Lean implementation
Indian pharmaceutical industry
Contents

Message & Foreword 04
Executive summary 06
Survey 08
Future 44
Indian Pharma industry is going through a very interesting phase. On the one hand it is rapidly achieving a distinctive position in the global pharma space with generics, CRAMS and clinical trials while on the other hand the fragmented domestic market is poised for a major consolidation. The common thread in this scenario is increased competition on the basis of speed to market, cost competitiveness, quality, customer orientation and distribution reach & penetration in the domestic markets. With these challenges, Indian pharma industry is seriously evaluating the ways and means to reduce supply chain costs and its effectiveness.

Over the last decade organizations across the world started adopting Lean Management philosophy to improve effectiveness of their supply chains. “Lean” is a management philosophy derived from the Toyota Production System (TPS) in the 1990s. The focus of “Lean” is to reduce / eliminate wastes across the supply chains so as to deliver maximum customer value. Initiatives like – TQM, Six-Sigma, TPM, JIT, TOC, business process engineering, Kaizen, QC Circles and 5S etc are proven to be helping companies eliminate waste and hence are considered as “Lean Initiatives”

To understand the current state of lean implementation in Pharmaceutical sector, OPPI collaborated with PwC to conduct an online survey among OPPI member companies Head of Supply chain, Procurement, Manufacturing participated. I am happy to release the survey findings to the OPPI members.

Tapan Ray
Director General - OPPI
Business has become more challenging, with intense competition & customers becoming more selective. With this increased complexity and formidable challenges Indian domestic pharmaceutical industry is moving ahead...

The Pharma sector has always been adopting new approaches to improve operations with focus on Quality and Regulatory Compliance. Of late, with increased competition and cost pressures, supply chain and operational cost effectiveness have also come under the focus. Progressive pharmaceutical companies have embraced operations improvement initiatives in the recent years and have realized benefits in their Operations.

Through this survey, we have tried to assess the improvement drivers for the pharma industry, identifying the challenges in making supply chain lean & the key success factors for sustenance. To support our analysis, we have also conducted a few interviews with SC Heads, Plant Heads of pharmaceutical companies to help us understand better, the challenges faced by the industry & the way ahead for Lean initiatives.

We would like to thank all the respondents, Materials Management Committee of OPPI led by Mr. Ajit Singh & other members who supported us in the process of this survey. A special thanks to Mr. Ashok Bindumadhavan who coined the idea of the survey & guided the project throughout. We hope that you find this report insightful and supportive of further discussions and action. We welcome comments and observations from the readers of this report.

Happy reading !!

Ravind Mithe
Executive Director - Consulting
Executive Summary
Over the last decade many Pharma organizations across India have started adopting various excellence initiatives. These initiatives are supposed to aid organizations in creating value and help face the challenging business needs. This survey was designed to check the status of current lean implementation in pharma companies.

The good news is that 87% of the respondents to our survey are driving one or the other excellence initiatives across various functions. Companies are actively driving initiatives like Lean, Six Sigma, Strategic Cost reduction, and TPM. Many of the organizations have reaped huge bottom-line benefits through these initiatives. Improvements in quality, throughput, service levels are some of the areas which have resulted in tremendous benefits as a result of implementation.

During this survey, we had also observed that the initiatives embraced by Pharma companies are similar in nature with other industries, however the improvement quantum is not very high in comparison to other industries. Pharma has lagged other sectors in terms of improvement in key operational parameters. These could be attributed to the fact that operations excellence is in nascent stages in Pharma. We are sure that the benefits would continue accruing in the long term and Pharma would reach a maturity level close to leading sectors like auto. The key parameter for successful implantation is transformation in culture. Globally and cutting across all industry sectors, this has come out as a significant need that the companies need to address.

80% of the surveyed participants feel that the implementation has been successful, though the full potential is yet to be realized, thus indicating gap between benefits envisaged by the top management and the actual benefits. These gaps can be attributed to multiple reasons like lack of proactive approach in understanding the challenges, multiple initiatives running at the same time & inadequate leadership focus & vision.

This report will prove as guide to organization in successfully driving the excellence initiatives and achieve maximum benefits. While there is no one right answer the experience of others could be a good way of ensuring success.
Survey
This Online Survey was designed by PwC along with OPPI and was carried over a period of 12 weeks. Supply Chain Heads, Operations Heads, Directors of various Indian & MNC Pharma Companies participated in the survey. This survey had 5 sections and a total of 52 questions.

Demographics of the surveyed participants
Includes information on company turnover, growth rates, nature of business, type of company (MNC/Indian), nos. of plants, employee strength etc

Understanding of participant’s existing Initiatives
Information on initiatives launched and currently being pursued by the company. Priority business needs as seen by the company. Involvement of leadership team in the initiatives, drivers of these initiatives etc

Benefits implementing Lean
Benefits that the company has seen while implementing these initiatives across various processes

Participant’s experience in implementing lean
Challenges faced while implementing Operations excellence initiatives

Understanding the participant’s supply chain process
Nature of supply chain in the organization, implementation and success of key SCM processes like S&OP, planning horizon considered for production as well as RM/PM. Sales forecasting accuracy, review structure etc

Out of the 23 companies who participated in the survey, 19 were OPPI members and 4 were non-OPPI members.
Both MNCs and Indian Pharma companies took part in the survey. Majority of MNCs are among the Global Top 25 and the participant Indian companies have been in the market for more than 15 Years.

More than 65% of the participants have had a CAGR above 15%.

In terms of business focus, more than half of the participants are entirely into formulations and the rest are integrated pharmaceutical manufacturers.
Improved service levels turned out to be the predominant business driver for implementing excellence initiatives

The survey highlights business needs that the Indian companies have identified as drivers for their growth & profitability.

The large influence that customers are having on these manufacturers is evident as most companies have cited ‘customer orientation’ as the top business need, levers rather than focusing on internal levers (like profitability and revenue growth).

**Current Business Needs**

<table>
<thead>
<tr>
<th>Business Need</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve service levels</td>
<td>92%</td>
</tr>
<tr>
<td>Enhance customer value</td>
<td>77%</td>
</tr>
<tr>
<td>Reduce cost</td>
<td>62%</td>
</tr>
<tr>
<td>Reduce lead time</td>
<td>38%</td>
</tr>
<tr>
<td>Reduce working capital</td>
<td>15%</td>
</tr>
<tr>
<td>Improve work culture</td>
<td>15%</td>
</tr>
</tbody>
</table>

**PwC Point of View:**

Drugs coming under the ambit of price control, dependency on commodities with fluctuating prices, government policies with reference to healthcare, customers expecting suppliers to give a year on year price reduction are all factors that are leading to a transition in Indian Pharma industry. With a lot of drugs going off-patent, the opportunities presented to Indian Pharma that has been traditionally focusing on generics is immense. With India heralded as a low cost destination for supply of generics, global customers would expect prices to be lower while at the same time demanding increased service levels.

Going forward, improving service levels and enhancing customer values are going to be the key differentiators. As competitive pressures intensify, more drug makers would be launching ‘Operations excellence’ programs to stay in the race.

Companies can leverage Lean philosophy, tools and techniques to improve service levels.
Thus it is no surprise that the surveyed companies have embraced at-least one improvement initiative over the last 3 years

This survey finds that most of participants (87%) have initiated some improvement initiative or other in their organizations. Indian pharma is sensitized to the future challenges that the industry needs to tackle. Awareness on lean manufacturing too seems high as nearly 50% of the respondents have initiated lean in their organizations.

Out of the surveyed participants 50% MNCs have implemented Lean and 57% Indian companies have implemented Lean.

<table>
<thead>
<tr>
<th>Improvement initiatives already in progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operations Improvement</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Lean</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Improvement initiatives at MNC and Indian companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>MNC</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Indian</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

PwC Point of View:

Global Pharma is not new to Operations Excellence tools. Several global pharma companies have adopted a lot of improvement initiatives and have gained substantial benefits. Since most of the companies surveyed are suppliers to global markets, it is quite natural that some of the improvement initiatives are adopted by the global players have started percolating to the surveyed participants.

Another welcome trend in the global CRAMS and generics manufacturing is global MNC players expecting their vendors to adopt Lean practices and share the gains. Similar move in auto sector helped Indian Auto component industry to rapidly adopt Lean practices which lead to drastic improvement in cost and quality. We believe that Pharma industry will take a leaf from such experiences.
ERP, Lean & Strategic cost reduction are amongst the most popular initiatives in Pharma Companies...

Popular initiatives taken up...

An overwhelming 85% of the pharmaceutical companies surveyed indicated that they have pursued some kind of Improvement initiative in the last 3 years.

PwC Point of View:
As business complexity increases, it is quite natural for organizations to ramp up their transactional IT capabilities. It is not a surprise that almost all of the respondents have chosen ERP as the first enabler. Data visibility to all and data based decision making are at the heart of operations excellence philosophies and IT is a good enabler.
The surveyed Pharma Companies have realized a host of benefits by embracing improvement initiatives

Improvement initiatives in Pharma companies has yielded maximum benefits in terms of Improved quality, Increased profitability & Improvement in service levels.

Lean in Pharma as compared with other Indian Industries:

- Improve service level: 100%
- Improved response time: 85%
- Reduce lead time: 62%
- Improved flexibility: 62%
- Increased profit: 54%
- Reduce cost: 46%
- Decreased inventory: 46%
- Improved quality: 46%
- Enhanced throughput: 38%
- Work culture: 38%
- Improve productivity: 38%
PwC Point of View:

The benefits realised by these companies are in line with what one would see while implementing such improvement initiatives. Pharma companies, traditionally have been focused on Quality and have successfully channelized these improvement initiatives to improve Quality. Their quality focus has also enabled them in increasing their global standing in terms of preferred supply base. Our experience suggests that a host of operational parameters get improved ranging from OTIF to yields.
Pharma companies who have successfully implemented these initiatives are seen to grow at a higher CAGR%

For pharmaceutical companies growing with more than 15% CAGR, 60% have implemented Lean initiative.

70% of the companies have derived benefits over Rs 50 Mn by implementing improvement initiatives.

Organizations have derived annualized benefits to the extent of Rs 200 – 400 Million by implementing these improvement initiatives.

The survey reveals, a greater top management involvement in improvement initiatives results in higher sustained benefits for the organization.

<table>
<thead>
<tr>
<th>With CAGR &gt; 15%, Lean Implementation</th>
<th>Benefits through Improvement Initiatives</th>
<th>Top Management Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>&gt;200 Mn: 30%</td>
<td>High: &gt; 200</td>
</tr>
<tr>
<td></td>
<td>100-200 Mn: 30%</td>
<td>Medium: 100 - 150</td>
</tr>
<tr>
<td></td>
<td>50-100 Mn: 10%</td>
<td>Low: &lt; 50</td>
</tr>
<tr>
<td>No</td>
<td>&lt;50Mn: 30%</td>
<td></td>
</tr>
</tbody>
</table>

With CAGR > 15%, 60% have implemented Lean initiative.
Surveyed Pharma Companies have adopted a mix of inward looking and outward looking initiatives

What the customer needs, or Value to Business?

While implementing any Operations Excellence or Lean program one of the major criteria should be the ability to deliver what the customer wants and ability to deliver business results.

A quick analysis along these 2 criteria shows that there is a preference for initiatives that have a high internal focus (i.e. the extent of customer involvement is low). While, it is quite natural to expect popularity of ERP as it enables transactional efficiencies, however many organizations have also taken up externally focused initiatives like lean.

Lean and Six sigma are methodologies that deliver value not only to the business but to the end customer as well. After all, customer is the king !!
PwC Point of View:

The choice of methodologies / tools adopted depend on various factors including experience, value delivered, resources required (effort, man, money), nos. of people involved, ability to create transformation etc.

The key lies in selecting the right tools based on the current business needs. Instead of going for a single minded approach for tools, a holistic approach of using combination of tools to work on various focus areas will yield much more results for the organisation.
Lean in Pharma as compared with other Indian Industries
As on date, more than 75% of the top 20 Pharma companies in India have adopted Lean in some form or the other

PwC Point of View:

There is a general impression within Pharma Industry that the latest cutting edge methodologies would not work in Pharma, because Pharma is different and more regulated. However our research suggests that such impression are fast changing. In recent times pwc is working with several Pharma companies in India to help them implement lean initiatives. Even regulatory agencies have started looking for evidence of systematic thinking while they do surveillance audits. Scientific thinking is at the heart of Lean and other Operations Excellence tools and hence the application of such tools in Pharma is beneficial from the regulatory view-point as well.

This is quite evident from the fact that some of the top-notch pharma companies have started embracing lean initiatives.

Source: Business Today/PwC Analysis
PwC research shows that the adoption of excellence initiatives in Pharma is not as mature in comparison to some industry sectors

More than 60% of the top 200 Manufacturing organizations in India (as per Business Today rankings) have shared their achievements in excellence initiatives through public domain

Discrete manufacturing companies have been at the fore-front of implementing excellence initiatives

<table>
<thead>
<tr>
<th>Industry</th>
<th>Continuous Manufacturing (%)</th>
<th>Discrete Manufacturing (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fertilizers</td>
<td>15%</td>
<td>32%</td>
</tr>
<tr>
<td>Diversified</td>
<td>32%</td>
<td>40%</td>
</tr>
<tr>
<td>Textiles</td>
<td>48%</td>
<td>60%</td>
</tr>
<tr>
<td>Chemicals</td>
<td>55%</td>
<td>68%</td>
</tr>
<tr>
<td>Cement</td>
<td>55%</td>
<td>72%</td>
</tr>
<tr>
<td>Mining</td>
<td>55%</td>
<td>74%</td>
</tr>
<tr>
<td>Oil &amp; Gas</td>
<td>60%</td>
<td>75%</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>68%</td>
<td>75%</td>
</tr>
<tr>
<td>Power Generation</td>
<td>72%</td>
<td>78%</td>
</tr>
<tr>
<td>Capital Goods</td>
<td>74%</td>
<td>80%</td>
</tr>
<tr>
<td>Electronic / Electrical Equipment</td>
<td>75%</td>
<td>80%</td>
</tr>
<tr>
<td>Consumer Goods</td>
<td>78%</td>
<td>80%</td>
</tr>
<tr>
<td>FMCG</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>Auto / Auto Anc.</td>
<td>90%</td>
<td>90%</td>
</tr>
</tbody>
</table>

Source: Business Today/ PwC Analysis
Different sectors are using improvement tools in different proportions

Split by Improvement Initiatives across sectors
PwC Point of View:

Pharma has traditionally been focused on cGMP and the above graph is quite reflective of this, as one might notice that the level of adoption is lower compared to some progressive industry sectors.

The thrust area of cGMP is adequate controls to deliver a safe pharma product, the focus is not so much on value creation for a customer. In other words, the thrust area of cGMP is only one element of value creation for a customer which is to provide him with a safe drug. However improvement concepts like Lean go beyond the cGMP thrust areas and leverages on other value creation opportunities like shorter delivery times and better OTIF performance. It is not that cGMP and Lean are different, in-fact cGMP can be one of the objectives that companies can drive through Lean, while striving for waste reduction and enhancing customer value.
A study published by some leading Lean implementers indicates the potential that Lean holds. The study demonstrates significant benefits in various industries, including:

- **Brakes India (Polabakkam Plant)**: 55% Manpower Productivity Increase, 13% % increase in OEE, -80% In process rejection decrease.
- **Sundaram Fasteners (Padi Plant)**: 75% Manpower Productivity Increase, 13% % increase in OEE, -60% In process rejection decrease.
- **Hindustan Unilever (Mangalore Plant)**: 58% Manpower Productivity Increase, 30% % increase in OEE, -84% In process rejection decrease.
- **Hindustan Unilever (Dadra Plant)**: 42% Manpower Productivity Increase, 19% % increase in OEE, -98% In process rejection decrease.
- **Tata Steel (Tube Division)**: 32% Manpower Productivity Increase, 23% % increase in OEE, -69% In process rejection decrease.
- **Hi-Tech Carbon (Renukoot Plant)**: 50% Manpower Productivity Increase, -35% % increase in OEE, -69% In process rejection decrease.
- **Bajaj Auto (Akurdi Plant)**: 300% Manpower Productivity Increase, -42% % increase in OEE, -20% In process rejection decrease.
- **Ispat Ind. (Kalmeshwar Plant)**: 40% Manpower Productivity Increase, -24% % increase in OEE, -70% In process rejection decrease.
- **JK Paper (Rayagad Plant)**: 33% Manpower Productivity Increase, -20% % increase in OEE, -20% In process rejection decrease.
- **Mukand Steel**: 40% Manpower Productivity Increase, -33% % increase in OEE, -20% In process rejection decrease.

PwC Point of View:

The above companies have been practicing Lean for over 5-10 years as compared to Pharma where it has started recently. However, some of the benefits that PwC's Indian Pharma clients have achieved in the first one year of Lean implementation indicates that Pharma too can achieve large benefits using Lean.
Initial results of Lean Implementation in Indian pharma

### API Regulated

<table>
<thead>
<tr>
<th>Category</th>
<th>Improvement</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yields</td>
<td>5% improvement</td>
<td>3-4 months</td>
</tr>
<tr>
<td>Throughput</td>
<td>25-30% improvement</td>
<td>3-4 months</td>
</tr>
<tr>
<td>OTIF performance</td>
<td>30-40% improvement</td>
<td>6 months</td>
</tr>
<tr>
<td>Recoveries</td>
<td>10-20% improvement</td>
<td>3-4 months</td>
</tr>
<tr>
<td>Energy costs</td>
<td>Rs 10 Mn / annum reduction in energy bills</td>
<td>5-6 months</td>
</tr>
</tbody>
</table>

### Formulations - domestic & regulated

<table>
<thead>
<tr>
<th>Category</th>
<th>Improvement</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity</td>
<td>20% release</td>
<td>4-5 months</td>
</tr>
<tr>
<td>Changeover times</td>
<td>30-40% reduction</td>
<td>3-4 months</td>
</tr>
<tr>
<td>Manufacturing Lead times</td>
<td>30% improvement</td>
<td>5 months</td>
</tr>
<tr>
<td>Plant OTIF performance</td>
<td>30-40% improvement</td>
<td>5-6 months</td>
</tr>
<tr>
<td>Salvage net</td>
<td>30-40% reduction</td>
<td>5-6 months</td>
</tr>
</tbody>
</table>

Note: All figures are approximate and based on PwC’s implementation experience.
Despite several Pharma companies taking up improvement initiatives, the industry has significant distance to cover in terms of key Operating benchmarks

<table>
<thead>
<tr>
<th>Measure</th>
<th>Pharma</th>
<th>Automotive</th>
<th>Aerospace</th>
<th>Computer</th>
<th>Consumer Package Goods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Equipment Effectiveness</td>
<td>10 ~ 60%</td>
<td>70 ~ 85%</td>
<td>50 ~ 70%</td>
<td>80 ~ 90%</td>
<td>70 ~ 90%</td>
</tr>
<tr>
<td>Annual productivity improvement</td>
<td>1 ~ 3%</td>
<td>5 ~ 5%</td>
<td>5 ~ 10%</td>
<td>1 ~ 3%</td>
<td>5 ~ 15%</td>
</tr>
<tr>
<td>First pass Yield – Zero Defects</td>
<td>60%</td>
<td>90 ~ 99%</td>
<td>70 ~ 90%</td>
<td>90 ~ 99%</td>
<td>90 ~ 99%</td>
</tr>
<tr>
<td>Production Lead Time ( Days)</td>
<td>120 ~ 180</td>
<td>1 ~ 7</td>
<td>7 ~ 120</td>
<td>5 ~ 10</td>
<td>3 ~ 7</td>
</tr>
<tr>
<td>Finished Goods Inventory ( Days)</td>
<td>60 ~ 90</td>
<td>3 ~ 30</td>
<td>3 ~ 30</td>
<td>5 ~ 50</td>
<td>10 ~ 40</td>
</tr>
<tr>
<td>Labour value- add time</td>
<td>20%</td>
<td>60 ~ 70%</td>
<td>60 ~ 70%</td>
<td>60 ~ 70%</td>
<td>60 ~ 90%</td>
</tr>
<tr>
<td>Direct/ Indirect Labour Ratio</td>
<td>1:01</td>
<td>10:01</td>
<td>10:01</td>
<td>10:01</td>
<td>10:01</td>
</tr>
<tr>
<td>Number of suppliers/ FTE</td>
<td>24</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spend / Supplier ( in US $ Million)</td>
<td>7</td>
<td>22</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PwC Point of View:
The pharmaceutical industry can no longer support the waste that has become locked into the manufacturing sector by the current operating model. As the FDA states, the potential annual cost savings from efficient product development and manufacture outweigh the cost of bringing new products to market.

Other industries have been quite adept at embracing the concepts of Lean and have reaped sustained benefits. Pharma companies have started embracing such concepts recently and it augurs well for the industry, as a whole. Considering the pricing and regulatory pressures that the industry players are experiencing, it is but natural to adopt such cutting edge thinking philosophies. Traditional improvement in Pharma industry has been triggered more by batch failures or customer complaints. These have been quite reactive in nature, however it has brought in some structured and scientific problem solving at the operating levels. Pharma companies now need to leverage the scientific and systemic thinking that they have embraced and progress towards proactive problem resolution and a thrust on variation reduction.
Even within pharma sector, there is large variation in operating performance of peers

Performance in operational-equipment effectiveness (OEE). 1 n = 25 global companies. percentage

Pharmaceutical manufacturers’ speed to market, number of days Top quartile = 80% faster than last quartile = 53% faster than median

PwC Point of View:

Cutting across industries, inefficiencies creep in even during the development stages of a product. Pharma is not very different in this dimension and we have seen umpteen numbers of occasions where—in the inefficiencies in manufacturing are due to a sub-optimal drug development process. Hence it is imperative to maximize efficiencies during the development stage itself. While maximizing efficiencies are important, it must be noted that it is important to have a shorter time to market as well. This is where concepts of waste reduction and DOE play a significant role and would help create leadership position through rapid scale-up. The principles of FDA’s PAT initiative appear to be extremely well aligned with lean manufacturing thinking, suggesting a positive outlook for lean pharma.
How Pharma is implementing Lean
Participants have taken up improvement initiatives across functions

While externally focused initiatives cover a wide range of functions, the surveyed companies have embraced improvement initiatives across the value chain.

**Top Improvement initiatives by function**

<table>
<thead>
<tr>
<th>Function</th>
<th>26%</th>
<th>35%</th>
<th>24%</th>
<th>21%</th>
<th>7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing</td>
<td>Six Sigma</td>
<td>Lean</td>
<td>Cost Reduction</td>
<td>Six Sigma</td>
<td>ERP</td>
</tr>
<tr>
<td>Planning</td>
<td>21%</td>
<td>26%</td>
<td>30%</td>
<td>52%</td>
<td>26%</td>
</tr>
<tr>
<td>Sales &amp; Distribution</td>
<td>22%</td>
<td>26%</td>
<td>35%</td>
<td>26%</td>
<td>26%</td>
</tr>
<tr>
<td>Buying</td>
<td>27%</td>
<td>21%</td>
<td>24%</td>
<td>21%</td>
<td>7%</td>
</tr>
</tbody>
</table>

**PwC Point of View:**

In most of the industries excellence initiatives start from operations areas like manufacturing and as the initiative matures it gets extended to other functions. Given the pressures on costs most of the organizations are undertaking procurement cost reduction initiatives. However the participating pharma companies have not undertaken such an initiative.
The surveyed participants have also created an initiative ownership structure

A small number (9%) are currently taking some external help for implementing lean. The rest have driven improvement initiatives internally.

Internally driven or Externally driven

70% of respondents have created excellence cell to drive these initiatives and remaining 30% are driving improvement initiatives internally.

Improvement Cells for driving Excellence initiatives

PwC Point of View:
Most often than not improvement initiatives get support from consultants at an early stage and then slowly organizations start driving the initiative internally through various internal structures/improvement cell.

Companies creating such internal structures do not run the risk of initiatives not getting sustained as it creates ownership.

The surveyed Pharma companies are doing well in this regard in terms of driving these improvements internally.
**Organizations are seen to as involving many key stakeholders in the initiative.**

While implementing the excellence initiatives, one would expect the level of customer involvement to be high, however only 35% of the respondents have involved the customer as a major stakeholder in the initiative. We would be able to relate this to the graphic seen earlier, wherein we said that most of the initiatives taken up had a high level of internal focus and not being oriented towards the customer. Of the total respondents only 48% have involved the customer as a stakeholder while building the agenda for improvement initiatives.

**Stakeholder Involvement**

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>High Involvement</th>
<th>Low Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer</td>
<td>48%</td>
<td>35%</td>
</tr>
<tr>
<td>Top management</td>
<td>61%</td>
<td>4%</td>
</tr>
<tr>
<td>Senior management</td>
<td>61%</td>
<td>4%</td>
</tr>
<tr>
<td>Middle management</td>
<td>61%</td>
<td>39%</td>
</tr>
<tr>
<td>Workmen</td>
<td>52%</td>
<td>35%</td>
</tr>
<tr>
<td>Workmen</td>
<td>52%</td>
<td>35%</td>
</tr>
</tbody>
</table>

**PwC Point of View:**

A matured Lean company works towards enhancing value delivered to the customer. However, at initial stages companies use Lean to improve internal efficiencies and costs which is again confirmed from this survey. Going forward, customer involvement in the initiatives should increase as customer expectations have increased and customers increasingly see suppliers as partners. Involving customers in excellence initiatives will not only help capture voice of customer but also can become a lever for increasing business share.

Auto and consumer durables industry has been quite successful in this dimension of customer involvement.
Top management involvement is crucial for the success of Lean initiatives

For driving improvement initiatives in the organization, top management commitment is paramount, if the initiative is to deliver results.

61% of the respondents feel that Top / Senior / Middle management have given adequate priority to the improvement initiatives, which is a good sign.

The survey points out that out of the improvement cells formed by companies, 60% report directly to the CEO / SBU head. Out of these 60%, majority are MNCs (64%) which indicates are high focus/priority assigned to improvement programs by the MNC companies.

PwC Point of View:

There is enough evidence available on the success of improvement initiatives and Top management involvement. Commitment of the top management with regular reviews of the excellence initiative will lead to sustenance & value creations for the organization.

Organizations where top management inputs are found wanting suffer from projects not being resourced adequately, employees giving second priority to the initiatives etc resulting in sustenance issues and ultimately not delivering benefits. Often, functional reporting prohibits the improvement cells from taking up cross-functional improvement projects. For the cells to be effective, the improvement cells should report to the CEO / MD of the organizations.
Participants had identified a few key challenges that they had faced during implementation...

Challenges faced in Lean implementation

- Multiple initiatives with conflicting objectives: 16% High, 3% Low
- Inadequate Leadership focus and vision: 9% High, 8% Low
- Lack of training: 8% High, 8% Low
- Lack of resources: 8% High, 8% Low
- No large measurable benefit: 8% High, 8% Low
- Inability to find time to do improvements due to high: 8% High, 8% Low
- Inadequate linkage with Reward & Recognition: 8% High, 8% Low
- Hard to apply to my industry: 7% High, 6% Low

Top three challenges that all companies are facing in implementing any improvement initiative (incl. Lean) are:

1. Multiple initiatives running within the organization
2. Inadequate Leadership focus and vision
3. Lack of training

In terms of recall; Multiple initiatives, No large benefit, Inadequate linkage with R&R are top of the mind recall as challenges faced in lean implementation.

PwC Point of View:

Seamlessly integrating multiple initiatives and aligning the entire organization through a unified vision for excellence is a need of the hour for Pharma Companies. Organisations have to progress through several stages of excellence and several pharma companies today are at best at the stage of technical transition. Excellence is a gradual journey and companies have to stay committed and overcome all these initial impediments. A well articulated excellence vision is the starting point.

Recent government policies have been focusing on affordable healthcare and the government is proactively working towards increasing availability of new and affordable medicines. Such policies should aid Pharma industry in moving towards developing new products at affordable costs and also producing their existing products at greater efficiencies. Lean thinking can aid companies and manufacturers need to leverage cGMP through Lean, rather than perceiving Lean and cGMP to be mutually exclusive.
It is not that other industries have not faced any challenges during their implementation journey...

A lean implementation survey showed that of the 62 unique challenges listed by respondents, biggest challenge sighted was 'changing the culture'

% of the respondents

<table>
<thead>
<tr>
<th>Challenge</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changing the culture</td>
<td>20%</td>
</tr>
<tr>
<td>Getting buy-in</td>
<td>16%</td>
</tr>
<tr>
<td>Sustaining Lean</td>
<td>10%</td>
</tr>
<tr>
<td>Support</td>
<td>9%</td>
</tr>
<tr>
<td>Finding Resources</td>
<td>6%</td>
</tr>
<tr>
<td>Expanding Lean</td>
<td>5%</td>
</tr>
<tr>
<td>Training</td>
<td>4%</td>
</tr>
<tr>
<td>Resistance</td>
<td>3%</td>
</tr>
<tr>
<td>Fear of Job Loss</td>
<td>3%</td>
</tr>
<tr>
<td>Integration of Lean</td>
<td>3%</td>
</tr>
<tr>
<td>Integration with Six Sigma</td>
<td>3%</td>
</tr>
<tr>
<td>Implementation Commitment</td>
<td>2%</td>
</tr>
<tr>
<td>Others*</td>
<td>17%</td>
</tr>
</tbody>
</table>

Majority of the surveyed companies have claimed that the implementation has been partially successful

“These methods are so hard that companies will only try them when they are desperate.”

Taiichi Ohno - Architect of Toyota Production System

PwC Point of View:

Lean implementation needs changing “basics” of managing supply chains and challenges some deep rooted paradigms. Even though companies are implementing Lean, they are probably not able to prioritize levers which is resulting in suboptimal results & non sustenance. It is also important to note that majority of the surveyed companies have started these initiatives in the recent past and it would take some-time for them to get the best benefits out of these implementations. Our experience suggests that with continued thrust and leadership commitment, companies can gain substantial benefits. The benefits coming out of such implementation is like a Chinese bamboo tree. It requires a lot of nurturing in the initial stages.

It is the combination of being able to perform the simple things right, while also having the ability to change and adapt to the lean customers’ demands, which makes lean such a successful improvement methodology and business survival tool.

The challenge for the pharmaceutical industry in moving towards lean is to design new operational procedures that comply with all external regulatory requirements, but at the same time support continuous improvement.
Cultural transformation and Change Management are key elements which need to be focused on.

**PwC Point of View:**

Daily Management structure with cross-functionality at a shop-floor level is crucial for setting basic workplace standards and systems. This is the heart of any excellence journey. Our experience suggests that any company that has such Daily Management structure institutionalized, has always gone from one orbit to another orbit year on year. It is quite possible that most of the respondents who have mentioned that the journey has been partly successful, do not have a robust Daily Management Structure in place. Change Management is another crucial link, as the journey involves challenging existing new paradigms and adopting new paths.

- Only 39% of the respondents have a daily management structure in place to monitor performance.
- A lot of surveyed participants have a R&R mechanism implemented.
- Only 30% of the organizations sampled have undertaken some sort of change management programs.

**Daily Management Structure**

- Have: 39%
- Do not have: 61%

**R&R mechanism**

- Sufficient: 83%
- Insufficient: 17%

**Change Management**

- Yes: 30%
- No: 70%
**During the survey, we identified some of the best practices followed by participant companies...**

Some of the pharma companies stand out in creating best practices for Excellence initiatives. These practices can be adopted by the other companies with customization wherever required. These practices are proven & will lead to create more awareness and successful implementation of Excellence initiatives.

<table>
<thead>
<tr>
<th>Improvement Initiatives</th>
<th>• Organization is driving various improvement initiative under umbrella of one common objective of achieving excellence across all functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement Initiative structure</td>
<td>• Organization has formed a team to drive the excellence initiative across all functions. There are core team members &amp; the remaining are nominees for defined period from various functions. This helped to create talent for driving these initiatives across all functions</td>
</tr>
</tbody>
</table>
| Driving Improvement Initiative   | • At the start of the every financial year top management objectives are linked to all the functions heads KRA (X-Matrix)  
  • High weightage to Excellence initiatives in the KRA (20 to 30%)  
  • A detail roadmap for next five years on where we want to be, is shared with all the people |
| Training & Reward & Recognition  | • Special incentives for people for getting certified in Six Sigma GB & BB levels.  
  • Training programs on Excellence Initiatives across all function to create awareness and improve participations |
### There have been several success stories in Global Pharma

<table>
<thead>
<tr>
<th>Company</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Bristol-Myers Squibb** | Exclusive Operational Excellence & Lean Six Sigma teams have led to the following outcomes:-  
- Cycle time reduction by 80%  
- 75% Work in Progress (WIP) reduction and five time faster inventory turns  
- Product variability significantly decreased  
- First-Pass quality risen to 95% over three years  
- Two sites went more than 800 days without a lot-work time accident  
| **Bayer**       | Using Lean principles, one of Bayer Healthcare’s fermentation and media teams at the company’s biotech manufacturing center in Berkeley, California, created a culture of improved communication, training and shared process ownership with the following outcome:-  
- Significant decrease in batch record error  
- Improvement in overall staff proficiency by over 20%  
- Boosted productivity by 50%  
- Eliminated OSHA Incidents  
| **Merck**       | Merck adopted lean manufacturing to slim down its supply chain cost and get closer to customer with following key benefit:-  
- Up to 30% reduction in production-related inventory cost  
- Up to 20% reduction in overall operating expenses at plant level  
- Up to 50% reduction in changeover time on some production line  
| **Pfizer**      | Pfizer demonstrated that ‘lean manufacturing works not only for manufacturing processes but also in quality control labs’ by implementing lean at five labs in Grange Castle in Ireland and preceded following outcomes:-  
- Consistent performance that reliably meets the needs of the business  
- Equitable and transparent division of labor within labs  
- Upgrading operations of strategic vendors  
- Less required tracking of samples  
- Decreased need for planning and scheduling by supervisors  
**Indian Pharma is not to be left behind, there have been equal phenomenal success stories**

| Dr. Reddy’S | • Viable Vision Initiative  
|• Company-wide constraints management initiative across areas of strategic planning, operations, supply chain/logistics, sales and marketing, project management, metrics and finance  
|• Has helped the company build a competitive advantage by synchronizing its end-to-end supply chain (manufacturing, R&D, distribution) in a systematic and organized way.  
|• Creating ‘partnership’ with customers in Global Generics business to increase availability with lower inventories  
|• Introducing more generic drugs and APIs to the market at lower risk and investment, thus increasing the productivity of R&D resources while improving the ability to complete R&D projects on time  
|• Lean Manufacturing Initiative  
|• Focused on reduction of process variation to increase flexibility  
|• Autonomous maintenance by operators is a key part of the initiative and has helped the company increase net operating times and decrease overall operating times by 22% |

| Piramal Healthcare | • The company initiated its Supply Chain initiative in 2005 with focus on cost reduction and reducing cash-to-cash cycle  
|• Reduced Raw/Packing Materials inventory from 22 days (FY2008) to 20 (FY2009) at its overseas facilities  
|• Plant operational efficiency through various projects/initiatives  
|• Reduced furnace oil consumption by plugging steam leakages and optimizing use of coal fired boiler to maintain steam pressure at peak load  
|• Awarded the “Healthcare and Life Science Manufacturing Supply Chain Excellence Award” under the aegis of the 2008 SCM Logistics Excellence Awards  
|• Only Indian company to figure on iSixSigma’s “10 Best Places to Work for Six Sigma Professionals” |

*Source: Company websites and Annual Reports*
Future
In this section we also see where the companies relatively stand with reference to some of the core lean principles.

Stated simply, Lean is nothing but minimizing waste while maximizing customer value. Value here is defined from the perspective of both the external and internal customer. It focuses on elimination of all forms of waste, continuous improvement, and simplification of business processes along with involvement of large number of employees.

- Specify what creates value from the customers perspective
- Identify all the steps along the process chain
- Make those processes flow
- Make only what is pulled by the customer
- Strive for perfection by continually removing wastes
Planning predominantly seems to be done in a longer horizon in contrast with Lean principles...

Planning & Forecasting in Pharma companies

- Majority of the participants are working on monthly planning process (30 days to 45 days).
- There are 20% companies which are working on fortnightly to weekly planning process.

- Overall sales forecasting accuracy is 70-90% at the national level. Still this is a long shot going by lean principles that profess a pull from the market should drive internal activities.

PwC Point of View:

Most pharma companies have long supplier lead times and hence planning cycle to be at least a month. Challenge lies in aligning all partners by optimizing the buffers across the supply chain.
The participants need to advance to the right side of the spectrum for a cultural transformation

PwC Point of View:
The organisation should also focus on cultural levers to strengthen the initiatives. We believe in creating multiple small cross functional team across the departments with common goals. These team create ownership at all levels and sustenance. This would also help in releasing top and senior management time being freed up from routine management. The challenges is to empower people and build leaders at all levels.
The implementation

The responses to our survey provide us some insights on how organizations should drive the excellence initiatives. While this is not a prescription for success these insights could definitely provide ideas on how the organizations should handle their excellence initiatives for greater chances of success.

Where are we? Understanding the current state of internal as well as external environment

Where do we want to go? Clearly stating the short term & long term goals for the organisation

How do we get there? Identifying the right set of tools, building capabilities, promoting team work

How do we sustain there? A proactive review mechanism with right set of KPIs & KRAs

Leadership vision & Communication

Competency Building, People Engagement & Opportunity assessment

Measurement focus, Culture of problem solving at root, culture of continuous improvement
**Lean if implemented systematically can help pharma companies bridge this gap**

<table>
<thead>
<tr>
<th>Functions</th>
<th>Industrial Operations</th>
<th>Business Operations</th>
<th>R&amp;D</th>
<th>HR, Finance, IS, HSE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Business Processes</strong></td>
<td>Producing</td>
<td>Market and Franchise Management</td>
<td>Developing New Products</td>
<td>Enabling Processes</td>
</tr>
<tr>
<td></td>
<td>Selling and servicing Customer</td>
<td>Discovering New Products</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lean Initiatives</strong></td>
<td>Manufacturing Excellence</td>
<td>Commercial Excellence</td>
<td>R&amp;D Excellence</td>
<td>Office TPM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Resources &amp; Competencies</strong></td>
<td>Black Belts, Green Belts Lean and Six Sigma Methods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Basic building blocks</strong></td>
<td>Foundation Processes for a Common ERP Platform</td>
<td>Plan to Manufacture</td>
<td>Order to Cash Procure to Play</td>
<td>Record to Report Project to Profit</td>
</tr>
</tbody>
</table>
The progress towards excellence is a gradual process and it requires a very high top management commitment

<table>
<thead>
<tr>
<th>Unfreezing</th>
<th>Technical Transition</th>
<th>Behavioral Transition</th>
<th>Institutionalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Leadership awareness</td>
<td>• Identification of pilot initiatives</td>
<td>• Creation of a critical mass</td>
<td>• Operations excellence as a way of life</td>
</tr>
<tr>
<td>• As-is state assessment</td>
<td>• Training internal champions</td>
<td>• Organization-wide OE structure roll-out</td>
<td>• Leveraging Operations Excellence for Future expansions</td>
</tr>
<tr>
<td>• Assessing Stakeholder dissatisfaction</td>
<td>• Rolling out improvement structure</td>
<td>• Leadership development at various levels</td>
<td></td>
</tr>
<tr>
<td>• Creation of a business case</td>
<td>• Rolling out focused improvement projects</td>
<td>• Organization-wide competency building</td>
<td></td>
</tr>
<tr>
<td>• Leadership vision and direction</td>
<td>• Awareness workshops</td>
<td>• Mass involvement</td>
<td></td>
</tr>
<tr>
<td>• Creation of strong top management commitment</td>
<td>• Competency building workshops for teams</td>
<td>• Scale-up projects organization wide</td>
<td></td>
</tr>
<tr>
<td>• Training the leadership team</td>
<td>• Showing early success to create pull</td>
<td>• Large cross-functional projects cutting across sites and corporate</td>
<td></td>
</tr>
<tr>
<td>• Communication to all employees</td>
<td>• Reward and recognition plan</td>
<td>• Link with Performance Management system</td>
<td></td>
</tr>
<tr>
<td>• Identification of few critical internal champions</td>
<td>• Monthly steering committee reviews</td>
<td>• Goal deployment for alignment</td>
<td></td>
</tr>
<tr>
<td>• Awareness training</td>
<td>• Create a mass-initiative plan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Identifying and deciding on plan for first one year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>9-12 months</strong></td>
<td><strong>9-12 months</strong></td>
<td><strong>9-12 months</strong></td>
<td><strong>9-12 months</strong></td>
</tr>
</tbody>
</table>
Level 1 Focuses on creating mindsets for excellence through early tangible results and ensuring involvement of all.

Level 2 focuses on building skills, setting higher standards for workplace and improving supply chain processes.

Level 3 would make the operations more predictable and flexible through Lean.

At Level 4 the organization builds excellence in a couple of areas that give it a competitive advantage over others and it sets benchmarks for others.

Leadership – Values, Vision, Benchmarking, Strategic Planning, Goal Setting & Communication

Enabling Structure, Manning policies & Process Based Teams

Supporting HR Policies, Competency Building & Training

Change Management, Audits, Self Assessment, Reward and Recognition

Unfreezing
Level 1
Create Basic Structure and conditions

Level 2
Set standards and show all round visible improvements

Level 3
Reduce variation and build process capability, lean and flexible organisation

Level 4
Build competitive differentiation and be best in class; become industry benchmark

Technical Transition
9-12 months

Behavioral Transition
9-12 months

Institutionalization
9-12 months

Enablers
About Pharma Consulting Practice

The Global Pharmaceutical and Life Sciences Industry Group at PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. A global leader in serving the pharmaceutical and life sciences industry, PwC has extensive experience working with companies on industry-specific strategic, operational, and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support. In helping our clients, we draw on the full knowledge and skills of PwC’s professionals.

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Notes
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