Six Sigma strategy applied to the pharmaceutical industry - how customers benefit.

MBA Thesis

By
Maria Jernelid and Steven Roan

Supervisor
Klaus Solberg Søilen
ABSTRACT

The pharmaceutical industry is extremely large, dynamic and a highly profitable industry. Pattison and Warren (2003, p 1) suggest that in 2002 the pharmaceutical industry pulled in profits that far exceed other industries and accounted for profits “five-and-a-half times greater than the median for all industries represented in the Fortune 500”. Drug discovery and development is however very expensive and the industry is plagued with drug failures during the development stage. Including the costs of failures, developing and taking a new drug to market, the estimated cost for drug development is in the region of US$1.5 Billion and continues to grow year on year (Gassmann et al. 2008). The industry is now faced with finding ways to improve productivity while meeting product and customer, regulatory and efficiency demands.

A couple of issues differentiate the pharmaceutical industry from most other industries. Firstly, consumers of pharmaceutical products often have very little say in the products that they use. Secondly, the pharmaceutical industry is one of only a couple of industries in which the patent protection essentially equals the product.

Six Sigma can be defined as many things, and to different people it may have different meanings. Some will define Six Sigma as a methodology that aims to produce near perfect production process. In numerical term, the vast amount of literature on the subject is supported by Pande et al. (2000) who suggests that Six Sigma aims for a performance target of only 3.4 defects for every million activities. Some will define Six Sigma is as change in organizational culture with the outcome to enhance the position a company, with the goal to achieve greater customer satisfaction, profitability, and competitiveness While Six Sigma is not statistical system, it does use statistics as a major tool for the use and interpretation of the data.

Six Sigma has been used by some of the world’s most successful companies in a variety of different industries as a means to increase their operational efficiency and improve quality while still facilitating compliance, and providing significant benefits to the customer. The focus of Six Sigma is to enhance customer satisfaction and reduce cost by using facts and statistical analysis to minimize the non-desirable variation in the business processes.

A number of different companies who have already implemented Six Sigma within the pharmaceutical industry have been contacted as a means to investigate if or how the customers benefit from Six Sigma. Six hypotheses were created to investigate if Six Sigma is indeed a suitable strategic method for the industry and if the industry can utilise the vast experience from other companies as a bench mark to apply Six Sigma.

Companies will invariably differ, regardless if they are involved in the same industry and this they will have different competencies. Hypothesis were therefore created to investigate if companies should embrace Six Sigma in the entire organisation rather than not just departments if they realise the full potential, and if different companies
have different application of the six Sigma Strategy. Leadership and commitment was also investigated to find out how critical this is to the success of Six Sigma in the pharmaceutical industry. As a means to answer the hypothesis, a number of Key Performance Indicators were used to measure customer benefits that consisted of; improved quality of product, price reduction, shorter delivery times to market and increased financial support for new development projects.

The results showed that fundamental to the success of Six Sigma are the support and leadership by management at every level. Companies who have senior management failing to drive and evaluate Six Sigma will not realise the full potential of the strategy. Companies have started to use another business strategy called Lean to compliment Six Sigma. Lean is a methodology to eliminate delays between process steps lining up these processes so that there is virtually no interruption.

It is also clear that little or no interest in passing on operational cost savings to the customers is the focus when implementing Six Sigma. This could be related to the nature of the industry, which is totally reliant on patent protection to maximise their profits. Customers may however potentially benefit from operational efficiency which leads to decreased R&D timelines which could result in drugs being available sooner on the market. Six Sigma is mainly thought of as a tool to seek operational cost savings which can be used to further strengthen or widen R&D. Customers may also receive some benefit as further R&D leads to new and innovative advances that enhance or offer improvement to current treatment.

The conclusion from this thesis work is that overall the customer benefits from the implementation of Six Sigma in the pharmaceutical industry because of higher quality, better control of quality and faster R&D processes.

**Keywords:**

Six Sigma
Pharmaceutical companies
Lean Sigma
Customer benefit
Key Performance Indicators
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My commitment and continuous strive to do my best is all thanks to you!
CONTENT OVERVIEW

This thesis is organized into seven chapters. The contents of all the chapters are elaborated on below.

**Chapter 1: Introduction**
Provides an overview of the pharmaceutical industry and the Six Sigma concept.

**Chapter 2: Literature Review**
Provides an overview of the information available to support or reject the hypothesis in question in this thesis.

**Chapter 3: Research Findings**
Presents the methodology used in this thesis and the research findings obtained in this study.

**Chapter 4: Recommendations & Conclusions**
Presents the conclusion of the research findings of this work and the recommendations derived from these findings.

**Chapter 5: Critical review of the value of the thesis**
Provides a review of the value of this thesis work

**Chapter 6: References**
A list of articles, books and reports used in this thesis

**Chapter 7: Appendix**
Appendix 1 Questionnaire used in interviews
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### GLOSSARY

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>CRO</td>
<td>Clinical Research Organisation</td>
</tr>
<tr>
<td>DFSS</td>
<td>Design for Six Sigma</td>
</tr>
<tr>
<td>DMAIC</td>
<td>Define, Measure, Analyze, Improve and Control</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FISH</td>
<td>Focus, Improve, Sustain, Honor</td>
</tr>
<tr>
<td>GSK</td>
<td>GlaxoSmithKline</td>
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<tr>
<td>HMO</td>
<td>Health Maintenance Organisation</td>
</tr>
<tr>
<td>IND</td>
<td>Investigational New Drug</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Products Regulatory Agency</td>
</tr>
<tr>
<td>NDA</td>
<td>New Drug Approval</td>
</tr>
<tr>
<td>NME</td>
<td>New Molecular Entity</td>
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<tr>
<td>NVA</td>
<td>Non Value Added</td>
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<tr>
<td>PDCA</td>
<td>Plan, Do, Check, Act</td>
</tr>
<tr>
<td>RA</td>
<td>Rheumatoid Arthritis</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>TPS</td>
<td>Toyota Production System</td>
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Chapter 1- Introduction to both the pharmaceutical industry and Six Sigma business strategy

1.1.1 The pharmaceutical industry

Drug discovery and development is very expensive. Of the thousands of compounds investigated for use in humans, very few are ever approved. Drugs very often fail during the development stage and thus do not return any revenue for the company. Including the costs of failures, developing a new drug to market is estimated to cost US $1.5 Billion and continues to grow (Gassmann et al. 2008). The time from drug discovery to approval can take up to 15 years. Section 1.3.1 will provide an overview of the drug development process.

Because of the huge cost of bringing a drug to market, companies apply for a patent for their drugs giving exclusivity rights typically in the range of 20 years. This patent protection is expected to enable the owner of the patent to recover the costs of research and development through high profit margins. However when a patent on a protected drug expires, a generic drug is usually already developed and prepared for immediate sale by a competitor. Section 1.3.2 will provide an overview of patents in the pharmaceutical industry, and section 1.3.3 will provide an overview of the impact of generic medicines.

The pharmaceutical industry has traditionally not been too concerned with being efficient perhaps due to the large profit margins. In recent years the industry has been focused on expanding R&D capabilities via an open innovation strategy as a means to capture as much innovation as possible to drive new opportunities. Section 1.3.5 will provide an overview of past and present research and development strategy in the pharmaceutical industry.

As many companies’ patents begin to expire, as drug research pipelines weaken, fewer companies are seeing products move from the clinical to the marketing stage. Thus pharmaceutical companies have to look inward, to strengthen processes and quality by design to become more efficient. Pharmaceutical companies need to find ways of reducing late stage failures, safety withdrawals and recalls and at the same time find ways to intensify their efforts to remain market leaders after patents expire if they are to compete with the cheaper generic drugs.

Pharmaceutical manufacturing techniques have not kept up with the advances in technology that most other industries have gone through in the last decade. The industry must now try to find ways of improvement while meeting product, customer, regulatory and efficiency demands. This has led to the need that most pharmaceutical companies have which is trying to reduce operational costs without affecting compliance. Their work includes looking at ways to increase the effectiveness of both their operational
and manufacturing processes by improving efficiency, optimising resources, reducing waste and rejects and controlling inventory.

The pharmaceutical industry is large and dynamic; however, as described above, it is not immune to the need for change. Proven management strategy from other industries perhaps offers the best solution but it will require committed leadership if is to be successfully implemented.

Six Sigma has been used by some of the world’s most successful companies leading to savings of billions of dollars, striking increases in speed and capacity and achieving better customer relationships. Six Sigma is a flexible system used to achieve, sustain and maximize business success. The focus of Six Sigma is to enhance customer satisfaction and reduce costs by using facts and statistical analysis to minimize the non-desirable variation in the business processes. Section 1.3.4 will provide an overview of customers of pharmaceuticals products.

This work investigates if the Six Sigma strategy which offers increased operational efficiency quality improvement while retaining and facilitating compliance, benefits the customer in the pharmaceutical industry by reducing the cost, shortening the time to market and increasing the perceived quality of the final product. Section 1.4 will provide an overview Six Sigma that will include its history, purpose and methodology.

The focus of Six Sigma is to enhance customer satisfaction and reduce cost by using facts and statistical analysis to minimize the non-desirable variation in the critical parameters in the processes. The ultimate goal for Six Sigma is to change the entire mindset and culture of the organisation to create systems and processes that are as close to perfect as achievable thus ensuring that they are functioning at the best possible performance levels.

A benchmarking analysis has been performed by interviewing three pharmaceutical Companies that have implemented Six Sigma to investigate how Six Sigma has benefited the customer by improving the Key Performance Indexes included in this thesis. These companies have an international or global reach with operations in Sweden, the United Kingdom and the United States of America. Descriptions of the companies can be found in chapter 3.2.1.

**1.1.2 Research Focus**

There is a significant quantity of published material highlighting the remarkable changes and improvements individual businesses have achieved by the implementation of Six Sigma. Most of the available information however explores companies outside of the pharmaceutical industry and very little literature is available comparing how the implementation of Six Sigma at different pharmaceutical companies has benefited their customers.

This research will investigate if the Six Sigma system benefits the customer in the pharmaceutical industry by performing benchmarking. Three pharmaceutical companies
that have implemented the strategy were surveyed to investigate how Six Sigma has benefited the customer by improving the Key Performance Indicators identified below. The following Key Performance Indicators were used to measure customer benefits:

- Improved quality of product
- Price reduction of products
- Shorter delivery times to market
- Increased financial support to new development projects

1.1.3 The Business of Drug Development

There are numerous companies worldwide that make huge investments in research and development with the aim of discovering new drugs. Drug discovery and development is however very expensive. In the UK alone, Ferner (2005) suggests the industry spends £3.3 million pounds annually and accounts for approximately 90% of the UK clinical drug research but develops only a few innovative drugs. Of the thousands of compounds investigated for use in humans, very few are ever approved.

Drugs very often fail during the development stage and thus do not return any revenue for the company. Charalambous and Gittins (2008) suggest that at most, only 20% of candidate drugs survive the clinical development process and become marketable. Figure 2, next page outlines the attrition rates of drug development during the clinical stages Phase I to Phase III, the different phases of Drug development will be explained in 1.1.4). Including the costs of failures, developing and taking a new drug to market is estimated by Gassmann et al. (2008) to cost US$1.5 Billion and continues to grow. Manchanda et al. (2005) is perhaps rather generous in the assessment that on average the time from drug discovery to approval can take up to 12 years. Charalambous and Gittins (2008) suggest even longer, that from the start of research to marketing can extend over periods of 15 years up to 30 years.

The development of new drugs usually starts with the discovery of new chemical compounds. Once the compounds have been identified, pharmaceutical companies obtain patent protection for their exclusive use. The compounds are then examined in greater detail investigating their effectiveness and safety. A number of phases of clinical development are used to test the new candidate drug. Finally, a new drug has to be approved by a regulatory authority, like the Food and Drug Administration (FDA) in the case of the US, or the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom.

Because of the huge cost of bringing a drug to market, companies apply for a patent for their drugs giving exclusivity rights typically in the range of 20 years. The patent protection enables the owner of the patent to recover the costs of research and development through high profit margins. However when patent protection drug expires, a generic drug is usually already developed and prepared for immediate sale by a competitor. Thus, Charalambous and Gittins (2008, p 221) says that “pharmaceutical
drug development is characterized by great uncertainty, long time horizons and large investments.”

1.1.4 The Drug Development Process

The drug development process can be dividend into clearly defined phases.

![Figure 1- The phases of the Drug development process](Source: www.pharmamotion.com.ar/drug-development-approval-process-powerpoint-presentation-and-cme-credit-available/)

The first phase in drug development is the preclinical stage which takes approximately 5 to 6 years to complete. If a compound under investigation shows future potential, the preclinical phase requires investigations with animals such as rodents and monkeys. The regulatory authority (please note in the chart above: the Federal Drug Authority –FDA is offered as the governing regulatory body. This is applicable for the United States only) requires that certain animal tests be conducted before humans are exposed. The results of these tests are used to support the Investigational New Drug (IND) application that is filed with the FDA. Lipsky and Sharpe (2001, p. 363) indicates that an IND application “includes chemical and manufacturing data, animal test results, including pharmacology and safety data, the rationale for testing a new compound in humans, strategies for protection of human volunteers, and a plan for clinical testing.” Unless the regulatory authority is completely satisfied with the documentation, compounds will be unable to move to the next stage of testing.
Phase I Clinical Trials: During this stage low doses of a compound are administered to a small group of healthy volunteers who are closely monitored. Halliday et al. (1997) indicates that the aim of a Phase I study is to establish safety at specific dose levels, to examine absorption, distribution, metabolism and excretion including bioavailability and pharmacological aspects of the compound under investigation. Generally, 20 to 100 healthy volunteers are enrolled in a Phase I trial. In cases of severe or life-threatening illnesses, for example oncology patients, volunteers with the disease may be used.

Phase II Clinical Trials: Studies are undertaken to examine the effectiveness of a compound. Typically, Phase II studies involve 100 to 300 patients who Halliday et al. (1997) suggest will suffer from the target disease that the new drug is intended to treat. During Phase II studies, Lipsky and Sharpe (2001) says researchers will try to determine an effective dose, the best method to deliver the drug (e.g.: oral, subcutaneous, intravenous, rectal.), and the dosing interval, as well as to reconfirm product safety. Many clinical studies are ceased during the Phase II as some of the drugs are shown to be ineffective, while others have safety problems or intolerable side effects for patients.

Phase III Clinical Trials: These studies are the final step before seeking regulatory approval. During Phase III, researchers try to confirm previous findings in a larger population. These studies can take from 2 to 6 years and can involve literally thousands of patients across multiple locations across the globe. These studies are used to demonstrate further safety and effectiveness and to determine the best dosage. Halliday et al. (1997) indicates that comparisons will also be drawn with other medications available on the market. Despite the intense research already undertaken in Phase I and II, approximately Lipsky and Sharpe (2001) suggests 10% of medications fail in Phase III trials.

If a drug is able to survive the rigorous testing at all the phases of the clinical trial process, a New Drug Approval (NDA) is submitted to the relevant regularity authority. Lipsky and Sharpe (2001) indicate that a NDA needs to contain all the relevant clinical information that has been obtained from preclinical to the clinical testing Phases I, II and III. Lipsky and Sharpe (2001, p 369) indicates that an application must contain information on “the chemical makeup and manufacturing process, pharmacology and toxicity of the compound, human pharmacokinetics, results of the clinical trials, and proposed labelling.”

After receiving an NDA application from a pharmaceutical company the regulatory authority will undertake a review and makes its recommendations about the drug. Lipsky and Sharpe (2001) suggest that reviews are generally undertaken with 12 months. During the review period, the regulatory authority can request additional information and once the review is complete, the regulatory authority has the power to approve or reject an NDA application. If in the event that a NDA is rejected, the companies who have undertaken the testing will be given information as to why this occurred, and what they need to do to make the application acceptable. Only when the regulatory authority offers approval can a drug be marketed.
Lipsky and Sharpe (2001) indicate that after marketing approval the regulatory authority may however request additional conditions to be addressed. For example, the authority might request a post-marketing study (Phase IV) that will examine the risks and benefits of the new drug in a different population or special population that are considered high risk. While authorities may request a Phase IV study, it is perhaps also in the best interest of a company to further investigate long term effects of a medication and medical indications that may be different to what was first investigated. Thus very often companies will initiate a Phase IV study themselves. Lipsky and Sharpe (2001) also suggests Phase IV studies are useful to uncover problems that were not first visible during the traditional clinical phases as perhaps the drug was not widely used by demographics such as the very elderly. Halliday et al. (1997) also suggests post marketing surveillance is useful to monitor abuse. During post marketing surveillance prescribing doctors are requested to report complications that they view in the clinical setting.

![Attrition rates in R&D by Phase](Source: Gassmann et al. (p.11 2008)](image)

**Figure 2- Attrition rates in R&D by Phase** (Source: Gassmann et al. (p.11 2008))

**1.1.5 Patents in the pharmaceutical industry**

To begin our discussion on pharmaceutical patents, let us first clearly define what a patent is. A patent is a property right granted to the inventor of a novel, non-obvious and useful invention. The inventor or owner of the patent is given the right to exclude others from making, using, offering for sale, or selling their invention for a period of time after filing of the patent (Lehman 2003).
The generic description above however does not take into consideration a number of characteristics that sets the pharmaceutical industry apart from other industries that utilise patent protection. The pharmaceutical industry is one of three technology based industries in which the patent essentially equals the product. The others suggested by Lehman (2003) are the chemical industry, and the biotechnology industry. Patents in the pharmaceutical industry are thought to play a significant role in bringing new products to market (Boldrin and Levine 2008).

What sets these three example industries apart from say the electronics industry is that these three industries require considerable capital investment to first establish and maintain the expensive and complex R&D infrastructures (Lehman 2003). The semiconductor industry has a similar business structure in that companies spend capital on research and development, design and manufacturing. There is however significant more expenses related to manufacturing. The set up costs for a manufacturing laboratory producing computer chips is estimated at approx US$3 billion (Keats and Young 2006).

In the pharmaceutical industry there is a very different situation. Drugs can be quite easily and cheaply replicated and reproduced by other companies with very little investment. Capital investment in the pharmaceutical industry is disproportionately associated to the laboratory research and extensive clinical trials rather process required by the regulatory authorities (Lehman 2003). Moreover, the lengthy time period between being granted a patent to the actual manufacturing of a product suitable for the market place is, as previously mentioned up to 15 years. This then means that pharmaceutical companies will receive substantially shorter periods of patent exclusivity than other companies in other industries. Lehman (2003) suggests that market exclusivity, and the higher prices companies are able to achieve as a result of patent protection, is basically reward to the companies who finance the research and development. Thus, suitable patent protection is essential for any decision to invest in drug development (EPA Office of compliance 1997).

1.1.6 Impact of Generic medicines to brand name medicines

A generic drug is essentially a copy that of the brand name drug produced by the original inventor. The dosage strength, route of administration and application is considered to be the same as the brand drug. The difference between a brand name and the generic copy is essentially in terms of capital investment developing the drug. A generic manufacturer will not have anywhere near the same costs to produce the copy drug as compared to the company who produced the brand drug. Instead of having to redo the numerous clinical trials themselves, a generic company can produce a drug by only showing that it is bioequivalent to the brand name product. The testing procedures required to do this are less costly than the original safety and efficiency tests that the brand name manufacturer has to conduct (Hellstrom and Rudholm 2003).

Once this is proven, regulatory approval is granted and the generic company is free to market the drug. The impact of the generic drug is very large to the brand name
producer. Generic drugs are generally less expensive because generic manufacturers have avoided the huge investment costs of the developing a new drug, and therefore they are able to sell the same product cheaper. Moreover, the number of generic manufacturers in the same market is related to the generic price compared to the brand name drug (Manchanda et al. 2005). Different countries have laws on substitution once patents expire. In the US for example, Wosinka and Huckman (2004) suggests that generic usage of a brand drug can rapidly reach over 95% in a short period of time. Whereas in the UK, PhRMA (2008) suggests that within 4 years a generic drug is likely to have gained about 50% of the brand name market share.

Globally the use of generics by government and health insurers has enabled the generic industry has grow steadily in recent years. Why is this occurring? To use the UK as an example, in the community setting, the prescribers are encouraged to prescribe generics, while in the hospital environment generic usage is automatic (PhRMA 2008). PhRMA (2008) suggests that the generic share of the market has risen from 51% in 2000 to 67% in 2007. With numerous drugs coming off patent every year, it is therefore likely this figure will continue to grow.

Because the high uptake of generic drugs, numerous pharmaceutical companies seek to minimize the impact of generic drugs reducing their market share and profitability. An “authorized generic” is a generic drug that will be marketed and sold by another company on behalf of a brand name manufacturer (Thomas 2006). The belief is that by offering a cheaper generic version, albeit manufactured by the brand name firm, consumers will be encouraged to substitute the brand name drug and switch to the lower-cost authorized generic that is now available (Thomas 2006).

This has however created a trend whereby some brand name companies seek to acquire generic firms, thus limiting the loss in revenue (Thomas 2006). PhRMA (2008) highlight Swiss pharmaceutical company Novartis, a top ten global pharmaceutical company in term of revenue (see table 1) that has purchased two generic manufactures. They have financial means and desire to protect their product marketing and are willing to venture into extended business lines to minimise loss of market share.
### Top 20 Pharmaceutical Companies (Rev in $ Billions)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Revenue ($ Billions)</th>
<th>Rank</th>
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<td>06</td>
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<td>$17,179</td>
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</table>

**Table 1** - Top 20 Pharmaceutical Companies Based on 2007 Revenues


1.1.7 Overview of customers of pharmaceutical companies

A notable feature that differentiates consumers of pharmaceutical products from consumers of other products is that the final consumers (patients) often have very little or no say in the medicine that is prescribed to them. Medical doctors who prescribe medicines, pharmacy boards within hospitals and pharmacies in the community essentially dictate what medicines a consumer will receive (Gassmann et al. 2008). The doctors and pharmacists will act as advocates for the consumer and are thus largely responsible for the consumer’s purchasing decisions. It is accepted that the patient has very little influence over these professional’s decision making as their own knowledge about the products is limited (Gassmann et al. 2008).

While undoubtedly the patients are the customers, they are however third party customers. The real customers are the doctors prescribing drugs, the pharmacist willing to stock certain medicine and the governments who oversee socialized healthcare. These governments have enormous buying power and wield this power to negotiate pricing of pharmaceutical produces. The USA is perhaps an exception to the above, whereby there is limited socialized healthcare; rather healthcare is managed by Health Maintenance Organisation (HMO) who insures individuals against health problems and have large leverage over what medicine treatment their insured clients will receive. Thus, these
organisations are customers to the pharmaceutical companies also (Gassmann et al. 2008).

1.1.8 Past and Present R&D Strategy in the pharmaceutical industry

The pharmaceutical industry has been particularly attractive to investors as many companies have enjoyed profitable returns and shareholder value seems guaranteed (Gassmann et al. 2008). Many companies had been focusing on finding the next blockbuster drug to drive growth and profitability. The industry is however suffering from a lack of innovative drugs via the companies own R&D pipeline (Gassmann et al. 2008). Therefore Gassmann et al. (2008) suggests companies can no longer rely on finding the next blockbuster alone.

To fill their R&D pipeline, companies have to look outside their own organisation to seek and stimulate innovation in the drug development process. One way that a drug company is able to do exactly this is referred to as an “Open Innovation Strategy”. Open innovation distances itself from the traditional process of R&D wherein the company itself own and manage the entire R&D process chain, rather the firm leverages outside help to stimulate and manage innovation (Chesbrough 2006). R&D in an open system assumes that even the most capable R&D organisation needs to identify, to connect with and work along side external companies as a means to enhance innovation (Chesbrough 2006). Pharmaceutical companies thus have been seeking to work with universities, hospitals government, private research institutions, biotech companies and competitors alike to enhance the innovation process.

Another path to strengthen the R&D process is forming a strategic alliance with external companies. Pharmaceutical companies unable to sufficiently undertake development internally align themselves to exploit the knowledge of other firms to complement their own resources (Chesbrough 2006). Covance, Clinical Research Organisation (CRO) recently entered into the largest and most comprehensive development relationship ever formed in the history of the CRO industry. The 10 year agreement with a pharmaceutical company called Eli Lilly that will includes numerous services from preclinical to Phase I-III clinical developments studies. This alliance is designed to help Covance respond to productivity challenges that confront the company. It is expected that the alliance will help Eli Lilly accelerate their R&D process; enjoy a more flexible cost structure, with the overall goal of reducing the time to market for new drugs. (Covance Report 2008)

1.2.1 Introduction to the Six Sigma strategy

Six Sigma has been used by some of the world’s most successful companies leading to savings of billions of dollars, striking increases in speed and capacity in their processes and achieving new, stronger customer relationships.

Six Sigma is a flexible system used to achieve, sustain and maximize business success. There is extensive published information on the growing number of Six Sigma users. An overview is shown in Figure 3 below.

Examples of companies that have implemented Six Sigma are GE, Siemens, Nokia, American Express and Volvo (Klefsjö and Bergman 2004).
1.2.2 History of Six Sigma

The concept of Six Sigma was started at Motorola during the 1980’s as a response to lost market share which made the company realize that an increase in quality was necessary to be able to compete with primarily the Japanese manufacturer who was growing rapidly (Klefsjö and Bergman 2004). An engineer at Motorola called Bill Smith spent a lot of time convincing higher management at Motorola that his new quality control system Six Sigma, would provide significant benefits for the company (iSixSigma Staff 2002).

On the advice of Bill smith, CEO Robert Galvin then looked at the Japanese models for their quality work and realized that total involvement of himself and his senior management team would be crucial for the success of this new quality control system and the improvement work (Klefsjö and Bergman 2004). The implementation was very successful.

Another company that early embraced Six Sigma strategy was General Electric. Their version of Six Sigma is focused on six key principles which are discussed by Bicheno (2006) and summarized below.

- **Critical to Quality**: The customer is the start and what is important for the customer needs to be identified.
- **Defect**: Anything that does not deliver exactly what the customer wants
- **Process Capability**: The processes need to be able to deliver what the customer wants
- **Variation**: As it is experienced by the customer
- **Stable Operations**: The goal is to secure reliable, robust processes that improve the customer’s experience.
• **Design for Six Sigma:** The design must meet all the customer requirements and the capability of the process.

Motorola’s and General Electric’s work have had a large impact on Six Sigma and their methods have in some cases then been further developed to include all the features that characterize the different use of Six Sigma today.

### 1.2.3 Purpose of Six Sigma

The focus of Six Sigma is to enhance customer satisfaction and reduce cost by using facts and statistical analysis to minimize the non-desirable variation in the critical parameters in the processes.

Critical parameters are those that affect features which are important for the end user/customer. It is important however to realize that the Six Sigma system is not a statistical system. It uses statistics as tools for the use and interpretation of the data; however the ultimate goal for Six Sigma is to change the entire mindset and culture of the organisation to create systems and processes that are as close to perfect as achievable thus ensuring that they are functioning at the best possible performance levels. Six Sigma can be seen as: a vision; a philosophy; a symbol; a metric; a goal; a methodology."

(iSixSigma Staff 2002).

By minimizing the variations in the processes the costs are not only reduced by an increase in the delivery of approved units. Also, this robust process avoids the timely and costly investigations that are caused by deviations in the process. The activities used in Six Sigma to reduce the variation should be measurable with regards to costs and customer satisfaction instantly to ensure that the implemented improvements have had the intended effect (Klefsjö and Bergman 2004).

The definition of a process in equilibrium according to the Six Sigma system is that the distance from the mean value of the process to the closest tolerance limits should be at least six times the standard deviation of the process. This corresponds to a maximum of 3.4 faults per million units (Bicheno 2006). This is the target for the Six Sigma work even though this level is almost unattainable; the goal of Six Sigma is to keep striving towards this by using the methodology to keep identifying possibilities for improvements (Klefsjö and Bergman 2004).

### 1.2.4 Six Sigma Methodology

As already identified by Robert Galvin the CEO of Motorola, to be able to successfully implement and use Six Sigma the top management of the company must be involved and fully support this system. The methodology of Six Sigma is focusing on a smaller number of projects that ensures large profits and the projects are run with a rather short time frame to ensure that people keep the focus and interest in the project (Bicheno 2006).

There are two main approaches in the Six Sigma methodology; the DMAIC (described below) approach which focuses on improving existing processes and Design For Six Sigma (DFSS) which focuses on designing new products and processes (Bicheno 2006).
To be able to achieve the set targets in Six Sigma in current processes or within set boundaries, a structured 5 phase methodology (similar to the PDCA-cycle by Deming) called DMACI is used; Define, Measure, Analyze, Improve and Control (Bicheno 2006). These 5 phases all use different methodology and tools appropriate for the tasks and activities in the individual phases. This structured approach does not only provide a clear work structure but creates a drive and a focus on following up the implemented improvements. The information in the short description of the phases below are taken from Bicheno (2006) and Department of Trade and Industry (2004).

Define: The problem is identified and described in specific terms. The goal of the project is set and the project team is selected.

Measure: The symptoms of the problems are identified and objective information is collected to give a baseline of the current performance. The symptoms in Six Sigma are defined as the output of the process that is causing the problem and the focus of this phase is to identify the sources that are thought to be largely responsible for the problem (DTI 2004).

Analyse: In this phase theories about the causes of the problems are formulated, tested and the hypothesis is then rejected or confirmed. The output of this phase is the root cause of the problem.

Improve: This phase starts with evaluation of the alternatives to determine which method that would most effectively eliminate or reduce the cause of the problem. When the improvement method has been selected, the process for implementing the improvement is designed to ensure that the improvement achieves the goal of the project and that the natural resistance to changes are dealt with to ensure that the implementation works as intended. The process effectiveness is then verified before the change is finally implemented.

Control: This last phase is integrated in the regular organisation and the optimized process is monitored by effective quality controls to ensure that the actual result of the improvements fulfils the expected results and that no re-occurrence is detected.

As discussed above, DMAIC is mainly used to improve existing processes whereas Design For Six Sigma (DFSS) is used to create improvements which cannot be incorporated in the existing processes and to ensure that quality by design is used when designing new processes (Bicheno 2006). The DFSS approach is seen by many as necessary to fully achieve all the benefits of Six Sigma since this approach builds in quality already in the initial design (Snee 2004). The importance of quality by design is assessed to be crucial to fully obtain customer benefits in the pharmaceutical industry and the use of build in by design is therefore investigated in the interviews in this thesis.

There is another important component that largely differs Six Sigma from most other quality programs; its educational structure. To be able to use the tools efficiently it is important that the users have great knowledge about these tools and the methods to be used. Six Sigma therefore uses a structured educational program with Six Sigma leaders and specialists on several levels (Klefsjö and Bergman 2004). These levels have taken their names from Japanese martial arts which are illustrated with title as “black belt” and “green belts”. Six Sigma also creates specialized positions in the company instead of
putting additional tasks on already overloaded managers or employees (Gale 2003). The importance of training of the employees is seen as very critical and is believed to highly impact the success of Six Sigma implementation and the importance of training is therefore investigated in the interviews in this thesis.

1.3. Outline of the Thesis

The thesis has explored the following hypothesis:

**Hypothesis 1**: Six Sigma is a suitable strategic method for the pharmaceutical industry to enhance customer benefits.

**Hypothesis 2**: The pharmaceutical industry can use the experiences of other industries as a benchmark to formulate applications of Six Sigma.

**Hypothesis 3**: Pharmaceutical companies need to embrace Six Sigma in the entire organisation and not just manufacturing to realise the full potential of the method.

**Hypothesis 4**: Leadership and commitment is critical to the success of Six Sigma in the pharmaceutical industry.

**Hypothesis 5**: There is a difference in the application of Six Sigma in different companies

Chapter 2- Literature Review

This section is divided into the two subsections covering the main areas of this work; the implementation and use of Six Sigma in other industries as well as in the pharmaceutical industry and the customer benefits of Six Sigma. Each section explores which information is available to support or reject the hypothesis in question in this thesis.

2.1 Six Sigma- Implementation and Use

Liu (2005) discusses the fact that only a few pharmaceutical companies are listed among the more than 300 member companies of the International Society for Six Sigma Professionals (ISSSP).

This suggests that there are still much for the pharmaceutical industry to gain from Six Sigma and much to be learnt from other industries. However; there are many pharmaceutical companies that have implemented Six Sigma and are successfully using it to accomplish their corporate strategy. Examples of pharmaceutical companies that have implemented Six Sigma are Baxter, Eli Lilly, Johnson & Johnson and Novartis (Stückrath 2006).
To be able to successfully implement and use Six Sigma the available literature is in agreement that committed leaders and management and supporting infrastructure are important factors no matter what type of industry or market the company is acting in (Snee and Hoerl 2005). The problems that companies encounter and the factors that make a successful implementation possible are therefore not unique to any industry and it is important to recognize the similarities rather than only focusing on the differences to be able to learn from other industries and make the most of the available knowledge and experience (Sewing et al. 2008). The importance of commitment, good leadership and benchmarking is seen as very critical and is believed to highly impact the success of Six Sigma implementation.

The importance of these factors is now further explored below and they are also investigated in the interviews conducted in this thesis.

*Awareness of the natural resistance to change*

One barrier to a successful implementation of Six Sigma is the inbuilt natural resistance to change in people (Snee et al. 2005). According to Kotter et al. (1979), people’s inbuilt resistance to change depends on several things such as the fear of losing something good, lack of knowledge about the impact of the change and a mindset that the change is not in the best interest of the organisation. The best way to handle the resistance to change is increased communication, motivation and education (Antony et al. 2003). Antony et al. (2003) emphasises the importance of a continuous support from the top management since the lack of this will create doubt about the initiative for change and the energy that drives the change will weaken resulting in people starting to do things as before.

Communication is also crucial to success with the Six Sigma implementation. Stückrath (2006) discusses the involvement of the communication department as a critical success factor when implementing Six Sigma. This focus on communication ensures that all employees are aware of the Six Sigma activities even though not everyone is involved in the actual projects. This is further supported by O’Rourke (2005) who has come to the same conclusion from comparing several companies in different industries to see what factors that were involved in successful implementation in these companies. O’Rourke (2005) also recommends that the communication methods used are both formal and informal and that the source and control of the communication should be centralized to avoid misunderstandings and misinformation.

*Commitment of top management and leaders*

Snee (2004) states, that the most important element when implementing Six Sigma is the commitment of organization leaders, since they have the greatest opportunity to affect the outcome. O’Rourke (2005) describes three specific activities that need to be performed by the top management to facilitate the implementation.

1) Engagement and commitment from the start with a firm belief that this is the strategic effort that will address the needs of the business.
2) A long-term plan with performance goals that reflects the gains of the implementation.
3) Resource allocation ensuring that the right people get the responsibility and authority to drive the implementation.

The importance of the right competencies is further discussed by Johnson (2006). Adequate resources with formal training working with the Six Sigma projects as well as inclusion of Six Sigma competencies and knowledge in the overall goals for succession planning are elements that further ensure that the Six Sigma work remains effective and beneficial in the long run.

When Xerox implemented Six Sigma for example, the lessons learned showed that the businesses that had direct and visible support from the top leaders had a more successful implementation (O’Rourke 2005). Pande et al. (2000) defines the Six Sigma management as “proactive” including defining ambitious goals and reviewing them frequently, a focus on problem prevention and being open to new insights and better ways of doing things.

Another example of the importance of committed management is the implementation of Six Sigma at Sanofi-Aventis. The reason why the Six Sigma implementation was more successful than previous quality improvement systems at this pharmaceutical company was that the Six Sigma was implemented at the site with the highest involvement of all levels of management and employees (Stückrath 2006). Earlier initiatives had been imposed on the site by global corporate functions and the support and acceptance by middle management was then low.

To conclude, Nunnally and McConnley (2007), emphasise the importance of visibility and credibility of the committed leaders. Leaders must have the “follow me” approach to be able to guide the organisation in the right direction.

**Realizing the full potential of Six Sigma for your organisation**

To be able to optimize the benefits of Six Sigma it is important that the work in all areas of the organisation utilizes the mind set of Six Sigma (Snee et al. 2005). There is data indicating that there is significant benefits to gain by including the non-manufacturing activities since these activities are only about 70% efficient (Pande et al. 2000).

As General Electric continued to develop the Six Sigma system originally created at Motorola, they realized that the potential of Six Sigma was far greater than the current applications on their manufacturing processes (Snee 2004). Snee (2004) describes how Six Sigma could be applied to all type of processes including finance, administration and new product development and that this use of Six Sigma significantly reduces barriers between functions. This ensures that the root causes for variation or bottle necks are truly eliminated and not just moved along in the system. Pande et al. (2000) further supports the benefits of using Six Sigma in the entire organisation stating that the potential gains from the implementations are equally significant if not greater in the service and non-manufacturing organisations compared to the manufacturing activities.
In addition, it is important that the application of Six Sigma is adjusted to the needs of the specific organisation. Pande et al. (2000) states that “there are many Six Sigma Ways” and emphasises that following a fixed script will make sure that the implementation falls short. Unlike for example with an ISO9000 implementation, there are no formal Six Sigma standards or certifying institutions that guides the implementation (Studt 2002). The knowledge from the organisation must be used and it is impossible to “copy and paste” an implemented Six Sigma from another company, no matter how similar the processes or organization seems to be (Klefsjö and Bergman 2004). The use of knowledge within the organisation is very important from the Six Sigma perspective as well as other strategies and is therefore included in the interviews to get more information on the experience from the pharmaceutical industry.

Internal staff are fundamental to the success of Six Sigma. Pyzdek (2003) provides an overview of the skill and quality required of the staff employed to facilitate implantation and long term application of Six Sigma within an organisation. (See table 2 below for a detailed description)
### Table 2-Overview of Six Sigma Green, Black and Master Black Belt Qualifications


<table>
<thead>
<tr>
<th>Belt</th>
<th>Roles</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GREEN BELT</strong></td>
<td>Project leaders, Capable of forming and managing teams and projects from concept to completion</td>
<td>5 days formal classroom training that covers:-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Project management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Quality management tools</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Quality control tools</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Problem solving</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Descriptive data analysis</td>
</tr>
<tr>
<td><strong>BLACK BELT</strong></td>
<td>Individuals are technically oriented individuals</td>
<td>Candidates may come from a wide range of disciplines</td>
</tr>
<tr>
<td></td>
<td>Held in high regard by their peers</td>
<td>Do not need to be formally trained statisticians or analysts</td>
</tr>
<tr>
<td></td>
<td>Actively involved in the process of change and development</td>
<td>Expected to master a wide variety of technical tools quickly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>University level mathematics useful</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Training in statistical methods a plus or even a prerequisite</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Approximately 160 hours of classroom instruction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 on 1 project coaching from Master Black Belts or consultants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Must be computer literate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Proficient with one or more operating systems</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Spreadsheets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Database managers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Presentation programs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Word processors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Proficient in the use of one or more advanced statistical analysis software packages</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Black Belts help Green Belts define their projects prior to the training</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Attend training with their Green Belts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assist Green Belts with their projects after the training</td>
</tr>
<tr>
<td><strong>MASTER BLACK BELT</strong></td>
<td>Highest level of technical and organizational proficiency</td>
<td>Provide technical leadership of the Six Sigma program</td>
</tr>
<tr>
<td></td>
<td>Ability to assist Black Belts in applying the methods correctly in unusual situations, especially advanced statistical methods</td>
<td>Statistical training should be conducted only by qualified Master Black Belts or equivalently skilled consultants.</td>
</tr>
<tr>
<td></td>
<td>Ability to assist Black Belts in applying the methods correctly in unusual situations, especially advanced statistical methods</td>
<td>Must know everything the Black Belts knows</td>
</tr>
<tr>
<td></td>
<td>Ability to assist Black Belts in applying the methods correctly in unusual situations, especially advanced statistical methods</td>
<td>Must possess excellent communication and teaching skills</td>
</tr>
<tr>
<td></td>
<td>Ability to assist Black Belts in applying the methods correctly in unusual situations, especially advanced statistical methods</td>
<td>Plus additional skills</td>
</tr>
<tr>
<td></td>
<td>Ability to assist Black Belts in applying the methods correctly in unusual situations, especially advanced statistical methods</td>
<td>o Deep understanding of the mathematical theory</td>
</tr>
<tr>
<td></td>
<td>Ability to assist Black Belts in applying the methods correctly in unusual situations, especially advanced statistical methods</td>
<td>o A gift for project management</td>
</tr>
<tr>
<td></td>
<td>Ability to assist Black Belts in applying the methods correctly in unusual situations, especially advanced statistical methods</td>
<td>o Coaching skills to help Black Belts</td>
</tr>
<tr>
<td></td>
<td>Ability to assist Black Belts in applying the methods correctly in unusual situations, especially advanced statistical methods</td>
<td>o Program organization at the enterprise level</td>
</tr>
</tbody>
</table>
2.2 Six Sigma- Customer Benefits

In this thesis the main focus is to investigate how the customer of the pharmaceutical industry benefits from the implementation of Six Sigma. To be able to follow the results of implementation of changes and improvements, key performance indicators can be used (Cortada et al. 2004). Johnson (2006) also emphasizes the importance of choosing relevant metrics to track the impact of each Six Sigma project with regards to customer satisfaction. The following Key Performance Indicators are used to measure customer benefits in this thesis:

- Improved quality of product
- Price reduction
- Shorter delivery times to market
- Increased financial support to new development projects

As presented in the introduction above, many pharmaceutical companies are experiencing increased operational and financial pressure caused by several issues such as customer’s demand for more innovative products at better prices, expiring patents and insufficient drugs in pipeline (Cortada et al. 2004). Many of the core businesses and processes in pharmaceutical industries are therefore in great need of change to be better aligned with the changing economic climate. In addition, a survey presented by Lenzer (2004) shows that only 13% of the Americans believe that pharmaceutical companies are “generally honest and trustworthy”. This survey also indicates that the public confidence in drug companies has decreased faster than for any other industry.

Using Six Sigma in the pharmaceutical industry requires that extra care is taken when identifying the customer as the customer definition is wider in this industry compared to many others as also discussed above (Young et al. 2004).

So even though the pharmaceutical industry is highly regulated to ensure that the companies meet all the requirements from regulatory agencies, many core processes are not meeting the requirements of today’s market and their customers. Cortada et al. (2004) specifically provides the process of drug development as a prime example. The process to develop a drug actually takes longer time in the year 2004 than it did a decade earlier.

One potential solution to the business issue and challenge of high costs and long time lines for product development is the use of Six Sigma (Cortada et al. 2004). Companies implement Six Sigma for a number of reasons and some of the main targets when implementing Six Sigma in the R&D organization include decreased costs, decreased time to market and improving the process and product quality (Johnson 2006).

Six Sigma was initially mainly used in the manufacturing processes but the benefits for R&D processes are being highlighted more and more (Marti 2005). However, the innovative nature of the work in the R&D departments opens up for a lot of discussions regarding the appropriateness of the use of Six Sigma in this type of work. Carleysmith et al. (2009) illustrates that no real consensus is to be found in the literature as to whether Six Sigma supports the innovation and creativity needed in the R&D work to be able to develop new products or not. Lewi and Smith (2007) conclude that productive medical research needs teamwork and intellectual freedom and that
hierarchical report structures and decision making by committees are two factors that suffocate the innovative process. Conclusions strongly indicate that systems like Six Sigma should not be applied to these processes. Pyzdek (2003) states it even more clearly saying that Six Sigma should never be applied to research since it kills the creativity needed in the process.

Studt (2002) emphasises the importance of analyzing the organizational management structure and procedure to determine if Six Sigma designs will fulfil the requirements of the specific R&D working environment in question. As discussed earlier, this is a critical step to ensure that the suggested changes actually benefit the organisation. Carleysmith et al. (2009) describes the challenge with product development as managing to reduce the variation within a process while still preserving the creativity. Sewing et al. (2008) furthermore suggests that by using Six Sigma approaches on the repeatable parts of the R&D organisations activities, more time will be available for experiments and innovation which in the end increases the creativity. Johnson (2006) is for the same reasons as Sewing et al. (2008) convinced that Six Sigma and its tools will ensure that R&D generates superior products which increase profitability.

Carleysmith et al. (2009) describes the benefits of the implementation of Six Sigma tools in the R&D Pharmaceutical department of GlaxoSmithKline (GSK) which resulted in increased productivity by eliminating and decreasing time spent on repetitive tasks thereby reducing cycle times and a better knowledge exchange due to increased teamwork and common best practice procedures. Johnson (2006) presents additional cases of successful Six Sigma implementation in R&D departments further supporting these findings using examples of companies describing how the use of Six Sigma has increased the overall product quality and the productivity and also led to an increase of sales from new products.

Chapter 3- Research Findings

3. 1. Methodology Used
Yin (2003) states, that research design is the logic that links the data that should be collected to the initial questions of the study. Two of the most popular research concepts used are qualitative and quantitative studies. Creswell (1994) defines the qualitative study as an inquiry process which is based on building a complex picture formed from detail reports from informants. The data for this thesis is qualitative in nature, as the design best serves the research questions in this study.

The interviews were made according to a predetermined protocol that was presented in a questionnaire. The set of questions used to investigate the questions in the thesis was divided into 3 sections:
1. Company Background
2. Usage of Six Sigma
3. Key Performance Indicators
The questionnaire was sent out to the participant in preparations before the interviews. The questionnaire can be found in the appendix, (section 7). The interviews were made via telephone or face to face meetings depending on locations and availability of the participants.
3.2. Results Obtained

3.2.1 Company background

Aspen Medical Europe Limited
Aspen Medical Europe Limited (hereafter called Aspen Medical) has facilities in UK and US which produces single use medical devices. The facility included in this study is located in UK and they are manufacturing single use medical devices for ophthalmic and specialist wound care. The facility has 70 employees with two black belts and two green belts to date. The Six Sigma implementation started less than two years ago and the implementation is still ongoing. The black belts do not work fulltime with Six Sigma since they are in charge of many of their original tasks as well. Six Sigma work currently mainly involves projects, manufacturing processes, work with supplier and marketing. Both the black belts participated in the interview.

GE Healthcare/Life Science
GE Healthcare/Life science (hereafter called GE) currently has facilities in U.S., Canada, England, Germany and Sweden. The person interviewed for this study is working in Sweden where they are manufacturing separation and detection instruments and separation media. In the Life Science section there is a total of 6000 employees. The GE corporate group was together with Motorola were the companies that started with Six Sigma. At the Uppsala site the start of the Six Sigma implementation was commenced about 6 years ago. All areas were targeted during the implementation of Six Sigma since all areas could benefit from Six Sigma. The Six Sigma positions are fulltime to allow the people in these positions to focus on this work which according to the philosophy at GE is necessary to be able to bring about the change of mind set that is needed for the success of this type of strategy. However, Lean manufacturing is now the focus of the company and the conclusion at GE is that Lean and Six Sigma complements each other very well. The R&D work is still much focused on DFSS but the manufacturing and several support functions are currently mostly working with Lean manufacturing.

AMO Puerto Rico
AMO Puerto Rico (hereafter called AMO) has their facility in Puerto Rico in UK and US which produces Intra Ocular Lenses. The facility has 600 employees and is a pure manufacturing site with no R&D functions etc. Their overall goal is to achieve manufacturing processes which are constantly improving and are targeting the Six Sigma level in all their processes. Lean manufacturing is now the focus of the company and they have made an intensive implementation of the Lean strategy in all levels of the manufacturing staff.
### 3.2.2 Usage of Six Sigma

#### Table 3. Overview of the usage of Six Sigma

Results from the interviews with the Pharmaceutical companies included in the thesis

<table>
<thead>
<tr>
<th>Questions on Usage of Six Sigma</th>
<th>Aspen Medical</th>
<th>GE</th>
<th>AMO Puerto Rico</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of years Six Sigma have been used in your company</td>
<td>&lt; 2 years</td>
<td>&gt;4 years but &lt; 6 years</td>
<td>&gt;4 years but &lt; 6 years</td>
</tr>
<tr>
<td>Is Six Sigma implemented throughout the entire organisation?</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Please indicate the business areas that utilize Six Sigma</td>
<td>• R&amp;D /project based sales and marketing • Manufacturing • Quality Assurance/Regulatory Affairs</td>
<td>• R&amp;D /project based sales and marketing • Manufacturing • Administration • Human resources</td>
<td>• Manufacturing</td>
</tr>
<tr>
<td>How were the business areas that utilize Six Sigma chosen?</td>
<td>• Projects • Process improvements • Commercial - Risk to business • Manufacturing costs • Raw material costs</td>
<td>All areas were targeted during the implementation of Six Sigma since all areas can benefit from Six Sigma.</td>
<td>The site is a manufacturing site but the logistic departments are not included in the continuous improvement work for example</td>
</tr>
<tr>
<td>Did the organization use information from other companies with Six Sigma before the implementation?</td>
<td>From a manufacturing standpoint to understand process capabilities and from a Quality Assurance/Quality Control standpoint to understand sampling plans for process inspection but no general benchmarking was performed.</td>
<td>GE was together with Motorola the companies that started with Six Sigma.</td>
<td>During the initial implementation information from other companies were used but the focus was quickly turned into Lean and this implementation was guided by an external company.</td>
</tr>
<tr>
<td>Did any of the Six Sigma facilitators have any Six Sigma experience from other industries?</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Does the organisation view Six Sigma as a business strategy?</td>
<td>YES</td>
<td>YES</td>
<td>NO, but Lean is now seen as a business strategy</td>
</tr>
<tr>
<td>Does the organisation use Six Sigma as a tool to fulfil the vision of the company?</td>
<td>YES</td>
<td>YES</td>
<td>NO, but Lean is now seen as it</td>
</tr>
<tr>
<td>Is Six Sigma driven by Senior Management?</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Is every level of Management accountable for the success of Six Sigma?</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Suggest the level of importance placed upon activities involved in Six Sigma commitment within your organization:</td>
<td>• Staff understand the Six Sigma concept • Staff receive Six Sigma training • Staff have the necessary Six Sigma support • Staff have the necessary resources for Six Sigma • Management has the right level of competency in Six Sigma • Management take great interest in the Six Sigma work</td>
<td>• Medium importance • Medium importance • Medium importance • Medium importance • Medium importance</td>
<td>• Medium importance • High importance • High importance • High importance • High importance</td>
</tr>
</tbody>
</table>
### 3.2.3 Key Performance Indicators

#### Table 4. Overview of the impact on Key Performance indicators

Results from the interviews with the Pharmaceutical companies included in the thesis

<table>
<thead>
<tr>
<th>Key performance indicators</th>
<th>Aspen Medical</th>
<th>GE</th>
<th>AMO Puerto Rico</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assessment of impact on quality of product</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has Six Sigma improved the overall quality of product/ products?</td>
<td>• Moderate impact</td>
<td>• Exceptionally</td>
<td>• Exceptionally</td>
</tr>
<tr>
<td>Has Six Sigma improved the way the overall quality of products is measured?</td>
<td>• Moderate impact</td>
<td>• Exceptionally</td>
<td>• Exceptionally</td>
</tr>
<tr>
<td>Has Six Sigma provided a long term change from the old practices affecting product quality?</td>
<td>• Moderate impact</td>
<td>• Exceptionally</td>
<td>• Exceptionally</td>
</tr>
<tr>
<td>How large impact do you think Six Sigma will have on the overall quality of products in the future?</td>
<td>• Great impact</td>
<td>• Exceptionally</td>
<td>Lean is now the main focus.</td>
</tr>
<tr>
<td><strong>Assessment of impact on price of product</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has Six Sigma influenced the pricing of product/ products?</td>
<td>• Moderate impact</td>
<td>No specific information available on the impact on price questions. Reduction of rejects leads to decreased costs but no correlation to decreases in price for the end customer that the interviewed person is aware of.</td>
<td>No correlation to price reductions that the interviewed people are aware of but the Lean implementation has caused a decrease in final price.</td>
</tr>
<tr>
<td>Has Six Sigma influenced how the pricing of product/ products is measured?</td>
<td>• Moderate impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has Six Sigma provided a long term change from the old practices affecting pricing of product/ products?</td>
<td>• Very little</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How large impact do you think Six Sigma will have on the pricing of products in the future?</td>
<td>• Moderate impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assessment of impact on times to get new product market</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has Six Sigma improved the overall delivery times to markets?</td>
<td>• Great impact</td>
<td>No specific information available on the impact on time to get new product to market. The use of DFSS gives a longer time period initially but saves a lot of time in the end so the time should be possible to reduce by using the DFSS according to the interview.</td>
<td>The AMO Puerto Rico company does not develop new product themselves. New products are tech transferred to AMO Puerto Rico. The duration of the tech transfer has been shortened with the implementation of Lean.</td>
</tr>
<tr>
<td>Has Six Sigma influenced how the overall delivery times to markets are measured?</td>
<td>• Great impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has Six Sigma provided a long term change from the old practices affecting the delivery time to market?</td>
<td>• Great impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How large impact do you think Six Sigma will have on the delivery time to market in the future?</td>
<td>• Exceptionally</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assessment of impact on financial support for new development projects</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has Six Sigma been able to lead to new development projects?</td>
<td>• Great impact</td>
<td>No specific information available on the impact on financial support for new develop projects. The higher focus on prioritising included in this strategy leads to that the focus is spent on the right projects and the others are parked or rejected. This increased focus gives a better support to the projects chosen according to the interviewed person.</td>
<td>The AMO Puerto Rico company does not develop new product themselves. New products are tech transferred to AMO Puerto Rico.</td>
</tr>
<tr>
<td>Has Six Sigma been able to lead to increased funding of new or ongoing development projects?</td>
<td>• Great impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has Six Sigma provided a long term change from the old practices affecting the financial support of new development projects</td>
<td>• Great impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How large impact do you think Six Sigma will have on the possibilities for increased funding of new or ongoing development projects in the future?</td>
<td>• Exceptionally</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.3. Discussion of results

3.3.1 The importance of leadership and commitment for the success of Six Sigma in the pharmaceutical industry

The interviews strongly suggest that leadership and support from management is critical to the successful implementation of Six Sigma in the pharmaceutical industry as well as in any other industry. What leadership actually is however needs to be discussed to fully understand its impact on Six Sigma. DuBrin (2007 p.2) suggests leadership is “the ability to inspire confidence and support of staff within an organisation which is needed to achieve organizational goals”.

Apple Inc. highlights just how important having the right leadership is to the success of an organisation. For a number of years, its success has been closely tied to its CEO, Steve Jobs. After well documented health problems in recent years, Jobs recently announced a break from the position due to continued ill health. As Jobs has been so instrumental to the success of Apple, this news has been received with great intrepidation by analysts worried about the future of Apple (Times Online 2009).

For most organisations the implementation of Six Sigma represents a break from traditional work practices. Introducing a business strategy that is statistical in nature, which required intensive analysis and examination may be vastly different from how companies may have been functioning for many years. For any organizational change to be entirely effective, managers of companies must be skilled and display strong leadership qualities. They must be able to recognize the emotional aspect for change and deal with this directly and openly (Dubrin 2007). As discussed by Aspen Medical Europe, having leaders that are committed to Six Sigma is crucial but they also need to have the knowledge to be able to fully support the long-lasting implementation and effects of Six Sigma. This lack of knowledge slows down the changing process in the organization which inhibits the full potential of Six Sigma.

Many people are afraid of changes if that comes with a risk of losing their job which sometimes come with change within an organization, especially if the changes includes process improvements and making the work more efficient. Suspicions are raised by change and leadership needs to build trust between affected staff /departments (Dubrin 2007). Moreover, moving from old practices to a more open and team based organization demanded by Six Sigma may mean that some within an organisation feel uncomfortable and become critical of changes. Any dislocation of an old practice will be met by organizational and personal resistance. Another key factor that became visible during the interviews was the need for dedicated Six Sigma staff. In GE Healthcare the Black Belts and Master Black belts are full time employees only working with the implementation of Six Sigma and Six Sigma projects. At Aspen Medical Europe the two Black Belts are only partly working with Six Sigma which makes it hard to prioritize the work in the organisation. At AMO the implementation of Lean has been revolutionary since the management has used external expertise to ensure that not only the knowledge about the change is properly spread but that the best way to implement major changes is also utilized. By taking this seriously they have created a site where all levels of staff have the understanding and feel proud of how they have changed their work.

Leadership can also be viewed as a relationship between the managers of an organisation and its group members/ staff that make up the organisation. Control does not solely rely
with the individuals tasked with leadership rather the partnership ship relies on shared decision making (Dubrin 2007). Leaders need to work hard on developing a partnership, emphasizing teamwork and a more open atmosphere among managers and employees if the implementation of Six Sigma is to succeed. By creating a positive and open attitude within an organisation, leaders are perhaps able to win people’s trust and get them on their side when implementing changes.

Dubrin (2007) suggests a number of ways leaders can directly influence change. To begin with, staff within the organisation has to be made aware. Getting the organisation aware of Six Sigma needs to be implemented from the top management to be effective. Leaders have to make sure staff are completely aware of the process, the requirements, the expectations and how the organisation will seek to achieve the required operational goals (Dubrin 2007).

Leadership is about helping people within an organisation look beyond self interest and look at the larger perspective of how the organisation benefits. While individuals in a company are undoubtedly used to changes, perhaps the scale has been smaller then what is expected by Six Sigma. Leadership is about educating those about the need for change. As shown by the companies included in this thesis, education also needs to include management if they are to be able to initiate complete involvement. In a competitive environment, companies need to be able to adapt to changing business conditions. A company implementing Six Sigma will not have an infinite budget or timelines to reach operational goals. Creating urgency is another way for leaders to enable change is within an organisation.

3.3.2 Lack of leadership and commitment creating a strategy to performance gap

Critical to the successful execution of any strategy that is implemented is monitoring of actual versus planned performance. Mankins and Steele (2005) suggests that a reason why many companies fail to realize their strategies full potential is poor financial forecasting preceding any strategic plan implementation.

Moreover, Mankins and Steele (2005) suggests that after strategy approval, strategies are often poorly communicated which leads to unsatisfactory resource planning and allocation. Generally lower levels within an organisation suffer the most when strategy is not clear to them. The interviews strongly suggest that making the entire organisation aware of the Six Sigma strategies are crucial for a obtaining the long-term benefits of Six Sigma. Worse still, our investigations found that at one of the companies contacted, senior management was unable to fully grasp the concept in its entirety and thus Six Sigma was floundering.

In this instance the senior management themselves lack understanding and will, perhaps unknowingly, have dramatic effect on the success of Six Sigma as they influence lower levels of the organisation. When lower level staff sees inadequate understanding at the most senior level, complacency may set in inside the organisation as staff realizes that Six Sigma is likely to fail. Worse still, is that any failure may potentially foster an internal culture of under-performance, because when an unrealized plan is experienced, future expectations are perhaps being based on previous experience of this failure (Mankins and Steele 2005).
This is however not too much of a surprise, as Mankins and Steele (2005) suggests that despite the huge financial and time commitments many companies allocate to the introduction of new strategy often they produce little in return. Mankins research suggests that only approximately 63% of companies are able to deliver on strategy performance. Where strategy goes wrong can be attributed to a number of factors inside an organisation (Mankins and Steele 2005). Please see Figure 4 below that outlines numerous reason why strategy goes astray in an organisation.

Figure 4  Where Performance Goes

Considering the fundamental change in thinking and work practices required by the introduction of Six Sigma, this may possibly account for a loss of productivity and perhaps impact a company’s financial position. Both of which are undesirable if an organisation is to remain competitive.

In view of poor senior management support, the company has essentially two options to explore.

1. Refocus attention of senior management level to required knowledge and commitment.
2. Consider investigating a new strategy. The questions remain if the first option is considered, who will initiate senior management push to embrace Six Sigma more readily.
There are however numerous examples of companies that have successfully managed to close the strategy to performance gap (Mankins and Steele 2005). Noteworthy are companies such as Barclays, Dow Chemicals and Cisco Systems that employ similar processes that require much disciplined planning and execution as part of their performance. The reward for companies who have previously failed in their endeavor to reduce the strategy- to- performance gap is in the region of 60 -100% increase in value to the strategy (Mankins and Steele 2005).

3.3.3 Using the experiences from other industries by benchmark analysis to maximize the benefits throughout the organisation

The interviews show that the pharmaceutical industry has used the experiences of other industries as a benchmark to formulate the applications of Six Sigma in their own industry with good results. In addition the interviews all give clear indications that Lean is currently being implemented in many organisations that have previously used only Six Sigma.

This finding is further supported by Carleysmith et al. (2009). Carleysmith et al. (2009 p. 96) states that Lean thinking and Six Sigma are “now frequently used in combination”. While both Lean and Six Sigma are business process improvements, individually they have different approaches to meet their goals. As companies seek to transform operations and enhance quality, many are turning to these management approaches both of which have proven effective in other industries (Danese and Constantinou 2008). One of the reasons for the turning into Lean / Sigma focus that GE Healthcare mentions as a key factor is the financial situation and the need for releasing capital from warehouse etc. These arguments are further supported by AMO. At GE Healthcare the R&D department is still very focused on DFSS and the manufacturing and sales and marketing area is mostly focused on Lean. AMO however has no R&D functions or similar which could be another reason that the Six Sigma strategy was rather quickly discontinued in favour of the Lean initiative. This division is further discussed below.

One difference between Lean and Six Sigma is that in Lean a solution is sought to a problem that is perhaps more easily identified after investigation. Lean thinking is centred on adding value for the customer, reducing waste and development time to ensure the smooth flow of work (Bicheno 2000). Whereas, Six Sigma, the focus is on minimizing variation in both product and process, with the aim to reduce product defects (Danese and Constantinou 2008). Six Sigma is more suitable when the root cause of the problem is perhaps unknown and a solution is sought only when the problem has been identified.

Lean business improvement started with (TPS) Toyota Production System in the early 19 hundreds. Lean originated as a way to solve practical internal problems and meet the needs of Toyota, evolving from trial and error. The system brought systematic improvements over time as the people involved had great autonomy in changing how things were done (Toyota Motor Corporation 2003).

The Lean system relied on a pulling function whereby as products were pulled by customers, they were replenished immediately. Toyota discovered that with reduced lead times and focusing on keeping flexible production, they had greatly improved quality,
responsiveness and productivity. Moreover space was better managed and equipped. (Arthur 2007) The pull system is designed with the intent of only producing what is required when it is needed. By doing so, it automatically reduces product stagnation and creates a flow of work (Sakai et al. 2007). Increased cooperation between departments has been seen at Fujitsu Corporation after the implementation of a Toyota Production System type of workflow process (Sakai et al. 2007).

Over periods of time, many companies’ processes unknowingly become inefficient and ineffective (Arthur 2007). Moreover, added complexities to processes increase time and cost requirements and leads to less and less being achieved. Arthur (2007) provides numerical values about how inefficient companies can be. He suggests processes within companies can remain idle up to 95% of the time. There are delays between process steps, delays caused by waste and reworking the same steps over and over. Lean is therefore essential if companies seek to increase the speed and relationship between the steps in a process, and seek to eliminate all non value adding factors that cause delays (Arthur 2007).

The fundamental goal of Lean is the elimination of any delays between process steps and the lining up these processes so that the product or service, throughout the entire chain, to ensure that there will be virtually none, or as limited as possible, interruption to the process. A number of different acronyms can be used to outline the Lean approach. Regardless of the acronym chosen, the methods and tools employed by Lean are designed as a means to seek the same goal, to improve quality and profitability (Arthur 2007).

The improvement steps cited by Arthur (2007) are called FISH (Focus, Improve, Sustain, and Honour).

- **Focus** - Focus any improvement efforts on critical business process and delays
- **Improve** - Reduce non-values added (NVA) delay, waste and reworking
- **Sustain** - Stabilize and monitor improvement
- **Honour** - Recognize, reward and refocus efforts

To strengthen a business position, to fend off increasing competition and to seek continual improvement is essential in all businesses. This is also the reason GE Healthcare gives for their new focus on Lean compared to Six Sigma. Arthur (2007) suggests the principle of Lean is quite simple and can be applied to manufacturing, service, R&D and administration. Regardless of which stream of business, the customer however remains the key focus. Many organizations still use Six Sigma for R&D even though Lean is the major focus in the rest of the organisation. This is the case at GE Healthcare and at Astra Zeneca.

A strategy such as Lean exemplify what Best (2009) suggests is ideal. Having a strong customer focus, leads to higher levels of customer satisfaction and loyalty. Both of which are factors that drive profitability. Moreover, customer focused businesses will consistently out perform competitors and have greater long term survival. At GE Healthcare the customer focus is very clear in Lean whereas in Six Sigma robust processes and decreased cost were the major focus.

However, Lean and / or Sigma are no wonder solutions to all organisations. Neither is Lean and Six Sigma combined a solution for everything inside an organisation. The implementation of one or both does not necessarily improve staff moral, supplier and
customer’s attitudes and needs, competitor’s positions or leadership issues. Lean and Six Sigma are tools to improve morale and leadership, to improve relationships or to make choices about suppliers and overall better serve existing and new customers (Arthur 2007).

The value of introducing Lean and Six Sigma as a business process improvement is supported widely by vast amounts of literature experience and information about the subject. Google search engine produced 6,340,000 hits alone supporting this statement. When however examining the impact in the area of R&D, there is no clear consensus to whether or not Lean methods diminish or support the innovation process and creativity (Carleysmith et al. 2009). The indications from this research further supports this since both Astra Zeneca and GE Healthcare uses Six Sigma in the R&D work even though the majority of the rest of organisation is Lean focused.

What is however clearly identified is that if a combination of Lean and Six Sigma is to be successful after it’s implementation, there required very high levels of commitment at an operational level. Moreover aggressive promotion internally is required, unbridled management support coupled with widespread training and understanding (Carleysmith et al. 2009). An IMB corporation report in 2007 compliments the above mentioned and indicates that any Lean initiatives must involve a period of intense training plus dedicated resources as a means to kick start the business improvement process. GE Healthcare provides excellent examples of the importance of committed leaders and their Lean leaders are dedicated to this role the same way as their Black Belts used to be when Six Sigma was the major focus of the organisation.

Over time, the report suggests that once the implementation became routine these processes contributed to continuous improvement and innovation. The report goes on to suggest another critical element of Lean and R&D innovation. Mimicking the needs of Six Sigma, Lean is only successful when leaders take active, enthusiastic roles in significant organizational change and not just introduce another business initiative. (IBM Report 2007).

3.3.4 The impact of Six Sigma on customer benefits in the pharmaceutical industry.

The purpose of Six Sigma has been clearly defined throughout this thesis. That is, Six Sigma is a strategy to increase customers’ satisfaction and reduce operational costs. While it is not a statistical tool, Six Sigma relies on statistical data to introduce measurable and significant change within an organisation so that the systems and processes are operating to the absolute highest possible, or near perfect levels.

The companies interviewed in this thesis all had experience and understood the Six Sigma strategy, yet it was difficult to make any clear conclusions regarding if their customers would benefit directly from them having implemented Six Sigma.

Evaluation of cost benefits for the customer

To begin, let us look at Aspen Medical, a company who themselves suggests that they are just in the beginning of Six Sigma implementation even thought the organisation implemented Six Sigma approaching 2 years ago. Aspen suggests customer satisfaction
is not the primary goal of the Six Sigma implementation at their company. Rather the company sees the benefits of Six Sigma related to process improvement, commercialization (evaluation of risk) and a means to examine and perhaps reduce manufacturing costs. In regards to overall pricing of their company’s products, Aspen suggested that Six Sigma would have little to moderate impact and the company held the view that even in the longer term, they did not expect great impact on the price of their products. Price reduction of products was not mentioned at all. While Six Sigma is not used throughout the organisation the manufacturing department within the company was dedicated to the successful implementation to Six Sigma. The department viewed Six Sigma as a very useful means to improve operational efficiency, with the view of becoming more competitive and to be able to determine more optimal solutions internally and with external suppliers.

Moreover, GE actually suggested while that in no way did the customer receive any benefit in regarding to the pricing of their products. This is quite ironic perhaps, as if companies are able to produce a product more cheaply then a competitor, and able to pass on these savings to customers, then they are likely to increase the volume they sell as they increase market share at the expense of their competitors. Yet, the feedback from the questionnaire suggested this is unlikely to happen and customers will not see any cost reduction initiated by themselves.

So, even with potential cost savings at the manufacturing level and other departmental levels as a result of the continued usage of Six Sigma, both companies held the belief that costs of products would not be affected. Right now, the customer is not as important to Aspen as analysis and determining root causes of problems as a means to develop metrics and internal standard operational procedures to guide them forward. Perhaps in the long term, with longer-term experience and with increased senior management understanding at Aspen the customer may see more straight forward cost benefits, but as of today, this does not seem likely.

Aspen compared to GE Life science is a very small company in comparison, with very little experience yet the results of the questionnaire suggest results that are very similar. Six Sigma has been implemented at GE Life Science throughout the entire organisation. With substantially greater history and experience, over 6 years and with numerous Black Belts dedicated to Six Sigma the company is absolutely dedicated to Six Sigma. Overall quality of all products produced by the company, how quality is measured and long term quality are of the highest priority.

While ensuring the highest quality of products first time will perhaps reduce timelines, no correlations to reduced prices of products intended for their customers can be seen from this data. At first, this may sound surprising, that reduced timelines, better quality products for the same input does not lead to customers receiving some direct cost benefit. This statement coming from a company that has an extremely brilliant track record of Six Sigma and has produced wonderful cost savings of a long period of time. Yet, this is their position and some more discussions on drug discovery are probably needed to explain why they would not pass on the operational savings straight to the customers.

As mentioned with drug discovery, there are frequently failures during the developmental stages of a products lifecycle and only approximately 20% of the drugs in developmental stages are likely to survive the research steps that include the Pre-clinical and Phases I-III of the strict regulatory process (Charalambous and Gittins 2005). Moreover, the
frequency of failures appears to be increasing, with less and less drugs progressing to become products available to the patient population with proven safety and efficiency.

A Congress of the United States Congressional Budget Office (CBO) Report (2006) suggests that from the 1970s until the 1990s, the number of new molecular entities (NME) given approval by the FDA showed increases year on year. The CBO Report 2006 goes on to indicate that this trend continue until the mid 1990, when the FDA saw a rapid drop in approvals of NME even though spending continued unabated. In 2006, the FDA saw only 29 NME approved, compared with approximately 53 NME about 10 years ago (Gassmann et al. 2008). The CBO Report (2006) also suggests that the increase of R&D expenditure has been particularly high compared with industries requiring significant R&D undertakings such as in communication and computing.

Moreover the cost of conducting research has shown to be rising significantly since the mid 1970 (Gassmann et al. 2008). The research and development process has very long time frames due to the highly regulated nature of the industry. As mentioned during the introduction, it is not unusual for discovery to a marketable product to take in the region of 15 years. If both trends continue, rising costs of R&D and increased failures, companies will need to spend an even larger proportion of their earning on R&D. Gassmann et al. (2008) suggests the relative contribution of the cost of development a drug is in the region of 20-40% of the total cost (see table 4). With an estimated cost to development a new drug at approximately $1.5 Billion (Gassmann et al. 2008), R&D expenditure is a significant figure.

<table>
<thead>
<tr>
<th>Relative Contribution</th>
<th>Cost factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-40%</td>
<td>Research, Development, Licenses</td>
</tr>
<tr>
<td>15-30%</td>
<td>Production</td>
</tr>
<tr>
<td>5-15%</td>
<td>Technical and Administration Costs</td>
</tr>
<tr>
<td>20-30%</td>
<td>Marketing and Distribution</td>
</tr>
<tr>
<td>20-35%</td>
<td>Margin</td>
</tr>
</tbody>
</table>

Table 5: Average cost structure of newly developed drugs
Source: Gassmann Et al (2008, p2)

Further increases will negatively affect the company’s bottom line. Companies are obviously aware of this fact and are therefore perhaps less inclined to pass on cost savings to customers and the customer benefit will then instead be more new drugs available on the market. The demand for pharmaceutical products comes from consumers who are generally insulated from the full cost of medicine by governments and health insurers. Patents protect companies from competing, thus demand for medicine is quite insensitive to the price. Therefore branded drugs are able to be sold at prices well above the open market value, and at prices vastly higher then the cost of production (CBO Report 2006). Instead, they are seeking to sell their products at the maximum price and still be able to negotiate with governments and health insurers.

The benefits to patients / consumers of pharmaceutical products are limited in a sense. Due to the highly regulated industry requirements, competition and rivalry between
companies and financial obligation to shareholders, companies appear to maximize their profits at every point in the development process as patents that once protected them and offered a time limited monopoly, will invariably expire and generic versions of the same product are made available to consumers. The impact of generic medicine is devastating to the revenue of most companies and will take money away from other research and development opportunities. How consumers may benefit is by having drugs available more quickly, given that time to market may be decreased due to process improvement by Six Sigma. The consumer/customers will benefit with access to drugs that may be potentially life saving or capable of providing systems relief and in turn an extended life period or higher standards of health.

As a contradiction to the discussion above is that AMO’s implementation of Lean has actually lead to price reductions for the final customers. The price reduction however was a necessity to be able to compete on the market and the Lean implementation caused cost savings in the actual manufacturing made these price reductions possible with out decreasing the profit. Since no development work is performed at AMO the Lean implementation has had no impact on the actual development work on the products.

**Evaluation of quality benefits for the customer**

Overall Aspen Medical believed that the quality of their products were likely to improve in the long term, however they did not expect Six Sigma to have great impact on the quality in the short term. The increase in quality will definitely benefit the customer so this indicates that Six Sigma in the long run provide customer benefits with regards to improved quality. This was also the main goal for Pfizer’s implementation of Six Sigma. Their focus was to ensure that a customer should never get a faulty product and to ensure this the processes should get it “right first time”. AMO has been able to increase the quality from 80-85% to 92-93% by their Lean implementation in the entire manufacturing process.

The importance of quality by design and control of development processes can be shown by the drug Vioxx. Vioxx, a drug produced by Merck is a case that clearly shows the importance of quality and function of drugs and the problems with uncontrolled drug developmental processes. Vioxx was introduced as a drug to treat a common rheumatic condition called rheumatoid arthritis (RA) and acute pain conditions. RA is characterized by pain caused by swelling and damage to cartilage and bone. As the disease worsens it can become very debilitating and will affect an individual’s ability to function normally. National Rheumatoid Arthritis Society Website describes RA is a “chronic, progressive and disabling auto-immune disease affecting 0.8% of the UK adult population.” In the EU alone, it is suggested that over 100 million people have a form of arthritis with more people suffering from any other chronic medical condition (Arthritis Factsheet 2007).

The normal method of treatment was using non-steroidal anti-inflammatory drugs, which were widely available and effective at offering pain relief. However these drugs caused or were known to cause irritation and damage to the linings of the stomach. Severe cases are known to led to ulcers and bleeding at the site of these ulcers. Vioxx of the other hand was marketed as a substitute for traditional treatment, particularly with its ability to lower the risk of gastrointestinal bleeding (Canadian Medical Association Journal, 2005).
Problems arose, first in 2002, when a study showed that this drug possibly increased the risk for heart attacks (Maleske 2008). In 2004 however, Merck problems were compounded when, ironically one of its own studies, seemed to confirm this position (Maleske 2008). The results were very damaging to Merck, CMAJ (2005) suggests Merck's market value dropped US$28 billion almost immediately and started a landslide of thousands of law suits against the company.

CMAJ (2005) suggests that there was no real need to fast-track approval of Vioxx. Moreover the regulators did not consider that initial findings would perhaps be magnified once the drug came into usage in the wider population. The use of quality by design and the Six Sigma DMAIC cycle could have provided the tools to avoid this type of event. Patients in practice are sometimes older and sicker then those used during the clinical trial stage, and as a result benefit and risk rates are very likely to change which needs to be taken into account when designing the studies (CMAJ 2005).

From the quality perspective one could argue that is there is already such intense oversight of the industry and that the case described above is an isolated event and that the quality of medicine has an extremely high standard. Still the information on the FDA web page (www.fda.gov) shows a large number of recalls, adverse events and warnings related to current approved products indicating that there is a need for a more robust quality approach in the pharmaceutical industry looking to build in quality from the start instead of ensuring it by inspection in the end.

**Evaluation of access to new product benefits for the customer**

Another benefit to customers, albeit indirectly is that all the companies interviewed suggests that Six Sigma is viewed as a means to support new projects. Given this, companies may be able to support new projects that eventually become fruitful; and consumers will benefit from new treatment options. In addition as discussed in several sections earlier the use of Six Sigma when designing products have the potential to shorten the time of the development process indicating that it can be possible to shorten the product development process without risking the quality of the product making it possible to get new products approved earlier.
Chapter 4- Recommendations and Conclusions

Hypothesis 1: Six Sigma is a suitable strategic method for the pharmaceutical industry to enhance customer benefits.

Conclusion: The results from all three companies shows that the Six Sigma implementation has the potential to enhance customer benefits with regards to increased quality and in some cases also by shortening time to market for new products. The interviews also indicates that price reductions for the end users are not the focus of the Six Sigma implementation and due to the market conditions in the pharmaceutical business this is not likely to be the focus in the future either. However; AMO shows that improvements processes have the capability to benefit the customer with regards to price reduction as well.

Recommendation: This research has shown a large interest in the combination of Six Sigma and Lean to further enhance the customer benefits. This combination has many benefits which have been indicated in these interviews and which are further supported in the available literature. It is important to remember that changes and implementation of new improvement strategies as with any strategies are timely and takes great effort. The individual company must therefore assess the cost and benefits for expanding the Six Sigma strategy before making this type of large change. The companies were all well aware of the problem with declining interest in new initiatives and depending on the maturity of the Six Sigma implementation, the company size and processes. The effort might be best spent trying to build in the Six Sigma focus in the entire organisation instead of trying to expand it.

Hypothesis 2: The Pharmaceutical industry can use the experiences of other industries as a benchmark to formulate applications of Six Sigma.

Conclusion: The interviews clearly show that experiences from other industries were used as a benchmark during the formulation of their Six Sigma strategies. A lot of material is available regarding common pitfalls and tools to use to enhance the performance of the strategy and all companies seem to have used this information before and during implementation. Several of the people participating in the interview also had experiences of Six Sigma from other companies and that knowledge was one main factor for their involvement in the implementation work.

Recommendation: Benchmarking is very important to be able to get the right understanding of the Six Sigma strategy itself and also the best ways of making sure the implementation is successful. It is equally important that the needs of the individual company are being investigated thoroughly to be able to tailor-make the strategy to the company’s needs. A pure “copy and paste” of a very successful implementation of a Six Sigma in a different company will be unsuccessful since each business is unique. There are therefore no shortcuts to a successful implementation of Six Sigma in any business.
or company and the implementation requires a full-hearted support from within the organisation.

**Hypothesis 3: Pharmaceutical companies need to embrace Six Sigma in the entire organisation and not just manufacturing to realise the full potential of the method.**

**Conclusion:** The literature review indicated that significant benefits from Six Sigma are excluded if manufacturing is the only target for the implementation of Six Sigma. This was further supported by the interviews which showed that these companies thought that in addition to the manufacturing the R&D processes as well as for example the regulatory affairs departments had benefited largely from the Six Sigma implementation. GE Life Science manufacturing were now mainly focusing on Lean whereas R&D worked exclusively with Design For Six Sigma. These results all clearly indicate that all processes within a company can be improved and made more efficient. Companies that use this overall approach have better opportunities to benefit greatly from the Six Sigma implementation.

**Recommendation:** When starting implementation of Six Sigma the entire organisation needs to be evaluated to see where to start the implementation work. During this process it is important to be open-minded and think out of the box to ensure that an area with great potential is chosen to start with. The initial successful implementation work will send out a message (to all the company staff) and facilitate future work.

**Hypothesis 4: Leadership and commitment is critical to the success of Six Sigma in the pharmaceutical industry.**

**Conclusion:** The conclusion from the literature and the interviews is unanimous; Commitment from leadership is critical for the success of Six Sigma in the pharmaceutical industry (as well as any other industry). For example in Aspen Medical a major difficulty was that even though their management were very supportive and committed to the Six Sigma implementation, they did not have the adequate knowledge to fully support it. This sent out mixed signals into the organisation regarding how and for what Six Sigma could and should be used to best put it to use. GE Life science also states that their successful implementation was due to awareness and understanding from the management on the importance of commitment at all levels in the organisation. It is clear; without a commitment and understanding at the management level, the Six Sigma implementation and use will face major problems and obstacles.

**Recommendation:** All management positions should participate in Six Sigma training to ensure that they have an understanding of the foundation that Six Sigma is built on. This understanding will then ensure that the right message is sent out within the organisation. Management also needs to be aware that a Six Sigma implementation requires resources, time and maybe larger investment to work. Changes in company culture takes time so a continuous effort is needed. It is also highly recommended that the staff working with Six Sigma are given time and resources to be able to perform the work. If possible at least one or a few dedicated positions will increase the focus and ensure that the implementation is being integrated into all the practices and processes of the company.
Hypothesis 5: There is a difference in the application of Six Sigma in different companies

**Conclusion:** All companies are unique and as discussed previously it is important to customize the Six Sigma strategy to the needs of the individual companies. However, one does not need to invent the wheel over and over again. The interviews show many similarities between the companies but also a handful of differences. The differences are both due to the size and the organisation of the company but also to some extent due to the people who has worked with the implementation and the overall focus of the companies. At Aspen Medical for example, one of their two Black Belts works in Regulatory Affairs. They have therefore naturally had a lot of focus on these processes with great success. Looking into the available literature, this is not the typical target process for Six Sigma and this is thereby a good example of the importance of the importance of unique applications of Six Sigma.

**Recommendation:** As per our recommendation for the hypothesis above, it is recommended that the individual business undertake extensive benchmarking to ensure that their design of Six Sigma is suitable for the needs of the business.
Chapter 5- Critical review of the value of the thesis work

Not much literature has been available comparing information from pharmaceutical companies on how Six Sigma has increased the benefits for their actual customer. The objective of this work was to provide useful information on the benefits for Six Sigma in the pharmaceutical industry in general as well as to be able to use the collected experience of the pharmaceutical companies included in this thesis to provide suggestions for improvements on the use and implementation of Six Sigma to further increase customer benefits. This thesis work has collected supporting data for many of the key concepts that are described for Six Sigma in other industries and has several suggestions for improvements in the use and implementation of Six Sigma. However, the analysis done is qualitative and the number of participating companies relatively low with only 1 or 2 people from each company interviewed. To make a full benchmarking of the Six Sigma use and benefits of Six Sigma in the pharmaceutical industry a larger study including more companies and more participants from each company would be needed.
Chapter 6- References

6.1 Articles


Charalambous, C. & Gittins, J. “Factors influencing the profitability of pharmaceutical research”, R&D Management 38, 2008, pp. 221-230

Carleysmith, SW., Dufton, AM. & Altria, KD. “Implementing Lean Sigma in pharmaceutical research and development: a review by practitioners”, R&D Management, 39/1 2009, pp. 95-106.


Gale, SF. “Building frameworks for Six Sigma Success- Case studies- quality management philosophy” Workforce, May 2003, pp.3-5.


**6.2 Books**


**Best, RJ. (2009)** Market-based Management: Strategies for growing Customer Value and profitability, Person International Publishing


**Chesbrough, HW. (2006)** Open Innovation: A new paradigm for understanding industrial innovation, Oxford University Press.

**Creswell JW. (1994)** Research Design: Qualitative and Quantitative Approaches, Sage Publications Inc.

**Debrin, A. (2007)** Leadership: research findings, practice and skills, Houghton Mifflin
Six Sigma strategy applied to Pharmaceutical industry - how customer benefit  MBA Thesis 2009


6.3 Reports On –line (World Wide Web):


Chapter 7- Appendix

7.1 Thesis Questionnaire

Introduction and Purpose:

We are two students at Blekinge Tekniska Högskola who are doing this Masters Thesis which is included in our MBA exams. We both have a background in the pharmaceutical industry and we look forward to get more information on the use and benefits of the Six Sigma strategy.

These interviews are the important input to the thesis work which investigates if the Six Sigma Strategy, by increasing the operational efficiency and improve quality while still facilitating compliance, benefits the customer in the pharmaceutical industry by reducing the cost, shortening the time to market and increasing the perceived quality of the final product.

We anticipate the preparations for this interview to take about 20 minutes. Your effort and time in preparing the responses to this interview is greatly appreciated.

The purpose of this benchmarking analysis is to investigate how Six Sigma has benefited the customer by improving the following Key Performance Indictors:

- Improved quality of product
- Price reduction
- Shorter delivery times to market
- Increased financial support for new development projects

Directions for preparation for the thesis interview:

This set of questions has been divided into 3 sections:

1- Company Background
2- Usage of Six Sigma
3- Key performance Indictors

Interview:

The interview will take about 60 minutes and will cover these questions. The interviews will be made via telephone or face to face meetings depending on locations and availability of the participants. Please contact Maria Jernelid +46 709 55 66 33 if you have any additional questions.
Section 1 – Company Background

Please provide a brief description of your company.

Company name:

Country/Countries:

Type of products:

Number of employees:

Business Unit’s Annual Sales:
Section 2 – Usage of Six Sigma

A. How many years have six sigma been used in your company?
   - < 2 years
   - >2 years but <=4 years
   - >4 years but <=6 years
   - >6 years but <=8 years
   - >8 years but <=10 years
   - >10 years

B. Is Six Sigma implemented throughout the entire organisation? Yes   No

Comment:

C. Please indicate the business areas that utilize Six Sigma.
   Cross all applicable areas and fill in additional ones on other below.
   - Research and development
   - Sales and marketing
   - Manufacturing
   - Administration
   - Human resources
   - Other, please specify_________

D. How was the areas listed in C above chosen?

E. Did the organization use the information from other companies with Six Sigma before starting the planning of the implementation?

G. Does any of the Six Sigma facilitators have any Six Sigma experience from other industries? Yes   No

Comment:

H. Does the organisation view Six Sigma as a business strategy? Yes   No

Comment:
I. Does the organisation use Six Sigma as a tool to fulfill the vision of the company? Yes
   No

Comment:

J. Is Six Sigma driven by Senior Management? Yes No

Comment:

K. Is every level of Management accountable for the success of Six Sigma? Yes No

Comment:

H. Commitment to Six Sigma

In your opinion/experience, please suggest the level of importance placed upon activities involved in Six Sigma commitment within your organization

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<tbody>
<tr>
<td>a.</td>
<td>Staff understand the Six Sigma concept</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>b.</td>
<td>Staff receive Six Sigma training</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>c.</td>
<td>Staff have the necessary Six Sigma support</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
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<tr>
<td>d.</td>
<td>Staff have the necessary resources for Six Sigma</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
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<td>e.</td>
<td>Management has the right level of competency in Six Sigma</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
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<tr>
<td>f.</td>
<td>Management take great interest in the Six Sigma work</td>
<td>O</td>
<td>O</td>
<td>O</td>
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Section 3 – Key performance Indicators

Please use the following scale to answer the questions in section 3:

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<tr>
<td></td>
<td>No not all</td>
<td>Very little</td>
<td>Moderate Impact</td>
<td>Great impact</td>
<td>Exceptionally</td>
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Improved quality of product

Does the organisation view Six Sigma as means to improve quality? Yes No

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<td>a. Has Six Sigma improved the overall quality of product/products?</td>
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<td>b. Has Six Sigma improved the way the overall quality of products is measured?</td>
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<td>c. Has Six Sigma provided a long term change from the old practices affecting product quality?</td>
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<td>d. How large impact do you think Six Sigma will have on the overall quality of products in the future?</td>
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Please provide an example of how Six Sigma improved the quality of your company’s product?

1/

2/

3/
Price reduction

Does the organization view Six Sigma as means to reduce the price of products?  Yes  No

Comment:

1  2  3  4  5

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<th>Yes</th>
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<td>e. Has Six Sigma influenced the pricing of product/products?</td>
<td>O O O O O</td>
<td></td>
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<tr>
<td>f. Has Six Sigma influenced how the pricing of product/products is measured?</td>
<td>O O O O O</td>
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<td>g. Has Six Sigma provided a long term change from the old practices affecting pricing of product/products?</td>
<td>O O O O O</td>
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<tr>
<td>h. How large impact do you think Six Sigma will have on the pricing of products in the future?</td>
<td>O O O O O</td>
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By what means is Six Sigma able to reduce the costs during the product life cycle?

Comment:

1/

2/

3/
Shorter delivery times to market

Does the organization view Six Sigma as means to reduce time to market? Yes No

Comment:

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<td>i. Has Six Sigma improved the overall delivery times to markets?</td>
<td>O</td>
<td>O</td>
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<td>j. Has Six Sigma influenced how the overall delivery times to markets is measured?</td>
<td>O</td>
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k. Has Six Sigma provided a long term change from the old practices affecting the delivery time to market? | O | O | O | O | O |
l. How large impact do you think Six Sigma will have on the delivery time to market in the future? | O | O | O | O | O |

Please provide an example of how Six Sigma increased efficiency and time saving at your company?

1/

2/

3/
Increased financial support for new development projects

Does the organization view Six Sigma as means to support new projects?  Yes  No

Comment:

1  2  3  4  5

m. Has Six Sigma been able to lead to new development projects?

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n. Has Six Sigma been able to lead to increased funding of new or ongoing development projects?

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o. Has Six Sigma provided a long term change from the old practices affecting the financial support of new development projects

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p. How large impact do you think Six Sigma will have on the possibilities for increased funding of new or ongoing development projects in the future?

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Please provide an example of how Six Sigma allow for new projects?

1/

2/

3/

Thank you for your time and we look forward to the interview!

Best regards,

Steven Roan and Maria Jernelid