pharmaceutical industry has not felt this need. The primary reason is that manufacturing has not been a focal point for the industry. Manufacturing has been considered a necessary evil, a cost centre instead of a profit centre; and often has been ignored by management. The most important task for the pharmaceutical industry, particularly so in the case of the Aspen General Facility, has been to rapidly bring new products to the market (Viswanthan, 2004).

Manufacturing essentially has two charges: follow the protocols or standard operating procedures and do not make mistakes. Pharmaceutical companies are now facing increased competition, cost pressures and a need to improve the performance of their manufacturing operations (Gerecke & Knight, 2001).

Pharmaceutical manufacturing lags behind other industries in process efficiencies. Original production processes for new pharmaceutical products usually are developed in a laboratory for producing clinical trial material. Many tests are conducted to understand these early processes and to ensure product quality and efficacy. The pressures are to create a product that delivers the active pharmaceutical ingredient and to develop a process that can be submitted for a new drug application – NDA. At this point in the research and development process, manufacturing efficiency is not a key consideration (Gerecke & Knight, 2001).

The problem develops as the research-based manufacturing techniques are documented in the NDA. The NDA then “locks up” these manufacturing steps, as prescribed by the research with a regulatory commitment for the future manufacturing process before the process is optimised. Analytical testing that were initially performed for the learning process inadvertently become the required quality control process (Lewis, 2006).

A “desired state” of pharmaceutical manufacturing includes improved knowledge of the products and processes and decreased dependence on inspection and testing. The pharmaceutical industry is still dependent on product testing at every step in the manufacturing process, but quality cannot be inspected into the product.
In reality, product quality is dependent on the quality of the raw materials and the processes that transform those materials into a finished product. Finished product quality is improved by understanding and monitoring the raw materials and the manufacturing process (http://www.fda.gov/cder/gmp/gmp2004/manufSciWP.pdf).

Rather than depend on inspection, the industry must create robust processes that produce consistent, high quality products (Lewis, 2006). This is true for most pharmaceutical companies in South Africa, more specifically; this is true for the Aspen General Facility at Port Elizabeth.

Having established a need for improving the efficiency and effectiveness of the manufacturing operations at the General Facility, a pilot team was selected to drive and facilitate the process of Lean implementation. A pilot area was selected in the Liquids and Solids manufacturing operations at the organisation under consideration using the following criteria:

- The operation is small enough to control
- The manufacturing process is not too complex
- The operation will provide a significant opportunity for success
- The lessons learnt can be used to roll out organisation wide.
- Employees within the area are supportive of the process

(Competitive Capabilities Africa; 2004).

Aspen General Facility produces various products for the Government and other private markets in South Africa. The organisations’ state tender and the demand associated with the Government as a customer, is clearly defined.

Bulk batch tablet sizes, the different packing variants and the timing of each order is known for the duration of the contract period (Elaine McKenzie, 2006).

It was with this known demand, that the pilot areas were derived for the Liquids and Solids Manufacturing operations. The pilot areas defined were as follows:

- Liquids Operations – the Woodwards Gripewater Lines

These defined areas were credible and had a significant chance of success to facilitate full implementation of the Lean Manufacturing System. The following measures were determined by the pilot team, including sub measures and the goals/objectives for the Lean Pilot implementation were determined after a value stream map for the current state was drawn for the two different manufacturing operations (Appendix 3).

The measures for the pilot are tabled below:

<table>
<thead>
<tr>
<th>Main measure</th>
<th>Sub measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 Time</strong></td>
<td>Lead time</td>
</tr>
<tr>
<td></td>
<td>Schedule adherence</td>
</tr>
<tr>
<td></td>
<td>Customer service</td>
</tr>
<tr>
<td><strong>2 Quality of product</strong></td>
<td>Cost of non-conformance</td>
</tr>
<tr>
<td><strong>3 Cost</strong></td>
<td>Inventory</td>
</tr>
<tr>
<td></td>
<td>Material usage variance</td>
</tr>
</tbody>
</table>

The objectives/goals were defined for the pilot as follows;

- To reduce the lead time by fifty percent by the end of the project.
- To improve the operational yield to ninety eight percent on the selected manufacturing processes.
- To reduce the product costs to pass on a zero increase to the marketing and sales operations

For the purposes of the research project, a final future state map has been drawn in both the manufacturing operations in order to facilitate the achievement of the Lean objectives (Appendix 5 and 6). These will be used to demonstrate the improvements, if any will be achieved by the participants of the Lean implementation.

The following chapters discuss research methodology, the journey to Lean implementation and the various techniques and tools utilised to facilitate the Lean journey.
CHAPTER FOUR
THE RESEARCH METHODOLOGY

4.1 Introduction
The main problem of this study evaluates the key success factors, as well as other factors that influence the implementation of Lean manufacturing in the Manufacturing Operations at the Aspen Pharmacare General Facility. In the previous chapters theoretical information was gathered through literature research. This information will be compared with the information obtained from the empirical study to determine if it supports the study.

In Chapter 2, the Lean theory as proposed by Womack and Jones in their book *Lean Thinking* (1996), has been used as the basis for discussion on the task of Lean manufacturing techniques in industry. This discussion was supported by various authors who, by their experience, have been involved in similar initiatives, providing their constructive responses in order to assist other organisations in applying the Lean methodology. Chapter 3 discussed some of the detail related to the generic pharmaceutical manufacturing industry and other role players in the business environment. The aim of this chapter is to determine the accuracy and the validity of the study.

4.2 Research Methodology
According to Leedy (1997:3) research is ‘the systematic process of collecting and analysing data in order to increase our understanding of the phenomenon with which we are concerned or interested.”

Rozakis (1999:3) agrees that research is the gathering and presenting of reliable information. The research paper is the medium used to communicate this research, that is, it argues the thesis. Rozakis (1999:4) states that the research is an analytical way of arguing a point using facts, details, examples and opinions as support.

According to Mauch and Birch (1998:16) research can be divided into two categories, namely quantitative and qualitative research. Below is an explanation of the differences between the two.
4.2.1 Qualitative research can further be divided into (Leedy; 1997:122):

- *Descriptive survey methods*: This data is obtained by observations and is also known as the normative survey method.

- *Historical survey methods*: Reviewing and analysing literature or documents in an attempt to solve problems that are historical in nature.

4.2.2 Quantitative research can further be divided into (Leedy; 1997:123):

- *Analytical survey method*: This is when statistical analysis is done on data that was obtained through quantitative techniques.

- *Experimental method*: Data is collected by comparison of a group under controlled conditions with a group that is under experimental conditions. The effects of the change in condition are analysed.

4.2.3 Data Collection Method

According to Preece (1994:96), the following methods for collecting data are available:

- *Observation*: The researcher unobtrusively observes the subject’s behaviour without active participation.

- *Experiment*: The effects of changes that are manipulated and controlled by the researcher are observed in laboratory and field studies.

- *Survey*: Conducted through interviews and questionnaires. They are the most common method of collecting data.

This study will apply the descriptive/normative survey using postal questionnaires for collecting data. The reason for this is discussed in the following section.
4.2.4 Using the Survey as a Data Acquisition Method

Leedy (1997:186) defines the term survey as “to look or to see over or beyond”. A survey therefore allows the researcher to obtain data in order to determine the outcomes of events.

According to Berry (1997:143) data collection instruments for surveys, identified by Schnetler et al (1989:16), are as follows:

- **Personal interviews**: These are expensive and time consuming, however respondents are willing to co-operate.

- **Telephonic interviews**: The cost of these is lower than the cost of personal interviews; however it is difficult to obtain sufficient quality time with respondents.

- **Postal survey**: These are in the form of questionnaires that respondents are required to complete. They are the only communication medium between the researcher and the respondent.

Meyer (2001: 128) describes the advantages of data collection by the postal survey method as identified by Schnetler et al (1989:19) and Emroy and Cooper (1991:338) as follows:

- This method usually costs the least and is not time consuming.

- It is perceived as anonymous.

- Respondents have enough time to think about the questions.

- The questionnaire is the only form of communication between the researcher and the respondent, therefore the stimuli provided for each respondent is identical for all cases.

- Data is obtained from respondents within a limited time frame.

- These questionnaires are usually highly structured and the use of open-ended questions is limited. This ensures that data capturing is easier to obtain from the questionnaire.
The disadvantages of the postal questionnaire are summarised by Schultz (1997:275) as identified by Lapovitz and Hagedorn (1976: 72). These are:

- It is limited to respondents that are literate.
- The response rate is low due to a high degree of self-selection.
- If the questionnaire is too long respondents may lose interest or become fatigued.
- Respondents are unable to qualify answers or discuss the meaning of statements with the researcher.

For the purpose of this study the appropriate data collection process is the survey method, this is due to the following benefits:

- It is perceived to be anonymous and is less time consuming than the other methods.
- The data can be obtained within a limited time period.
- The data is relatively easily captured on computer.

### 4.3 A Pilot Study

A pilot study is done before the actual study to establish the feasibility of the study and to identify any problems that may exist (Mauch & Birch; 1998: 124).

The questionnaire was distributed to three respondents at the General Facility, Port Elizabeth, before the actual study commenced.

These respondents were the Union representative of the Chemical, Energy, Paper and Pulp Allied Workers Union (Ceppawu), the Technical Laboratory Manager and the General Facility, General Manager at the manufacturing operations. The pilot respondents differed from the actual study respondents by their position at which they were in the hierarchy of the organisation. The respondents were asked to identify any problems that they may have had with the questionnaire. After a discussion with these respondents the questionnaire was amended and the consequent concerns or additional contributions were taken into consideration.
4.4 The Research Sample

Leedy (2001:211) categorises sampling into probability and non-probability sampling. All types of sampling techniques will fall into one of these categories.

4.4.1 Probability Sampling

Probability sampling is described as a sample that can predict that each segment of the population will be represented. These types of sampling are outlined below.

- **Simple random sampling**: This sample is taken randomly, with each segment having an equal chance of being selected.
- **Stratified random sampling**: This sample is taken from the different levels or strata of the population.
- **Proportional random sampling**: This sample is taken from different levels or strata of the population that are not equal in size.
- **Cluster sampling**: This sample is taken randomly from a population, which was broken up into its smallest unit.
- **Systematic sampling**: This sample is taken by using a predetermined sequence.

4.4.2 Non Probability Sampling

These categories of sampling techniques describe techniques that have no guarantee that it would be representative of each element in the population. These types of sampling are outlined below:

- **Convenience sampling**: This type of sampling makes no pretence that the sample is representative of the population. The sample is taken of people that are readily available.
- **Quota sampling**: This sampling is the same as convenience sampling except that the ratio of the different strata coincides with the population.
- **Purpose sampling**: The sample is taken from people or units for a particular purpose.
For the purpose of this study convenience sampling will be used because of the convenience with respect to time and expense. The sample was taken from one generic pharmaceutical manufacturing site – the Manufacturing Operations at the Aspen Pharmacare General Facility. The sample was taken from various levels of employees in the following operational departments: liquid manufacturing and packing, granulation, tablet compression, tablet coating, tablet packing, quality control, quality assurance departments, including production planning, materials procurement and raw material analysis – the encompassing value chain of the operations.

4.5 The Development of the Questionnaire
The purpose of the questionnaire is to extract accurate information from respondents as well as to standardise the format for the recording of this information (Hague; 1994:12). According to Saunders et al (200:279), the following can increase the response rate, reliability and validity of the data:

- the clear layout of the questionnaire;
- a clear explanation of the intention for the study;
- carefully designing individual questions; and
- Conducting a pilot study.

4.5.1 Design of Questionnaire
The theory that was discussed in Chapters 2 and 3 provided the framework for the data required from the questionnaire. The aim of the questionnaire is to obtain information that will support the study.

According to Leedy (2001:202), the following considerations must be taken when setting the questionnaire:

- It must be only long enough to elicit the information that is needed.
- The language that is used must be clear and concise.
- There must be no assumptions inferred in the questions.
- There should be no indication given on what the preferred answer would be.
• Incorporate questions that will verify respondents’ standpoints.

• Know before hand how the responses are to be coded.

• Ensure the respondent’s duty is easy.

• Instructions must be clearly stated.

• If there are any items that are unclear, clearly explain the reason why they were used.

• Ensure that questionnaires are attractive and expertly done.

• Conduct a pilot test.

• The final product must be carefully scrutinised.

4.5.2 Layout of Questionnaire

The layout of the questionnaire was designed to ensure it was easy to complete and easy to analyse the data. The following components that are suggested by Allison et al (1996:75) were therefore used.

• Title

• Introduction to provide assurance of confidentiality and anonymity

• Instructions to completing the questions

• Demographic data of respondents

• Core data: the main focus of the empirical study

• Closing remarks: thanking respondents for their participation

The questionnaire was subdivided into the following parts:

Section A [A1 – A4]

This section was designed to extract biographical information regarding the respondent’s area of work, department size and position held.
Section B1

The question in Section B1 was used to determine whether or not the operational area or department actually implemented elements of the Lean Manufacturing systems.

Section B2

The objective of this section was to determine the reasons for not implementing any Lean initiatives in their environment by certain operational areas. In addition, this section will assist with the feedback obtained in the remaining sections of the questionnaire.

Section B3

This section of the questionnaire covers the theoretical components discussed in Chapter two and in Chapter three. The respondents will answer questions relating to the Lean implementation, elements of basic stability before the implementation and other components of the Lean system. This section of the questionnaire will also cover issues relating to training, elements of the Value Stream for the Pilot study selected for the research, as well as continuous improvement initiatives after the implementation of the Lean systems, or elements thereof.

4.6 Covering Letter of the Questionnaire

A covering letter accompanied the questionnaire that explained the objectives of the study and invited recipients to participate in the research effort. Potential respondents were assured of complete anonymity and confidentiality. Contact information was provided in the event of any additional information being required by the respondents (Appendix 1).

4.7 Response Rate

Fifty questionnaires were distributed to individuals and the purpose of the research explained. A response rate of 76 per cent was realised with 38 of the 50 questionnaires being returned for the purpose of analysis.
4.8 Concluding Remarks

In this chapter, the elements of the research design were discussed, culminating in the development of an empirical study. The sampling procedure, distribution and response rate were determined. In Chapter 5, the results of the empirical survey will be analysed and interpreted.
CHAPTER FIVE
ANALYSIS AND INTERPRETATION OF SURVEY RESULTS

5.1 Introduction
Chapter 4 described the design considerations of the survey as the chosen research methodology for the empirical study. The results of the survey are consolidated and analysed.

The data was analysed and interpreted following the questionnaire structure, namely:

- Section A1 – A4: The biographical information;
- Section B1: Whether or not the operational area has implemented Lean systems, or elements of the Lean system;
- Section B2: Potential reasons for not implementing Lean systems;
- Section B3: The extent of the Lean system implementation applicable to each area.

5.2 Analysis and Interpretation of Biographical Information
The profile of the respondents was obtained from the biographical information in Section A of the empirical study. In this section respondents were asked to provide information about their manufacturing area, nature of operation, number of employees and the nature of their position. Each of these categories will be analysed and presented.

5.2.1 Manufacturing Area [Division]

<table>
<thead>
<tr>
<th>Category</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid manuf</td>
<td>0%</td>
</tr>
<tr>
<td>Liquid Packing</td>
<td>32%</td>
</tr>
<tr>
<td>Solid manuf</td>
<td>46%</td>
</tr>
<tr>
<td>Solid Packing</td>
<td>8%</td>
</tr>
<tr>
<td>Quality</td>
<td>3%</td>
</tr>
<tr>
<td>Other</td>
<td>11%</td>
</tr>
</tbody>
</table>

The graph shows that a large percentage of the respondents are employed in the manufacturing departments, although the research was specifically aimed at various functional areas within the General Facility, the dominant areas are
taken up by the manufacturing departments. Liquid Packing and Solids Manufacturing implemented various elements of the Lean system.

5.2.1 Manufacturing Area [Operation]

From the results it appears that a significant portion of the respondents were from the Packing and Laboratory department, however, it must be pointed out that the Granulation, Compression and Coating departments combined, make up the Solids Manufacturing operation – a combined total of 46 per cent. As stated in Chapter 2, Lean systems implementation must include all elements of the value chain, from the receipt of raw materials at the factory to the delivery of the product to the customer. The respondents in the category “other” make up the support functions required to achieve organisational Lean implementation – production planning, procurement, warehousing and distribution.

5.2.3 Department Size

Information regarding the size of the department where the respondents work is indicated in the graph above. From this graph, it is evident that 70 per cent of respondents work in departments or processes that contain more than 50 employees and only 3 per cent of the responses indicate that there are less than 21 employees in their respective department. The response is congruent
with the number of employees in the manufacturing and packing operations at the General Facility.

5.2.4 Nature of Position
By analysing the nature of the positions occupied by respondents, the perceptions or experiences of the individuals can be analysed, since different levels have different perceptions of any change initiative or improvement exercise. The nature of the positions listed illustrates that 27 per cent of respondents occupy team member roles within the manufacturing operations, while the more significant component of 54 per cent is made up of the support functions within the value chain.

In ensuing sections of the questionnaire, the response by the participants indicates that at the different levels of the organisation, the efforts, more specifically from the support functions, with respect to the Lean System implementation may not have been congruent with the response of the participants at the Team Member level.

5.3 The Implementation of Lean Systems
Respondents were asked to indicate if their operational areas had implemented Lean systems or Lean techniques. The results have shown that there were operational areas that did not implement any Lean systems fully, even though they were considered by the executive management as being part of the process.
5.3.1 Reasons for not utilising Lean Systems

5.3.1.1 Trade Union resistance

<table>
<thead>
<tr>
<th></th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not a Factor</td>
<td>13%</td>
</tr>
<tr>
<td>To Some Extent</td>
<td>38%</td>
</tr>
<tr>
<td>A Big Factor</td>
<td>50%</td>
</tr>
</tbody>
</table>

In the operational areas where Lean systems were not implemented, the respondents were of the opinion that the Union at the organisation was not consulted on the matter of change management. Thirteen per cent of the respondents indicated that the Union was not a factor. Just like any change management initiative, it is important that all the stakeholders are involved before any change takes place or is implemented.

5.3.1.2 The organisational structure

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<thead>
<tr>
<th></th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not a Factor</td>
<td>0%</td>
</tr>
<tr>
<td>To Some Extent</td>
<td>50%</td>
</tr>
<tr>
<td>A Big Factor</td>
<td>50%</td>
</tr>
</tbody>
</table>

Based on the nature of the response, it is evident that the organisation lacks the appropriate structure for Lean implementation. The structure at the General Facility is hierarchal, typical of any pharmaceutical manufacturer. Each division of management has its own areas of responsibility and the South African Pharmaceutical industry or regulatory authority insists that the organisation should be managed in this form, since compliance is a significant component of the business.
5.3.1.3 Lack of training and understanding

Sixty-three per cent of the respondents were of the opinion that a lack of training or understanding of the training contributed to the fact that Lean systems were not implemented. Even though training was provided to the functional divisions in the organisation as part of the sensitisation process, the depth and understanding of the content may have prevented effective, or any, Lean implementation.

5.3.1.4 Lack of financial support

Depending on the organisational level of the individual in the collective group of responses, it is evident that varying opinions existed on the question of financial support for any of the Lean efforts. This fact may have been directly related to different functions having to perform different techniques with regards implementation, creating the idea that varying approaches to the implementation programme required varying financial input. Respondents in the Quality Control Laboratory, for example, indicated that financial input was vital for Lean success.
5.3.1.5 Organisational resistance to change

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<th>Not a Factor</th>
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<th>A Big Factor</th>
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<tbody>
<tr>
<td>Results</td>
<td>13%</td>
<td>63%</td>
<td>25%</td>
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</table>

Since there was no agreement, or consistency in response related to the impact of the Union at the work place, it seems that across the organisation, individuals were of the opinion that the failure to implement Lean at the organisation was related to resistance from the employees, within different functional areas at the General Facility. The high result obtained – 63 per cent - indicates that this may have been significant in not implementing the Lean System.

5.3.1.6 Executive management did not drive the change

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<tr>
<td>Results</td>
<td>50%</td>
<td>38%</td>
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</table>

It is important to realise the impact that the sensitisation process has on the success of any change initiatives. Despite the perceived success of the roll-out by the Executive management, some departments or operations did not implement any Lean systems or Lean Techniques. Respondent’s equivalent to 38 per cent claimed that the Executive Management of the organisation did not drive the Lean initiative effectively, while 13 per cent believed that the Executive Management were inactive in the change process.
5.3.1.7  **Total employee resistance**

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<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
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<tr>
<td>Results</td>
<td>25%</td>
<td>50%</td>
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</table>

Fifty per cent of the respondents were of the opinion that the employees themselves were not committed to the Lean initiatives, resulting in the reluctance to implement the systems.

5.3.1.8  **The nature of the business [pharmaceuticals]**

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<tr>
<td>Results</td>
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After the completion of the sensitisation of the employees, it is natural to discuss whether or not the specific industry was ready for the implementation of the Lean System. The principles of the Lean system are universal, and as a result, were considered not to affect the business significantly enough for successful implementation. This is demonstrated by the result, however, it is not seen as the contributing factor to the failure to implement, rather, it was considered not a factor by majority of the respondents.
5.3.1.9 **Employees did not understand the systems or concepts**

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<th>Results</th>
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<th>A Big Factor</th>
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<tbody>
<tr>
<td>Results</td>
<td>25%</td>
<td>0%</td>
<td>75%</td>
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</table>

It is evident from the responses from the operational areas that did not implement any Lean System initiatives that they did not understand the Lean concept well enough in order to facilitate an effective implementation.

5.3.1.10 **Other [please specify]...**

There were no responses under this response by the respondents in the questionnaire.
5.4 The Concept of Basic Stability

As stated in the literature review discussed in Chapter 2, the concept implies general predictability and consistent availability in terms of manpower, machines, materials and methods – the 4M’s. Under each of these basic building blocks of manufacturing, organisations must establish a consistent and predictable process before getting too far down the road with the Lean elements of flow and takt time. This section of the questionnaire seeks to determine whether or not the operations at the General Facility were in a reasonable position of general predictability and availability with regards the manufacturing operations. This section of the questionnaire also handles responses from individuals in operations where the Lean System initiatives were implement.

5.4.1 Element 1: Manpower

5.4.1.1 The department had sufficient staff to handle the implementation

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<tr>
<th>Results</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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</thead>
<tbody>
<tr>
<td>23%</td>
<td>63%</td>
<td>7%</td>
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</table>

Sixty three per cent of the employees who were involved in the Lean implementation considered themselves adequately or appropriately resourced for their specific operation or process, while 23 per cent considered themselves significantly staffed for their operation.
5.4.1.2 The staff were trained in the elements of the lean systems

Sixty per cent of the staff was of the opinion that they were adequately trained in the elements of the Lean Systems. A collective 27 per cent of the remaining employees considered their operation as either uncertain or disagreed with the remaining respondents.

5.4.1.3 The training was effective and assessed by a responsible person

Having determined that the staff was trained to a reasonable level of effectiveness, the employees have considered that they may not have been effectively assessed for the purpose of implementation. By comparison, 60 per cent of the employees who implemented the Lean systems were of the opinion they were trained, however, 53 per cent were of the opinion that they may not have been effectively assessed.
5.4.1.4 The information was transparent and sufficient for planning purposes

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<tr>
<th>Results</th>
<th>Strongly agree</th>
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<th>Uncertain</th>
<th>Disagree</th>
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<tbody>
<tr>
<td>13%</td>
<td>63%</td>
<td>7%</td>
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The information provided to the employees with regards resource (manpower) for the effective allocation of task and team was considered transparent and was considered as sufficient for planning purposes.

5.4.1.5 The Team Leaders were able to assist and deal with staff issues [people]

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<tr>
<th>Results</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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<tbody>
<tr>
<td>17%</td>
<td>47%</td>
<td>13%</td>
<td>17%</td>
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</table>

The teams were of the opinion, based on the responses (47 per cent), that the Team Leaders were able to assist and deal appropriately with employee issues (people issues).
5.4.1.6 A performance management system was discussed and in place before the start

The responses from the employees indicate that there was a system in place to support the Lean implementation on the basis of performance.

5.4.2 Element 2: Machines

5.4.2.1 The average outputs of the machines were known before implementation

A significant response of 70 per cent indicates that the average output of the operational machines were known by the teams, while 10 per cent indicated that they strongly agree and were thus aware of the machine capability at the facility.
5.4.2.2 The available capacity of manufacturing was known

In line with the response obtained for the output of the machines, 70 per cent of the participants believed that the available capacities of the machines were known.

5.4.2.3 A routine and planned maintenance system was in place at the company

The results of the survey have shown that a routine and planned maintenance system was in place prior to the Lean implementation project.

5.4.2.4 Change parts or tooling was sufficient to support improved change-over times were in place
It is clear from the responses that although a significant portion of the employees agreed that change parts or tooling was available to support the various product changeovers that were in place, some employees were of the opinion that there was a lack of such support. Seventeen per cent disagreed; 3 per cent strongly disagreed with the current system before implementation.

5.4.3 Element 3: Materials

5.4.3.1 The production system had enough raw materials to support an improvement

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<th>Results</th>
<th>Strongly agree</th>
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<tr>
<td></td>
<td>10%</td>
<td>50%</td>
<td>23%</td>
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Based on the fact that there are many of the same raw materials that are standard ingredients / excipients in different pharmaceutical products, it makes sense from the results that at least 50 per cent of the employee’s believed that there were sufficient materials on site at the General Facility to support any change initiative.

5.4.3.2 The system is set-up to support new stock and urgent orders

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<tr>
<th>Results</th>
<th>Strongly agree</th>
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In relation to the previous question on raw material availability, the individual respondents considered the raw material system that is able to support the Lean implementation.
5.4.3.3 There is a basic stock level of raw materials to support production

The respondents were significantly unanimous with respect to this response. Raw materials were considered to be available to support production.

5.4.3.4 Classification of stock types is in place to support production

As a result of the training sessions held prior to implementation, the employees became aware that the stock is classified according to its relative importance. As a consequence, this knowledge created support for the implementation of the Lean systems and provided confidence to the employees to facilitate the initiatives with respect to Lean, along with the awareness that the critical items are classified and prioritised for the production system.
Element 4: Methods

5.4.4.1 Standard methods of operation are in place

![Bar chart showing the results]

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<th>Uncertain</th>
<th>Disagree</th>
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<tbody>
<tr>
<td>Results</td>
<td>43%</td>
<td>57%</td>
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There was absolute certainty amongst the respondents that there were standard methods of operation in place at the General Facility.

5.4.4.2 The teams understand the functioning and importance of the standard procedures

![Bar chart showing the results]

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<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
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<tr>
<td>Results</td>
<td>43%</td>
<td>53%</td>
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In the operational areas, it is evident by the results that the manufacturing teams understand the functioning and importance of the standard operating procedures in place at the facility.

5.4.4.3 Equipment used for production is maintained according to planned schedules and methods of operation are available

![Bar chart showing the results]

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<th></th>
<th>Strongly agree</th>
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<tr>
<td>Results</td>
<td>37%</td>
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</table>
Having perused the detail of the response group, it is clear that this response was directly related to the operational function that was performed by the respondents. Only employees directly involved with equipment, were aware of equipment that was maintained according to planned schedules or methods of operation.

5.5 Elements of Lean Manufacturing

Understanding of the Lean System and its techniques that are usually employed is critical to the success of any Lean or continuous improvement exercise. It is important that the role players understand the key concepts and are able to exercise and implement these learned concepts. Lean manufacturing does not exist in the boardroom, but rather of the shop floor.

5.5.1 The teams have acquired lean training/techniques/tools previously

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<th>Disagree</th>
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<tr>
<td>Results</td>
<td>27%</td>
<td>57%</td>
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A combined total response of 84 per cent agreed that the necessary training was received at the time of the Lean implementation project.

5.5.2 The teams understand the concepts of the 7 wastes

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<th>Strongly agree</th>
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<th>Disagree</th>
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<tbody>
<tr>
<td>Results</td>
<td>23%</td>
<td>60%</td>
<td>10%</td>
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</table>
The teams who were involved in the implementation agreed, or strongly agreed, that the concept of waste and waste removal were understood and that the employees were able to apply this knowledge.

5.5.3 The teams understand the need for a pilot area or operation

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<th>Strongly agree</th>
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<th>Strongly disagree</th>
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<tbody>
<tr>
<td>Results</td>
<td>10%</td>
<td>67%</td>
<td>13%</td>
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Sixty seven per cent of the respondent employees understood the need for a pilot operation or area. Some employees were of the opinion that a pilot area may not have been suitable for the Lean programme.

5.5.4 The teams have defined value for the customer and they know who the customer is

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<tr>
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<th>Strongly agree</th>
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<th>Uncertain</th>
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<tbody>
<tr>
<td>Results</td>
<td>43%</td>
<td>40%</td>
<td>3%</td>
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The operational teams agree, or strongly agree, that they had indeed identified their internal and external customers along the process of manufacturing. This significant agreement regarding the defined value was collectively 83 per cent, while a collective 16 per cent were uncertain, disagreed or strongly disagreed that the perceived customer had been identified.
5.5.5 The production plans have been designed around the needs of the customer

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<td>Strongly disagree</td>
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The individual responses believed that the production plans were derived from the needs of the customer, and that they were geared towards delivering to the customer based on these plans for the individual operations or departments.

5.6 Elements of the Value Stream for the Pilot Study

The value stream is the set of all the specific actions required to produce a specific product. According to Womack and Jones (1996:36), the objective in creating a value stream map is to define exactly every step in the manufacturing process required to design or research, order and to produce a specific product.

5.6.1 The specific manufacturing process was identified and communicated

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<td>Disagree</td>
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Seventy per cent of the respondents agreed that the manufacturing process was identified and communicated to the teams.
5.6.2 The teams/leadership drew the value stream map for the manufacturing process

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<th>Results</th>
<th>Strongly agree</th>
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<th>Uncertain</th>
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<tbody>
<tr>
<td></td>
<td>23%</td>
<td>50%</td>
<td>10%</td>
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There were members of the teams that were actively involved in mapping the value stream for the manufacturing process / pilot area of operation intended for the Lean System implementation – 23 per cent. The remaining members of the team were aware of the active participation and consequently were of the opinion that they themselves participated.

5.6.3 Potential problem areas were identified and corrected prior to lean system implementation

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<tr>
<td></td>
<td>13%</td>
<td>57%</td>
<td>23%</td>
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Potential problems were identified along the manufacturing process of the pilot area, as a consequence, a varied response has been found in the analysis of the results from the questionnaire. It is significant that 23 per cent of the employees were of the opinion that the problem areas were identified but possibly not corrected prior to the implementation.
5.6.4 The non-value-adding steps were identified

As a result of the training the employees had received, an acute awareness of the elements of waste was raised, making the identification of the non-value-adding steps possible. Sixty three per cent of the respondents were of the opinion that these were successfully identified.

5.7 Flow and Production [Lean Implemented]

When the *value* is accurately defined by the organisation, the *value stream* mapped for the particular product family and all the wasteful steps are eliminated, Womack and Jones (1996:21) emphasises that the remaining value-creating steps must be made to *flow*.

5.7.1 The flow of materials and the overall process improved after the implementation of Lean tools

It was the opinion of a majority of the respondents – 70 per cent - that the flow of materials and the overall process of manufacturing the product improved when Lean was implemented.
5.7.2 The flow of the process became easier to control

Seventy three per cent of the employees who participated in the Lean process agreed that the flow of product and of the process became easier to control.

5.7.3 The teams identified areas for improvement by creating flow of materials and product

The teams were able to identify areas in the manufacturing process by creating flow of materials and products. It must be mentioned that 13 per cent of these respondents were not certain that any areas of improvement were identified along the process.

5.7.4 The lead time for production/manufacturing improved
A visible improvement in the lead time for the production of the product was realised by the teams on implementing the Lean system. Thirteen per cent were uncertain, while 53 per cent of the respondents who participated stated that the lead time for manufacturing had improved.

5.7.5 The manufacturing and product quality showed signs of improvement

Fifty seven per cent of the employees who participated in the project stated that both the quality of manufacturing as well as the product quality showed signs of improvement, compared to previous manufacturing practices. Twenty seven per cent strongly agreed with this result.

5.7.6 The teams developed the ability to define/dictate/predict stock levels of the product – related to customer demand

Various Lean techniques like Kaizen and Kanban were utilised to demonstrate the power of improvement before the full implementation of the Lean system. Since the teams were able to establish flow in its manufacturing practices, they could develop the ability to define, dictate or predict the stock levels of the product required at the various stages of the manufacturing processes. Fifty three per cent of the employees considered themselves to have been in this
position, 30 per cent were uncertain and approximately 10 per cent were of the opinion that they were unable to perform or develop this skill.

5.7.7 The Kaizen blitzes assisted to identify minimum order manufacturing levels and cycle time of the products

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<tbody>
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<td>13%</td>
<td>63%</td>
<td>17%</td>
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</table>

Sixty three per cent of the team members agreed that the techniques learned as part of the training enabled identification of minimum orders and cycle times of the products contained in the identified value stream.

5.8 Continuous Improvement, Facilitation and Support
As organisations begin to accurately specify value, identify the entire value stream, make the value-creating steps for products to flow continuously and let customers pull value from the organisation – it dawns on those involved that there is no end to the initial improvement. This concept is continuous improvement. During and after the initial implementation, it became apparent to the employees at the General Facility that continuous involvement was required by Lean systems. The questions contained in this section of the questionnaire attempt to establish the impact of continuously engaged employees focused on continuous improvement initiatives.
5.8.1 The teams organised and participated in continuous improvement exercises

A significant portion of the employee responses, at the different levels, agreed by as much as 60 per cent, that there was participation in continuous improvement exercises. The teams became organised and actively participated in improvement initiatives.

5.8.2 The level of operator understanding in the system improved after Kaizen and other Lean interventions

The results obtained are congruent with those obtained in the previous question (5.8.1). Operators’ understanding improved after the Lean intervention.
5.8.3 Continuous generation of ideas from the teams are received to facilitate further process improvement

Although a continuous generation of ideas with regards improvement was evident from the teams and the team members, a significant portion of 20 per cent considered that this may not have been the case.

Fifty seven per cent agreed however that there was a continuous generation of ideas for process improvement.

5.9 General [before, during and after – the Lean implementation]
5.9.1 Everyone in the organisation understands the need to implement the Lean techniques

The response to this particular question indicates that everyone in the organisation did not understand the need to implement Lean Systems. This may be due to certain factors that will be summarised in the following chapter. Forty three per cent of the employees indicated that they understood a particular need to undergo the change initiative; 27 per cent disagreed with this position.
5.9.2 Executive management supported the Lean initiatives and communicated often

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<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>10%</td>
<td>53%</td>
<td>20%</td>
<td>10%</td>
<td>7%</td>
</tr>
</tbody>
</table>

Seven per cent of the individual responses indicated that the Executive Management did not support the Lean initiatives and they did not communicate often enough with regards the progress of the project. Although only a small percentage indicated as such, it is significant enough to assume that the Executive team did not support the project as expected, or as demanded by such improvements intended for the facility. In addition, 20 per cent were uncertain as to whether or not the team was supportive of the change.

5.9.3 The Lean implementation was systematic and clearly understood

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>7%</td>
<td>57%</td>
<td>20%</td>
<td>13%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Significantly, it was perceived that the implementation was systematic and reasonably understood by the teams who participated in the project. Fifty seven per cent agreed that the process was systematic and clear.
5.9.4 The principles of the system were applied consistently in the manufacturing operations

<table>
<thead>
<tr>
<th>Results</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>53%</td>
<td>23%</td>
<td>20%</td>
<td>3%</td>
<td></td>
</tr>
</tbody>
</table>

Fifty three per cent agreed that the principles of the Lean System were consistently applied in the manufacturing operations, while 23 per cent were uncertain and at least 3 per cent did not approve of the application of the process.

5.9.5 The teams were able to cope with the idea of change

<table>
<thead>
<tr>
<th>Results</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>13%</td>
<td>57%</td>
<td>17%</td>
<td>10%</td>
<td>3%</td>
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</tbody>
</table>

The results show that a significant portion of the employees were able to handle change initiatives like Lean System implementation. Fifty seven per cent were able to cope with the idea of change, while a portion of 3 per cent not able to do so.
5.9.6 The Lean implementation uncovered hidden problems that prevented further improvements

Lean Systems implementation usually produces this result. A significant number of participants agreed that problems were uncovered as a result of the improvement process. Seventy per cent responded in this manner.

5.9.7 The system was able to accurately identify customer requirements and was flexible enough to adapt to constant change and demands

The participants in the Lean implementation agreed that the Lean System was able to identify customer requirements and that it was flexible enough to adapt to constant change and demands. Fifty seven per cent of the employees responded in this manner.
5.9.8  Improved production efficiency resulted from the Lean implementation

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>27%</td>
<td>57%</td>
<td>7%</td>
<td>7%</td>
<td>3%</td>
</tr>
</tbody>
</table>

It is noted that at least twenty seven percent of the respondents strongly agreed that improved production efficiency was possible as a result of the implementation. A further 57 per cent responded positively to this statement.

5.9.9  Opportunity for growth and development was recognised and supported by the Leaders

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>13%</td>
<td>60%</td>
<td>13%</td>
<td>10%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Opportunities for growth and development of the employees at the General Facility were recognised by the participating employees. Three per cent strongly disagreed with this statement. Collectively, 26 per cent of the employees who partook in the exercise, were unsure, or otherwise did not see perceive any benefits.
5.9.10 Elements of the organisational values were understood, particularly by the operators, as a result of the Lean Implementation

At least 10 per cent of the respondents did not agree that the elements of the organisational values were understood. Fifty three per cent however were of the opinion that they understood the elements of the values of the organisation as a result of the implementation of the Lean System.

5.9.11 A culture of continuous improvement is visible on the shop floor and in the organisation

A combined response of 24 per cent did not agree that a culture of continuous improvement was visible after the implementation. Fifty seven per cent agreed however that this culture was created.
5.10 Conclusion
In this chapter the data in the survey was presented in graphical form. Responses were analysed and interpreted to determine if the empirical study supported the concepts discussed in Chapter 2. Responses were interpreted in order to evaluate the effectiveness of the Lean Systems to improve the production efficiency at the General Facility manufacturing operations.

On the basis of the interpretation and the presentation of the results, recommendations for continuous improvement of the manufacturing operations using Lean Systems to achieve enhanced productivity will be formulated. These are presented in Chapter 6 together with the final conclusions drawn from the study as a whole.
6.1 Introduction
The objectives of this study were underpinned by the need to resolve the main problem and sub-problems. These will be reiterated and the findings of the theoretical and empirical studies will be presented. Through integration of these findings, solutions to the main problem and sub-problems will be recommended.

6.2 Objectives of the research project
The objectives of the research project were as follows:

- To establish the impact on the manufacturing processes before, during and after an implementation project based on the theory and concepts of continuous improvement to achieve efficient and effective processes.
- To determine whether the organisation under consideration have the basic characteristics in place in order to implement Lean Manufacturing Systems.
- To identify the techniques included in the concept of continuous improvement and to determine if these were implemented and understood in a systematic or appropriate manner.
- To determine whether the implementation of the Lean Manufacturing Systems was effective in order to facilitate efficient and improved productivity along with continuous improvement.

In Chapter 2, the following critical factors were defined regarding effective implementation and management of a Lean organisation and these factors included:

- An absolute focus on satisfying the customer daily, in three specific areas:
  - Increasing responsiveness in everything that the organisation does.
  - reliability
  - Implicit quality standards in all that is performed.
• Motivating and treating employees in a similar capacity as the organisational assets.
• Constant innovation in the products and services that the organisation provides – first to market and end-to-end solutions.
• Providing seamless synchronisation throughout the value chain, in order to achieve line of sight from the moment contact is made with the customer.
• Sustaining a culture of continuous improvement – doing more with less; eliminating waste; reducing the product lead time.
• Strategic agility to adapt to the market conditions and flexibility.
• To achieve growth in the top and bottom line and to reduce trade working capital. It is important to realise a multiple of the industry average.

From the above mentioned critical factors it has been reasonably established what is required of organisations to be world class and to manufacture products for the defined customer derived from value-adding processes. The findings of this study can now be examined in relation to the sub-problems presented.

6.2.1 Summary of the Analysis

6.2.1.1 The concept of basic stability

The results observed from the analysis have demonstrated that the organisation under consideration possessed the basic elements associated with stability, prior to any change initiatives implemented at the facility. The elements associated with the concept of basic stability include – manpower, machines, materials and methods – the 4M's.

Manpower

Approximately 57 per cent of the employees involved in the Lean implementation were confident that the manufacturing system had sufficient resources in terms of manpower prior to any Lean System initiatives. As indicated in the pilot areas of the facility selected for the project, the employees received sufficient training and were assessed in the elements in which they were trained. A significant portion of sixteen percent strongly agreed that the basic element of manpower was sufficiently addressed.
The manufacturing organisation under consideration clearly then possessed the necessary resource prior to the project implementation.

*Machines*

In general, the average output of the machines, the average daily capacity of the manufacturing operations, a routine and planned maintenance system was in place. Sufficient change parts were available to support any improved change-over times.

The response by the participants has demonstrated that basic stability with respect to equipment and machinery was achieved.

*MATERIALS*

It must be highlighted that in the pharmaceutical industry, there are many product ingredients that occur in more than one product variant, or one product dosage form. Single active and multi-active components for example, may share the same active ingredients as well as excipient (inactive) raw materials and components.

The participants therefore agreed that the production system possessed a suitable level of raw material availability and that the system was set up to support new or urgent raw materials that may be required.

The planning and manufacturing system possessed a basic stock level and these were classified according to stock types ranging from "critical" to "normal" items required for manufacturing and packing. It can be reasonably concluded that the manufacturing system possessed basic stability with respect to materials and components.

*Methods*

The industry is governed by standard operating procedures (SOP's) and work instructions in order to manufacture product in the manufacturing system. It has been shown that basic methods were in place at the facility, the teams understood the functioning and importance of these standard procedures and the equipment used for production was maintained according to planned schedules and methods of manufacturing operation were always available.
Having reviewed the concept of basic stability required for the successful implementation of Lean Manufacturing in Chapter 2, and based on the response by the participants in the research exercise, it can be concluded that the manufacturing system under consideration possessed the elements of basic stability, prior to Lean implementation.

6.2.1.2 Elements of Lean Manufacturing

The teams had previously received training in various elements of Lean Manufacturing and had participated in Kaizen Blitzes in various operational areas prior to the full implementation of a Lean System. The respondents agreed that they had acquired Lean training and that there are different Lean techniques and tools that they could successfully utilise for the duration of the project.

The teams understood the concept of the 7 wastes and understood the need for a pilot operational area. A pilot is a small area of the production process together with its own natural working group which has formed a team, along with the critical support of the Line management and other functional support areas (CCI International). Pilot areas were also selected at the General Facility and these included two lines selected from both the Solids and Liquids Manufacturing and Packing operations.

The participants were of the opinion that they had defined value for the customer and that they knew who the customer was, while the production plans were designed around the needs of the customer.

In summary, 29 per cent of the respondents strongly agreed that the elements of Lean Manufacturing were in place, while 53 per cent agreed with the general statements contained in the questionnaire.

6.2.1.3 Elements of the Value Stream

The selected pilot areas were identified and communicated to the participants of the Lean implementation project. Seventy per cent of the respondents agreed that this was indeed the case. The respondents also indicated that they were, to
some extent, involved in the mapping of the value stream for the two pilot areas used for the research.

The employees were able to, as a result of the training received, identify potential problem areas within the manufacturing process prior to the implementation and played an active role in identifying the non-value-adding activities contained in the current practices of the manufacturing process.

A summary of the responses received to determine whether the participants had received the necessary tools to gain the required understanding of the value stream mapping process prior to implementation indicates this requirement positively – 60 per cent agreed, while 19 per cent strongly agreed that the teams possessed these requirements.

6.2.1.4 Flow and Production

When the value is accurately defined by the organisation, the value stream mapped for the particular product family and all the wasteful steps are eliminated, Womack and Jones (1996:21) emphasises that the remaining value-creating steps must be made to flow.

The employees involved in the research project believed that the flow of materials and the overall process improved after the implementation of the Lean tools were employed. The flow of the process became easier to control and the teams identified areas for improvement by creating flow of materials and product. At least 60 per cent of the respondents believed that this was possible. A significant portion of respondents (27 per cent) strongly agreed that the lead time for production improved. It has been shown that the manufacturing and product quality showed positive signs of improvement, while the teams developed the ability to define, dictate and predict stock levels of the product or products contained in the selected product family that were related to customer demand. The Kaizen blitz exercises employed as part of the implementation contributed to establishing minimum order manufacturing levels and contributed to improved cycle time of the products.
In summary, flow and production improved after the implementation of the Lean System. This response was validated by the results produced after having established objectives that were possible to achieve. These objectives were established at the preparation phase of the implementation stage. Eighteen per cent strongly agreed, 60 per cent agreed, while only 12 per cent were uncertain and the remaining respondents were in disagreement with the improvements achieved after the Lean implementation.

6.2.1.5 Continuous Improvement, Facilitation and Support

The results have shown that there was a significant focus on continuous improvement exercises as the teams became organised and displayed an increased level of participation. The level of operator understanding of the system improved particularly with the assistance of Kaizen and other Lean tools. A continuous generation of ideas for improvement were received in order to facilitate further manufacturing improvements.

What is significant is the fact that a portion of the respondents indicated that the results may be misleading, as some employees disagreed that continuous improvement did in fact take place – 27 per cent believed that this was the case.

6.2.1.6 General – before, during and after the Lean implementation

Beginning from a general point of view with regard to the awareness or understanding of the need to implement such an initiative, only 43 per cent of the employees responded positively, while 23 per cent indicated that they were uncertain.

What is significant about the responses is that 27 per cent of the employees were of the opinion that the Lean System implementation uncovered hidden problems that prevented further improvements, while 17 per cent strongly agreed with this statement.

On average, 20 per cent of the participants were uncertain of the rewards and benefits associated with such an initiative. Twenty per cent of the employees disagreed with the process of implementation, citing that the principles of the
system were not applied consistently in the manufacturing operations, while 23 per cent were uncertain. Collectively, 30 per cent were of the opinion that the Executive Management did not support the Lean initiatives and that they did not communicate as often as expected.

To conclude this section of the summary, approximately 57 per cent perceived that a culture of continuous improvement was visible on the shop floor and in the organisation.

6.2.1.7 Reasons for not using Lean Systems
Having reviewed this area of the research, the following factors have been perceived as the most significant for not having implemented Lean Systems in some of the operational areas:

- The employees did not understand the systems, tools or the concepts – 75 per cent.
- A perceived lack of training and understanding – 63 per cent.
- The organisational structure – 50 per cent.

Other factors that may have contributed to the fact that no participation occurred, to some extent, are listed below:

- Organisational resistance to change – 63 per cent.
- The organisational structure – 50 per cent.
- Total employee resistance – 50 per cent.

It is critical to mention that although these employees did not participate in any of the improvement exercises, 75 per cent of the employees did not consider the nature of the organisation under consideration or the pharmaceutical industry as an obstacle to Lean System implementation.
A summary of the reasons are tabled below for ease of reference:

<table>
<thead>
<tr>
<th>Reason for not using Lean Systems</th>
<th>Not a factor</th>
<th>To some extent</th>
<th>A big factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>➢ Trade Union resistance</td>
<td>13%</td>
<td>38%</td>
<td>50%</td>
</tr>
<tr>
<td>➢ The organisational structure</td>
<td>0%</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>➢ Lack of training and understanding</td>
<td>13%</td>
<td>25%</td>
<td>63%</td>
</tr>
<tr>
<td>➢ Lack of financial support</td>
<td>38%</td>
<td>38%</td>
<td>25%</td>
</tr>
<tr>
<td>➢ Organisational resistance to change</td>
<td>13%</td>
<td>63%</td>
<td>25%</td>
</tr>
<tr>
<td>➢ Executive management did not drive the change.</td>
<td>50%</td>
<td>38%</td>
<td>13%</td>
</tr>
<tr>
<td>➢ Total employee resistance</td>
<td>25%</td>
<td>50%</td>
<td>25%</td>
</tr>
<tr>
<td>➢ The nature of the pharmaceutical business</td>
<td>75%</td>
<td>25%</td>
<td>0%</td>
</tr>
<tr>
<td>➢ Employees did not understand the systems or the concepts.</td>
<td>25%</td>
<td>0%</td>
<td>75%</td>
</tr>
<tr>
<td>➢ Other [please specify]</td>
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</table>

### 6.2.1.8 Summing Up

In line with the established objectives of the research project, the impact on the manufacturing process before, during and after the implementation, it was found that the organisation under consideration did in fact have the basic elements of stability in place, prior to any of the change initiatives.

It was found that the concepts of continuous improvement that were implemented may not have been clearly understood by all the employees concerned.

The results have shown that the implementation of Lean Manufacturing Systems was effective to facilitate efficient and improved productivity as well as some measure of continuous improvement demonstrated by the participants.
6.2.1.9 Recommendations

The feedback received from the respondents who participated in the survey indicated that the Lean Systems implementation was successful. The future state maps for the Liquids and the Solids manufacturing operations were derived from the results and the feedback obtained from the employees (Appendix 5 and 6).

A significant reduction in lead time was achieved for the pilot areas selected for the Liquids and the Solids operations, for example;

- A reduction of 57 per cent was achieved for the Solids operation – 131.6 days down to 56 days.
- A reduction of 89 per cent achieved for the Liquids operation – 9.35 days down to 761 minutes.

Key elements to success

Lean Manufacturing is based on the Toyota Production System (TPS). Lean Manufacturing implementation is a never ending improvement based on customer focus and waste elimination. There are many principles, ideas and tools that are used to make up this system. A good way to understand the Lean principles without getting into the technical details is to remember the 7 principles:

- Empower the people
- Eliminate the waste
- Make it as simple as possible
- Do one thing at a time
- Keep it flowing
- Make it visual
- Build in quality

(http://www.gemba.com/consulting.cfm?id=201).

It is thus recommended that the organisation goes beyond the surface of the Lean Principles and then implement what is suited to the organisation. The key elements must be understood by all, making the implementation and the consequent Lean journey, a continued search for excellence.
A step-by-step approach

Although there is an increasing consensus on the order of steps to take when implementing Lean, the following is more or less the preferred order;

- Education
- Business assessment
- Goal setting
- Value stream mapping
- 5 S
- Change management
- Lean tools implemented through Kaizen teams

(http://www.gemba.com/consulting.cfm?id=201).

There is no single recognised standard for the implementation of Lean. It is dependent on the organisation and what the organisation has perceived as its value creating activities that will influence the implementation. A significant portion of the non-implementation of the Lean project arose from the fact that total employee involvement was not in place. It was perceived by the employees that the organisational structure was not suited for the project and training received was not adequate. Direction, support and guidance must be consistent from both the Executive management team and the project team driving the Lean pilot implementation.

Top Management

Lean can be implemented only when there is support from the senior team. If the Chief Executive of the organisation does not support it, the progress of the Lean implementation will be limited. Depending on the type of issues faced at the organisation under consideration, the project is likely to fail without the support of the senior team. It is suggested that the organisation first establish senior management support and then communicate this to all, in order to understand the importance of the project.

Training at the organisation

It is important that everyone understands the importance and the need for the understanding of the Lean principles. It is critical that everyone is involved in one or more Kaizen events and everyone should think of suggestions and ways
to improve their functions and responsibilities. While it may not be practical to provide everyone in the organisation with classroom training all at once, it is recommended that communication occurs often to allow the people the opportunity to learn more through larger group meetings, newsletters or demonstrations of the concepts and principles of Lean.

6.2.1.10 Conclusion

It is important to understand that Lean is a journey and not a destination. The end of the road is never near. It has been shown that everyone in the organisation must understand that Lean Manufacturing is here to stay (http://www.gemba.com/consulting.cfm?id=201).

The rate of change at any organisation depends on many factors. In the case of the General Facility, this may include changes to the tender process which may imply a change in the customer demand; private sector change in movement of products, or outsourcing the manufacturing to affiliate pharmaceutical companies. The work that has been completed in the pilot study must serve as a motivation for the complete implementation of Lean Manufacturing. It is essential that the critical support services like production planning and the Quality Control Laboratory become part of the value stream; and not merely serve as a support service to the manufacturing operations.

The staff and management at the General Facility must own the process while constantly working and thinking through their progress at any time during the Lean journey, bearing in mind the following:

- Lean is a continuous process requiring constant evaluation and adjustment. It is not a process to be completed and then left to sustain itself.
- The journey must be owned. What works for one organisation may not necessarily work for the General Facility.
- It is important to define clear expectations for each segment of the programme before fully implementing the Lean systems.
- There is no specific recipe for success as it varies with every organisation’s implementation and needs.
To conclude, Lean manufacturing concepts appear to have taken hold at the General Facility’s manufacturing operations and the study has shown that when an organisation is involved in Lean, shortened delivery times are possible along with other improvements. However, there is evidence of a variety of barriers preventing full implementation at the General Facility. These barriers must be accurately identified appropriate action must be taken to overcome them before the full benefits of Lean Manufacturing can become a reality.
REFERENCES


October 2006

Dear colleague

SURVEY: IMPLEMENTATION OF LEAN TECHNIQUES IN THE MANUFACTURING OPERATIONS AT THE GENERAL FACILITY, PORT ELIZABETH.

I would like to invite you to participate in a survey aimed at investigating the impact of implementing Lean principles in the manufacturing operations at the Aspen Pharmacare General Facility in Port Elizabeth. The results of this research effort will be submitted to the Nelson Mandela Metropolitan University (NMMU) in partial fulfilment of a Master’s degree in Business Administration (MBA).

Your assistance in this regard will be greatly appreciated. Please complete the following questionnaire to the best of your ability. The questionnaire has been designed to minimise the demands on your time and will take only a few minutes to complete. All the responses will be treated as strictly confidential and the respondents will remain anonymous.

The objective of the questionnaire is to determine your perceptions of the lean implementation and the benefits associated with such a system of operation. Based on the information gathered in the survey, the researcher will integrate the appropriate guidelines to determine the success and the consequent factors associated with a lean manufacturing system implementation at the General Facility in Port Elizabeth.

Should you require any additional information, please feel free to contact Lyndon Jozaffe at telephone extension 2160 or on e-mail at lyndonj@aspenpharma.com.

Thank you for your co-operation.

LYNDON JOZAFFE
RESEARCHER
SURVEY QUESTIONNAIRE

SECTION A : BIOGRAPHICAL INFORMATION

Please answer the following questions by marking the appropriate block with an “X”.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A1. In which manufacturing area do you work?</strong></td>
<td>Liquid manufacturing</td>
</tr>
<tr>
<td></td>
<td>Liquid packing</td>
</tr>
<tr>
<td></td>
<td>Solid Manufacturing</td>
</tr>
<tr>
<td></td>
<td>Solid Packing</td>
</tr>
<tr>
<td></td>
<td>Quality Assurance</td>
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<tr>
<td></td>
<td>Other [please specify]</td>
</tr>
<tr>
<td><strong>A2. In which process of operation is your department involved?</strong></td>
<td>Granulation</td>
</tr>
<tr>
<td></td>
<td>Compression</td>
</tr>
<tr>
<td></td>
<td>Coating</td>
</tr>
<tr>
<td></td>
<td>Packing</td>
</tr>
<tr>
<td></td>
<td>Laboratory</td>
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<tr>
<td></td>
<td>Other [please specify]</td>
</tr>
<tr>
<td><strong>A3. What is the total number of employees in your department?</strong></td>
<td>0 – 20</td>
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<tr>
<td></td>
<td>21 – 30</td>
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<tr>
<td></td>
<td>31 – 40</td>
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<tr>
<td></td>
<td>Over 50</td>
</tr>
<tr>
<td><strong>A4. What is the nature of the position that you hold?</strong></td>
<td>Group Leader</td>
</tr>
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<td></td>
<td>Production Leader</td>
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<td></td>
<td>Team Member</td>
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<td>Other [please specify]</td>
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<td>Other [please specify]</td>
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</table>
**SECTION B: ENSURING BASIC STABILITY AND LEAN IMPLEMENTATION**

**What is basic stability?**
In the simplest sense this implies general predictability and consistent availability in terms of manpower, machines, materials and methods – the 4M's. Under each of these basic building blocks of manufacturing, organisations must establish a consistent and predictable process before getting too far down the road with the latter elements of flow and *takt* time.

**Lean Thinking versus Muda**
*Muda*. It is the one word of Japanese that must be known. Womack and Jones (1996:15) interpret directly from the Japanese language and describe *Muda* as “waste”. In terms of Lean thinking, this waste applies to any activity in manufacturing that absorbs resources but does not add value to the final product. Taiichi Ohno (1912 – 1990), the Toyota executive, identified the first seven types of waste. In their book, *Lean Thinking*, Womack and Jones (1996: 15) include final goods and services that do not meet the customer’s requirements as an additional form of *muda* or waste.

**B1: Has your area of operation implemented Lean production systems?**

<table>
<thead>
<tr>
<th>Yes</th>
<th>[ ] [if Yes, please proceed to B3]</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>[ ] [if No, Please proceed to B2].</td>
</tr>
</tbody>
</table>
**B2: Please indicate the reasons for not utilising the concept of Lean production systems.**

<table>
<thead>
<tr>
<th>Reason for not using Lean systems</th>
<th>Not a Factor</th>
<th>To Some Extent</th>
<th>A Big Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Trade Union resistance.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. The organisational structure.</td>
<td></td>
<td></td>
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<tr>
<td>3. Lack of training and understanding.</td>
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<td></td>
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<tr>
<td>4. Lack of financial support.</td>
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<tr>
<td>5. Organisational resistance to change.</td>
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<tr>
<td>6. Executive management did not drive the change.</td>
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<tr>
<td>7. Total employee resistance.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>8. The nature of the business [pharmaceuticals].</td>
<td></td>
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<tr>
<td>9. Employees did not understand the systems or concepts.</td>
<td></td>
<td></td>
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<tr>
<td>10. Other [please specify].</td>
<td></td>
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</tr>
</tbody>
</table>
### THE CONCEPT OF BASIC STABILITY

#### Element 1: Manpower

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The department had sufficient staff to handle the implementation.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2.</td>
<td>The staff was trained in the elements of the lean systems.</td>
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<tr>
<td>3.</td>
<td>The training was effective and assessed by a responsible person.</td>
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<tr>
<td>4.</td>
<td>The information was transparent and sufficient for planning purposes.</td>
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<tr>
<td>5.</td>
<td>The Team Leaders were able to assist and deal with staff issues [people].</td>
<td></td>
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<tr>
<td>6.</td>
<td>A performance management system was discussed and in place before the start.</td>
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</tbody>
</table>

#### Element 2: Machines

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The average outputs of the machines were known before implementation.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2.</td>
<td>The available capacity of manufacturing was known.</td>
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<tr>
<td>3.</td>
<td>A routine and planned maintenance system was in place at the company.</td>
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<tr>
<td>4.</td>
<td>Change parts or tooling was sufficient to support improved change-over times were in place.</td>
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<tr>
<td>Element 3: Materials</td>
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<tr>
<td>-----------------------------------------------------------------------------------</td>
<td></td>
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</tr>
<tr>
<td>1. The production system had enough raw materials to support an improvement.</td>
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<tr>
<td>2. The system is set-up to support new stock and urgent orders.</td>
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<tr>
<td>3. There is a basic stock level of raw materials to support production.</td>
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<tr>
<td>4. Classification of stock types is in place to support production.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Element 4: Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Standard methods of operation are in place.</td>
</tr>
<tr>
<td>2. The teams understand the functioning and importance of the standard procedures.</td>
</tr>
<tr>
<td>3. Equipment used for production is maintained according to planned schedules and methods of operation are available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Elements of Lean Manufacturing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The teams have acquired lean training/techniques/tools previously [Kaizen Blitz, etc.].</td>
</tr>
<tr>
<td>2. The teams understand the concepts of the 7 wastes.</td>
</tr>
<tr>
<td>3. The teams understand the need for a pilot area or operation.</td>
</tr>
<tr>
<td>4. The teams have defined value for the customer and they know who the customer is.</td>
</tr>
<tr>
<td>5. The production plans have been designed around the needs of the customer.</td>
</tr>
</tbody>
</table>
### Elements of the Value Stream for the Pilot Study

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The specific manufacturing process was identified and communicated.</td>
<td></td>
<td></td>
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<tr>
<td>2.</td>
<td>The teams/leadership drew the value stream map for the manufacturing process.</td>
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<tr>
<td>3.</td>
<td>Potential problem areas were identified and corrected prior to lean system implementation.</td>
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<tr>
<td>4.</td>
<td>The non-value-adding steps were identified.</td>
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</table>

### Flow and Production [Lean Implemented]

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The flow of materials and the overall process improved after the implementation of Lean tools.</td>
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<tr>
<td>2.</td>
<td>The flow of the process became easier to control.</td>
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<tr>
<td>3.</td>
<td>The teams identified areas for improvement by creating flow of materials and product.</td>
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<tr>
<td>4.</td>
<td>The lead time for production/manufacturing improved.</td>
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<td>5.</td>
<td>The manufacturing and product quality showed signs of improvement.</td>
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<tr>
<td>6.</td>
<td>The teams developed the ability to define/dictate/predict stock levels of the product – related to customer demand.</td>
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<tr>
<td>7.</td>
<td>The Kaizen blitzes assisted to identify minimum order manufacturing levels and cycle time of the products.</td>
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<tr>
<td>Continuous Improvement, Facilitation and Support</td>
<td>Strongly agree</td>
<td>Agree</td>
<td>Uncertain</td>
<td>Disagree</td>
<td>Strongly disagree</td>
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<tr>
<td>1. The teams organised and participated in continuous improvement exercises.</td>
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<tr>
<td>2. The level of operator understanding in the system improved after Kaizen and other Lean interventions.</td>
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<tr>
<td>3. Continuous generation of ideas from the teams are received to facilitate further process improvement.</td>
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<tr>
<td>General [before, during and after – the Lean implementation]</td>
<td>Strongly agree</td>
<td>Agree</td>
<td>Uncertain</td>
<td>Disagree</td>
<td>Strongly disagree</td>
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<td>-------------------------------------------------------------</td>
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<tr>
<td>1. Everyone in the organisation understands the need to implement the Lean techniques.</td>
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<td>2. Executive management supported the Lean initiatives and communicated often.</td>
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<td>3. The Lean implementation was systematic and clearly understood.</td>
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<td>4. The principles of the system were applied consistently in the manufacturing operations.</td>
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<td>5. The teams were able to cope with the idea of change.</td>
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<tr>
<td>6. The Lean implementation uncovered hidden problems that prevented further improvements.</td>
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<td>7. The system was able to accurately identify customer requirements and was flexible enough to adapt constant change and demands.</td>
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<td>8. Improved production efficiency resulted from the Lean implementation.</td>
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<td>9. Opportunity for growth and development were recognised and supported by the Leaders.</td>
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<tr>
<td>10. Elements of the organisational values were understood, particularly by the operators, as a result of the Lean Implementation.</td>
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<tr>
<td>11. A culture of continuous improvement is visible on the shop floor and in the organisation.</td>
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</tbody>
</table>

Thank you for your participation. Please return the completed questionnaire by the 30th October 2006.
THE ROAD TO (AND AWAY FROM) LEAN

SIGNIFICANT DATES

1893  F.W. Taylor begins work as a "consulting engineer'.
1896  Vilfredo Pareto publishes law of economic distribution.
1898  F.W. Taylor begins his time studies of shovelling of iron.
1904  Cadillac begins building using interchangeable parts.
1908  Ford Model T.
1909  Frank and Lillian Gilbreth study bricklaying. Beginnings of motion study.
1911  F.W. Taylor "Principles of Scientific Management".
1913  Ford establishes Highland Park plant using the moving assembly line.
   First lean?
1915  Wilson EOQ formula.
1922  Gantt "The Gantt Chart: A Working Tool for Management".
1925  "Mass Production" phrase coined by Encyclopaedia Britannica.
1926  Henry Ford "Today and Tomorrow".
1927  Establishment of Toyota Motor (Toyota looms established in 1922).
1927  Mayo and Roethlisberger studies at Hawthorn Plant of Western Electric.
1931  Walter Shewhart “Economic Control of Quality of Manufactured Product”
   Van Nostrand. First book on SPC.
1934  H.B. Maynard coins the term "Method Study".
1936  An engineer at General Motors coins the term "automation".
1942  Juran: Re-engineering procurement for Lend Lease (90 days to 53 hours).
1943  Flow production of bombers at Boeing Plant II and Ford Willow Run.
1945  Shigeo Shingo presents concept of production as a network to JMA.
   Also identifies batch production as the main source of delays.
1948  Deming first sent to Japan.
   Lectures on waste as being the prime source of quality problems.
1949  Juran first goes to Japan.
1950  Eiji Toyoda visits Ford's River Rouge plant.
1950  Ohno begins work on the Toyota Production System following strikes.
1951  Deming Award established in Japan.

1961  Jay Forrester "Industrial Dynamics" MIT Press describes supply chain system dynamics and demand amplification.

1961  Ishikawa devises Quality Circles, and first are set up in 1962 Juran. Introduces the concept in Europe in 1966.

1969  First microchip designed at Intel by Ted Hoff.
1971  WalMart begins point of sale. Forerunner of EDI, Quick Response FMCG.

1974  Wickham Skinner "The Focused Factory" HBR.
1975  Shingo explains "non stock production system".
1978  APICS MRP Crusade.
1980  NBC televisions screens "If Japan can, why can't we?".
1983  Hall, "Zero Inventories" Dow Jones Irwin APICS.
1983  Monden, "Toyota Production System" Ind Eng and Management Press.
1984  Eli Goldratt "The Goal".
1984  Hayes and Wheelwright, “Restoring our Competitive Edge”, Free Press.
1984 Kaplan" Yesterday's Accounting Undermines Production" HBR and 1987 Kaplan & Johnson "Relevance Lost: The Rise and Fall of Management Accounting".


1985 Porter "Competitive Advantage" Free Press proposes Value Chains
1986 MaasakIi Imai "Kaizen - The Key to Japan's Competitive Success".
1986 Nissan's UK plant established at Sunderland. In 1999 it remains the most productive car plant in Europe with 105 vehicles per man per year.

1986 Goldratt and Fox "The Race".
1987 Baldridge award established.
1987 American Apparel Manufactures "Getting Started in Quick Response".
1987 Boothroyd and Dewhunt "Design for Assembly".
1988 Nakajima "Introduction to Total Productive Maintenance".
1988 Akao introduces QFD into manufacturing.
1988 Cooper and Kaplan, "Measure Costs Right Make the Right Decision", HBR (First paper on ABC).


1994 Hammer "Re-engineering Work: Don't Automate Obliterate" HBR, and Hammer and Champy "Re-engineering the Corporation".

1990 Womack and Jones "The Machine that Changed the World", Rawson.
1990  GM’s Saturn plant begins production. Later to be top of JD Powers for four successive years. GM makes a loss of $2 billion.

1992  EFQM award established.
1993  WWW established. Internet expands from military and university area.
1993  AME popularises "Kaizen Blitz'.
1994  Altshuller, First English translation of book about TRIZ.
1996  Womack and Jones "Lean Thinking", Simon and Schuster.
1999  Gates: “Business at the Speed of Thought' proposes "The Digital Nervous System".

2000  Ford begins Amazon plant. An attempt to bring back the ideals of Highland Park.

Note: HBR denotes Harvard Business Review.
<table>
<thead>
<tr>
<th>#</th>
<th>Main Measure</th>
<th>Sub Measure</th>
<th>Calculation</th>
<th>Source</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Time</td>
<td>Lead Time</td>
<td>Date of First Issue - Date Released</td>
<td>Baan</td>
<td>1, 3,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Schedule Adherence</td>
<td>Orders Closed on or before Due Date</td>
<td>Baan (Schedule Adherence report)</td>
<td>1,</td>
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<tr>
<td></td>
<td></td>
<td>Customer Service</td>
<td>Orders Released on or before Due Date</td>
<td>Baan (Customer Service report)</td>
<td>1,</td>
</tr>
<tr>
<td>2</td>
<td>Quality</td>
<td>Cost of Non Conformance</td>
<td>Returns from marketing + Returns to Suppliers + Reworks + Overtime past Budget + Write offs not provided for + Obsolesence + Expired Stock + Cost of Downtime (Machines/Baan) + Accounts Payable (Settlement Discounts vs Cost of Capital) + Casuals + Contractors over budget + Safety Stock + Budget Variance + Buyouts + Absenteeism + Orders not accepted from Marketing - Emergency accepted</td>
<td>To be determined</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Cost</td>
<td>Inventory</td>
<td>Days Cover</td>
<td>Baan</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Material Usage Variances</td>
<td>Material Usage variance greater than standard</td>
<td>Baan</td>
<td>2, 3</td>
</tr>
</tbody>
</table>

Goal

1. Reduce Lead Time by 50%
2. Improve yields to 95%
3. Reduce Product Costs to pass on a 0% increase to marketing
Aspen Pharmacare
Future State Map
Woodwards Gripe Water

Supplier Loop

Supplier Loop

Supplier

Supplier

Production

Demand

Customer Orders

Customer Orders

QA

QA

Shipment

Supplier

Production

FIFO

FIFO

Pack

Pack

QC

QC

Documentaries

Flow

T&LF

Leadtime 9.35 Days
Processing 761
89% Leadtime

Appendix 5

TAKT = 1.37 sec/bottle

Leadtime 9.35 Days
Processing 761
89% Leadtime

Appendix 5

TAKT = 1.37 sec/bottle