OAKBROOK
BUSINESS REVIEW

Papers

Learning from Lean Six Sigma implementation in Indian Pharmaceutical Firms

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Abstract

With more and more patented drugs are coming under the gambit of generic drug manufacturers, pharmaceutical manufacturers are under presure to reduce cost of production without compromising on quality. This research focuses on the question: How Lean Six Sigma (LSS) is perceived and implemented among Indian pharmaceutical firms under regulatory environment, mainly current Good Manufacturing Practice (cGMP)? Based on case study based research method this research explores how LSS have been instrumental in improving key performance indicators (like product quality, price reduction and shorter delivery time-to-market etc.) given the highly regulated Indian pharmaceutical environment. What learning does this offer to other players in this sector? The study investigates the main research question by designing five key research issues which it tests through qualitative research.

Key words: *Pharmaceutical industry, cGMP, PAT, Lean Six Sigma, case study, TQM*

Background

The process of achieving maturity through continuous improvement is a well-known practice among organisations. In most firms and sectors the focus of continuous improvement is found to be cost reduction; but in the pharmaceutical industrythe focus is observed to be improvement of quality of product as well as services(Greene & Rourke, 2006).One of the prime reasons for the relatively low focus on improvement efforts in manufacturing productivity is the high cost of product and process revalidation from regulatory point of view(Liu, 2005). Manufacturing accounts for about 36% of manufacturers total cost. With increasing competrition from generic drug manufacturers, pharmaceutical manufacturers are under pressure to reduce cost of production without compromising on quality. This research focuses on the question: How Lean Six Sigma (LSS) is perceived and implemented among Indian pharmaceutical firms under regulatory environment, mainly current Good Manufacturing Practice (cGMP) ?

Research Objective

The primary objective of this research is to explore the experience of pharmaceutical firms who have implemented LSS. How LSS have been instrumental in improving key performance indicators (like product quality, price reduction and shorter delivery time-to-marketetc.) given the highly regulated Indian pharmaceutical environment. What learning does this offer to other players in this sector?Knowing the obstacles and the manner of overcoming them in the light of the key research areas would be significant addition to the body of knowledge of sustaining the pharmaceutical industry and LSS implementation.

Investigating Research Issues

Five key research issues are identified for investigations.

1. Meaning of LSS as understood and interpreted by the top-management of the pharmaceutical industry
2. How critical are leadership and commitment to the success of LSS among the pharmaceutical firms?
3. Whether the pharmaceutical firms can use the experiences of other industries as a benchmark to formulate applications of LSS?
4. WhetherLSS is an appropriate strategic method for pharmaceutical firms to enhance customer benefits by reducing lead time and cost yet maintaining the cGMP?
5. To what extentLSS has been accepted by pharmaceutical industry as a strategic method for continuous improvement vis-a-vis Quality Circles and TQM?

Methodology

This research is based on case-study method. Since there are very few Indian pharmaceutical firms who have implemented the LSS, the number of cases available is small. However the literature on case-research supports validity of studies based on limited number of cases also (Willis, 2014). The method adopted is to understand the context of the case, understand perceived concept of LSS and its implantation process and finally gather data on the key performance areas – both before and after the LSS implementation,. The interviews were carried out following a predetermined protocol that was presented in a questionnaire. The questionnaire was divided into 3 sections :

1. Company background
2. Usage of Lean Six Sigma
3. Key Performance Indicators

All firms of the sample have implemented LSS; at the time of study the LSS implementations in these organizations were at different stages of maturity. The data were analyzed in the context of the five key research issues.

Research design

A research design is “the logic that links the data to be collected (and the conclusion to be drawn) to the initial questions of study”(Yin, 2003). For a research project, its “logic” is the paradigm that has been used to understand the social phenomenon(Cresswell, 1994).The research aimed to capture the experience of the practising executives in the implementation of LSS and use the insight towards development of a theoretical framework. For this purpose qualitative research method has been considered most appropriate. Qualitative research involves close observations and in-depth interviews(Lapan, 2011). Case study method is appropriate to seek insight into the contextual factors of 'how' and 'why'(Hunt, 2015). The sources of data include responses to interviews and filled-in questionnaire. The conclusion drawn from the interviews and the data collected through questionnaire was compared with the existing body of knowledge from the literature wherever relevant. The organizations were selected from the sector specific information and personal contact. The questionnaire was sent out to the participants before the interviews with fair amount of written explanation on the objective. The interviews were conducted directly where feasible; otherwise through telephones.

Analysis and Results

Data from each of the firms have been gathered through structured questionnaire as also through in-depth interview of key persons. Annexure-1 is a brief write-up on each of the firms that have been studied for this research. Annexure -2 gives basic data gathered from each of them relating to the usage of LSS. Annexure-3 presents the summary of Key performance Indicators of each of the firms.

The interview proceedings are documented and analyzed to arrive at the relevant features relating to the key research issues. Through a careful analysis of the interview documents vis-a’-vis the key research issues has yielded the summary table shown in Annexure-4.

General Observations from the Study

a. There is a direct correlation between time span of LSS implementation in the organization and its level of penetration across the organization. This signifies that as LSS starts delivering results in a given pilot area, the organizations become confident to replicate it in other parts of the organizations and over a period of time entire organization embraces LSS leading to a cultural change.
    - Pro Life Science Ltd has had LSS in its organization for six years at the time of study; the firm has already taken LSS to every part of the organization.
    - Universal Pharma Ltd has had LSS for two years at the time of the study; LSS was implemented only in the manufacturing and quality departments.

b. Pharmaceutical firms are leveraging the experience of LSS in other sectors with lot of customization.

c. Pharmaceutical firms are embracing LSS as a strategic asset (just like firms in other sectors) and are driven by the top management.

d. LSS is helping the firms in improving quality, price and deliveries to a great extent (Annexure-3: Performance Indicators). All these are achieved due to the comprehensive and structured approach of LSS and the development of a culture of improvement across the organization.

Observations on the Key Research Findings

a. *With respect to Key Research Issue-1:* In the absence of a standard definition of LSS, the perception of each firm about LSS is significant. PSL perceives LSS as a methodology that tried to identify the critical areas and talents, focused on them until the initiative generated competitive advantage to the firm. UPL perceived LSS as a methodology that focused on the problem areas, worked on them to find resolutions and developed a culture of root-cause analysis. RLL perceived LSS as an organization wide culture that envisaged a practice of reducing efforts and improving performance, bench marking with the best in the world, a means to achieve daily targets faster and in an easier manner etc.

b. *With respect to Key Research Issue-2:* PSL perceived the role leadership in educating the organization about the need to change and the urgency involved in it. UPL echoed this perception. It emphasized the need for commitment from the top leadership of the firm. It felt that the leadership should anticipate the implications of the LSS initiative and it should manage the attitude of the entire organization. It also feels that shared decision making would yield better results. RLL while sharing these perceptions also indicated that the top management should strive to remove the fear and anxiety among the employees of the organization to ensure successful implementation of LSS

c. *With respect to Key Research Issue-3:* Pharma industry is highly regulated and hence PSL feels that bench marking with the experience of non-pharma industries needs significant customization. UPL perceived that LSS brought in focus on financial deliverables. It also felt that hiring persons from non-pharma industries had helped in implementation and increase in productivity.

d. *With respect to Key Research Issue-4:* PSL observed that LSS minimized documents. Through careful modification of SOPs it has been possible to monitor targets closely without compromising technical targets. UPL observed that conflicts of interest that prevailed among departments in terms of objectives and responsibilities were resolved substantially. LSS ensured equal importance to quality and cycle-time of production. On the whole UPL felt that LSS brought down the grey zones of responsibility. RLL perceived that through LSS flow of operations got standardized leading to better learning process and economy.

e. *With respect to Key Research Issues-5:* UPL perceived that LSS brought cohesive and comprehensive approach to problem solving. It brought disciplined approach to measurement and customer focus. LSS requires extensive education and training and hence engagement of full-time specialists is considered a good option. RLL perceived that LSS was result oriented and to get full results the LSS initiative must be sustained. It also perceived that LSS approach must be structured and comprehensive with full-time specialists.

The focus on financial and business results is to some extent unique in Six sigma. Deming (Deming,1986) warned against focusing on results and instead preferred a process focus. On the other hand, the Baldrige Award and related quality awards around the world which focuses on TQM have focused on process and results too. The difference is that Six

Sigma usually requires financial returns from most projects and from each full-time Six Sigma specialist.

Thus the financial focus is at the project level, in contrast to being on the organizational level in TQM and the Baldrige award. In addition, results are tracked on a pre-project and post-project audit basis by the financial department of respective organization.

This aggressive insistence on a financial return from improvement projects is new to most organizations. However, Six Sigma recognizes that not all projects produce short-term financial returns; therefore, projects with purely strategic value may also be undertaken (Pande et al, 2000). Many of our interviewees emphasized that having strong financial measurement was new dimension compared to past quality efforts.

Impact of LSS Structure, penetration and Culture on results

Table-1 presents the salient features of the organization structure of the firms that have gone through LSS implementation.

Table 1: LSS Organizational Structure.

Company	Universal Pharmaceutical Ltd (UPL)	Royal Laboratories Ltd (RLL)	Pro Life Science Ltd (PSL)
Using LSS Since	2 years	4 years	6 years
Structure			Master Black Belt
	1 Black Belt	2 Black Belts	6 Black Belts
	2 Green Belts	5 Green Belts	12 Green Belts
			Model for Business Excellence
LSS Penetration	Manufacturing, Quality assurance	Manufacturing, Quality Assurance / Control	Manufacturing, Quality Assurance / Control, R&D, Sales and Marketing
Culture	Breaking the old mind set	Mid-level alignment	Companywide LSS alignment

LSS has a tendency to bring about an evolution in the organization structure; this can be observed in the above table. The Universal Pharmaceuticals Ltd(UPL) is at the beginning stage of the LSS evolution and has a small team driving the system limited to manufacturing and quality. This team consists of a Business Excellence Manger who is the Black Belt and the main driver of the LSS initiative. The two Green Belts assist him in this task. This is the scenario in companies that launch LSS and those who are at the beginning stage.

The LSS processes are first applied in a small area and checked for its acceptability, success and sustenance. As the LSS acceptability increases within the organization, the team size and structure change to suit the need of the evolving processes around LSS.

The Royal Laboratories Ltd(RLL) has a comparatively bigger structure of its LSS drive consisting of 2 Black Belts, 5 Green Belts and 5 Functional Black Belts. Functional Black Belts are area leaders with deep knowledge of LSS processes. This leads to culture building within the different departments of the

organization as leaders drive the processes in line with LSS methodology. Going further ProLifeScience Ltd(PSL) has evolved to such a level of LSS that they have deployed a business excellence model based on LSS.

The results obtained by the firms lead to further conclusions about the impact of LSS working structures. The history (time span) of LSS implementation has direct impact on the quality levels achieved by the firm. PSL with 4years of LSS implementation indicated exceptional quality levels; UPL with 2 years of LSS implementation showed only moderate quality levels. RLL and PSL have deeper penetration in LSS as compared to UPL. Similar results are evident from price of product and time to market i.e. delivery. PSL is way above compared to RLL and UPL.

Research summary

Key Research Issue-1: What is the meaning of Lean Six Sigma as understood and interpreted by the leaders and management of the pharmaceutical industry.

From a practitioner's perspective different definitions may be pertinent, depending on the firm's prior experience, strategic outlook and application. The evolution of Lean Six Sigma in the organization will also play a major role in the level of understanding and interpretation of Six Sigma. Lean Six Sigma should be used in different levels and dimensions as the organizations grow along with it. In the initial stage LSS may be seen as a metric for the improvement of the basic Key Performance Indicators (KPIs). As the concept become more stronger with LSS penetration and time, LSS can acquire significance as one or more of the following :

1. a goal setting tool within the organization
2. a bench marking tool with outside world.
3. a locomotive tool to drive the growth of the organization.
4. a way of life for the entire organization
5. a culture to be strongly embedded in the organization.

Key Research Issue-2: Leadership and commitment is critical to the success of Lean Six Sigma in the pharmaceutical manufacturing.

Commitment from leadership is critical for the success of Six Sigma in the pharmaceutical industry like any other industries (Snee,2004; O'Rourkee,2005). Top management need to be aware of the implications of the LSS implementation. For example in UPL a major difficulty was that even though their management was 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 organization about the relevance of Six Sigma and its utility. PSL has stated that its successful implementation was due to awareness and understanding from the management on the importance of commitment at all levels in the organization. It is clear; without commitment and understanding at the management level, Six Sigma implementation and use will face major problems and obstacles. It is desirable to create few dedicated positions to enhance the success of LSS implementation.

Key Research Isue-3: The pharmaceutical manufacturing can use the experiences of other industries as a benchmark to formulate applications of Lean Six Sigma.

The interviews clearly show that experiences from other industries were used as a benchmark during the formulation of their Six Sigma strategies. Several of the people participating in the interview also had experiences of Six Sigma from other companies and such knowledge was a main success-factor in the LSS implementation. Bench marking is very important 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. There are therefore no shortcuts to a successful implementation of Six Sigma in any business or company. Involvement of experienced consultants will expedite the process of implementation and help buy-in the concept across the organization.

Key Research Issue 4: Whether Lean Six Sigma is a suitable strategic method for pharmaceutical manufacturing to enhance customer benefits by reducing lead time and cost yet maintaining the cGMP?

GMP has evolved gradually, representing a complex system of rigorous rules and institutionalized tradition of drug manufacturing in order to ensure the safety, reliability and quality. While cGMP focuses on manufacturing as a means to produce safe and effective products for the patient, lean focuses on manufacturing as a location for improvement and value creation from a customer's perspective. In a lean pharma manufacturing environment, cGMP and lean must be equal partners. The cGMP standards together with lean principles must be embedded into the culture of an organization and the business strategy must reflect this.

This challenge is less problematic because of recent changes in regulatory thinking like introduction of PAT (Process Analytical Technology) by Federal Drug Administration which aims to removal of real and perceived barriers to bring improvement in pharmaceutical manufacturing efficiency and quality(FDA (2011).

Research Question 5: Lean Six Sigma processes have been accepted by pharmaceutical industry as a proven strategic method for continuous improvement as compared to other processes like Quality Circles and TQM.

Although Lean Six Sigma builds on prior quality management practices and principles, it offers a new structure for improvement. The structured and comprehensive approach of LSS promotes better control and exploration in improvement efforts. Its strong emphasis on results has motivated the management to go for LSS with more sustained enthusiasm.

Limitations of the Research

The study is restricted to three firms which have implemented LSS and depth interviews of key executives involved in the implementation. Limitations of case study research remain valid in this study also (Willis, 2014).Depth interviews supported largely by data; they are used to generalize into learning relevant to pharmaceutical firms implementing LSS. Attempts have been made to verify the opinions expressed by the executives; however it has not been possible to verify all aspects since many are based on perceptions. The authors do not rule out the possibility of existence of other latent factors responsible for the improvements observed in the firms studied. Despite these limitations, the authors feel that the study has yielded good insights on the relevance of LSS to pharmaceutical firms and the key success-factors of implementation.

Conclusion

The main research question is: How Lean Six Sigma (LSS) is perceived and implemented among Indian pharmaceutical firms under the present regulatory environment and current Good Manufacturing Practice (cGMP)? The research concludes that Indian pharmaceutical firms have started taking advantage of the frame-work of Process Analytical Technology under cGMP and have initiated LSS implementation. These firms have reaped benefits in terms of manufacturing efficiency and product quality improvement. It is also noteworthy that LSS is being seen as a platform for goal setting, benchmarking and setting a culture of continuous improvement.

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Annexure-1: A brief write-up on the firms under study

Universal Pharmaceutical Ltd

Universal Pharma Ltd (UPL) is a topical formulation manufacturing company. It has state of the art facility in its plant at Goa; it is the largest single site topical manufacturing facility in the world. The facility has strength of 700 employees and in operation since 1990. The company has started Business Excellence journey two years back with a full time Black Belt and 2 Green Belts. They are currently working on improving manufacturing processes. The head of Business Excellence department participated in the interview. The firm's overall goal is to achieve excellence in manufacturing processes through continuous improvement. It is targeting the Six Sigma level in all its processes. Lean manufacturing is now the focus of the company.

Royal Laboratories Ltd.

Royal Laboratories Ltd (RLL) is a major active ingredient producerof India with presence across the world. The facility under the study is located inTelangana and has employee strength of 450. RLL is practicing operational excellence since 4 years across all its operations. RLL has a full time Operation Excellence department which has 2 Black Belts and 5 Green Belts. Other than this there are 5 Black Belts which do not work full time on Lean Six Sigma but are functional experts and have specific projects under them. The interview was conducted over phone with one of the Black Belts from the Operation Excellence department.

Pro Life Science Ltd.

Pro Life Science Ltd (PSL) is a MNC and a leading bio pharma company, manufacturing Vaccines and other lifesaving drugs. PSL has a huge manufacturing facility in Goa with employee strength of 650. PSL is practicing LeanSix Sigma for last 6 years under a process excellence system called PSL Model for Business Excellence. This model has various levels and a detailed execution methodology. PSL has 1 Master black Belt, 6 Black Belts and 12 Green Belts in its manufacturing plant. The interview was conducted with two Black Belts.

Annexure-2: Data Summary showing Usage of LSS

Questions on Usage of Lean Six Sigma	Universal Pharmaceutical Ltd	Royal Laboratories Ltd	Pro Life Science Ltd
Name of years Lean Six Sigma have been used in your company	2 years	> 4 years	> 6 years
Is Lean Six Sigma implemented throughout the entire organization ?	No	Yes	Yes
Please indicate the business areas that utilize lean Six Sigma	Manufacturing Quality assurance	Manufacturing Quality Assurance / Control	Manufacturing Quality Assurance / Control R&D, Sales and Marketing

Did the organization use information from other companies with Lean Six Sigma before the implementation ?	Limited to companies in the vicinity	Used consultants from different field to benchmark processes and matrix	Yes, used vast knowledge of other sectors and experts
Did any of the Lean Six Sigma facilitators have any Six Sigma experience from other industries ?	Yes	Yes	Yes
Does the organization view Lean Six Sigma as a business strategy ?	Yes	Yes	Yes
Does the organization use Lean Six Sigma as a tool to fulfill the vision of the company?	Not Yet	Yes	Yes
Is Lean Six Sigma driven by Senior Management ?	Mid Level	Yes	Yes
> Staff understand the Six Sigma concept	Medium	High	High
> Staff receive Six Sigma training	Medium	High	High
> Staff have the necessary LSS support	Medium	High	High
> Staff have the necessary resources for Six Sigma	Medium	High	High
> Management has the right level of competency in LSS	Medium	High	High
> Management take great interest in the LSS work	Medium	High	High
What are some of the other continuous improvement tools used in the past before switching over to Lean Six Sigma.	NA	Quality Code	TQM
Are the old tools still in use ? If not how and why is Lean Six Sigma considered better over them ?	No	No	No
What is your understanding of Lean Six Sigma	Metric	Growth Driver	Culture
Structure	1 Black Belt & 2 Green Belts	2 Black Belts, 5 Green Belts and 5 Functional Black belts	1 Master Black Belt, 6 Black Belts and 12 Green Belts Model for Business Excellence
Culture	Breaking the old mind set	Mid-Level alignment	Companywide LSS alignment

Annexure-3 : Key Performance Indicators

Key Performance indicates	Universal Pharmaceutical Ltd	Royal Laboratories Ltd	Pro Life Science Ltd
Assessment of Impact on Quality of Product			
Has Six Sigma improved the overall quality of product / products ?	Moderate Impact	Exceptionally	Exceptionally
Has Six Sigma improved the way the overall quality of products is measured ?	Moderate Impact	Great Impact	Exceptionally
Has Six Sigma provided a long term change from the old practices affecting product quality ?	Moderate Impact	Great Impact	Exceptionally
How large impact do you think Six Sigma will have on the overall quality of products in the future ?	Great Impact	Great Impact	Exceptionally
Assessment of Impact on Price of Product			
Has Six Sigma influenced the pricing of product / products ?	Moderate Impact	Great Impact	Exceptionally
Has Six Sigma influenced how the pricing of product / products is measured ?	Moderate Impact	Great Impact	Exceptionally
Has Six Sigma provided a long term change from the old practices affecting product quality ?	Moderate Impact	Great Impact	Exceptionally
How large impact do you think Six Sigma will have on the pricing of products in the future ?	Moderate Impact	Great Impact	Exceptionally
Assessment of Impact on Time to market of Product			
Has Six Sigma improved the over all delivery times to markets ?	Great Impact	Exceptionally	Exceptionally
Has Sigma influenced how the overall delivery times to markets is measured ?	Moderate Impact	Great Impact	Exceptionally
Has Six Sigma provided a long term change from the old practices affecting the delivery time to market ?	Moderate Impact	Great Impact	Exceptionally
How large impact do you think Six Sigma will have on the delivery time to market in the future ?	Great Impact	Exceptionally	Exceptionally

Annexure - 4 : Analysis of Research Findings		
Response from Pro Life Science	Response from Universal Pharma	Response from Royal Pharma
Key Research Issu-1 : Meaning of LSS as understood and interpreted by the top-management of the pharmaceutical industry		
LSS facilitates the following : Identification of critical areas Identification of potential talent Focus to enhance the capabilities Enhance competitive advantage	LSS means : Identify the problem areas Culture of root-cause driven approach	LSS Implies : Practice of reducing efforts and improving performance. Bench marking with the best in the world. Method of achieving daily target faster and easier. It develops a productivity culture
Key Research Issue-2 : How critical are leadership and commitment to the success of LSS among the pharmaceutical firms ?		
Leadership is about educating the target audience about the need for change. Educating about urgency	Leadership needs to be committed to the implementation. It should have knowledge on the impact of implementation of LSS. Need to bring about change in the attitude and willingness of the entire team for improvement. Shared decision making; Helps increase production not work.	Maximum emphasis from top management. Dispel the fears of dislocation as a result of the LSS implementation Taking all employees into confidence
Key Research Issue-3 : Weather the pharmaceutical firms can use the experiences of other industries as a benchmark to formulate applications of LSS ?		
Challenges of implementing LSS : Pharma is highly regulated sector. Hence cautions approach & customizing on the experience of other industries are relevant.	LSS focuses on financial deliverables Hiring talent from non-pharma to lead implementation: proved that diversity improves productivity.	No Response
Key Research Issue-4: Weather LSS is an appropriate strategic method for pharmaceutical firms to enhance customer benefits by reducing lead time and cost yet maintaining the cGMP ?		
LSS has been used to minimize the documents. Careful blend of the SOPs to ensure that targets are monitored without compromising technical standards.	LSS enables : Resolutions of conflict of interest among departments in terms of objectives and responsibilities. Giving equal importance to quality and cycle-time of productions. Reduces the grey zones of responsibility.	Flow of operations gets standardized ensuring better learning process and economy.
Key Research Issue-5: To what extent LSS has been accepted by pharmaceutical industry as a strategic method for continuous improvement vis-a-vis Quality Circles and TQM ?		
No Response	LSS Brings in very cohesive & comprehensive approach to problem solving. Disciplined approach to measurement. Customer Focus Extensive education and training required. Hence firms are not averse to engaging full-time specialists for improvements.	It is result oriented. LSS Program must be made sustainable; it would produce results. The approach must be structured, comprehensive with training of full-time specialists.

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