Operational Excellence in the Indian Pharma Industry
Real-time Online Delphi Study – Results

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Institute of Technology Management (ITEM-HSG)
The St.Gallen Operational Excellence team is lead by Prof. Dr. Thomas Friedli

Key Facts

10 years of experience in pharmaceutical OPEX Benchmarking!
➢ Our database consists of 277 production sites from over 122 different companies (2014)

As university we are independent!
➢ We are an independent benchmarking centre at an university with strong focus on research in OPEX

Transfer of academic knowledge into practice!
➢ We conduct projects based on your real needs and provide know-how from methodological, operational and strategic support

The St.Gallen OPEX Books

“Operational Excellence in the Pharmaceutical Industry”
Friedli et al. (2006), Editio Cantor

“The Pathway to Operational Excellence in the Pharmaceutical Industry”
Friedli et al. (2010), Editio Cantor

“Leading Pharmaceutical Operational Excellence”
Friedli et al. (2013), Springer

Activities

▪ OPEX Benchmarking: The largest independent OPEX database of pharmaceutical production sites - worldwide
▪ OPEX assessment on site and network level
▪ Identification of site complexity drivers & the impact of OPEX
▪ OPEX workshops and training based on individual needs
▪ Process mapping and analyses of as-is processes and derivation of improvement potential

Project Partner

[Logos of various companies]
ASIA CONNECT Center (ACC-HSG)

The ASIA CONNECT Center (ACC-HSG) is lead by Prof. Dr. Roger Moser who also serves as Visiting Faculty at IIM Bangalore and Adjunct Professor at IIM Udaipur

Key Facts

Supporting Indian companies in Europe and European companies in India – ACC-HSG provides:

- Access to local industry experts in India and Europe to develop better business models in new markets and understand how the future industry environment in India respectively Europe looks like for foreign companies
- Access to local decision makers in India and Europe through its academic partners University of St.Gallen, IIM Bangalore and IIM Udaipur

As ACC-HSG we are independent!

- ACC-HSG is NOT a consultancy but is an integrated part of the University of St.Gallen; we provide independent advice to European and Indian companies along their market entry and expansion activities in foreign markets

ACC-HSG service offerings:

- Industry & Cluster Intelligence studies to support market entry/ expansion strategies
- Intercultural management support to make better decisions and design processes across cultures

Activities

- Conducting Industry Intelligence studies based on a proprietary Delphi software to provide decision makers with key insights about how the institutional environment in an industry in Europe or India looks like in the future
- Conducting Intercultural Management studies to improve your managerial interaction as well as your process design when dealing with different cultures
- Conducting Cluster Intelligence studies to tell you where you need to invest, look for suppliers or search for new IP

Academic Partners

IIM Bangalore and IIM Udaipur are the Indian partners of the ASIA CONNECT Center to jointly do studies in India while ACC-HSG is their partner supporting studies for Indian companies in Europe

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Indian Pharmaceutical Association (IPA)

The IPA is led by Dr. Rao Vadlamudi as the President and a team of 10 office bearers

Key Facts

The Indian pharmaceutical association (IPA) is a not-for-profit premier association with over 10,000 members from pharmaceutical profession spread across India:

- 75 years of existence
- 19 State and 30+ local branches across India
- Representation on international pharmaceutical associations and government of India in their council and statutory bodies
- Training and development in advances of science
- Recognition of pharmacy professionals contributions through awards and fellowships
- Sensitizing through advocacy initiatives by representing issues concerning pharmacy profession to government
- Networking through five divisions, viz. community pharmacy, education, hospital, industry and regulatory affairs divisions
- Vibrant students’ forum
- Promotion of ‘Good Pharmacy Practice’ among Community and Hospital Pharmacist in partnership with leading pharmaceutical companies and Hospitals

Activities

- Organization of annual conventions (e.g. International Pharmacist Day – September 25th every year)
- Knowledge sharing through training workshops & seminars
- Promotion of pharmacy profession (National Pharmacy Week)
- Supporting of research activities through scientific publications in the Indian Journal of Pharmaceutical Sciences
- Publication of IPA activities, articles of current interest, news, book reviews through monthly publication (Pharma Times)

Project Partner

[Images of logos from various organizations]
Agenda

1. Authors of the Delphi Study
2. Goals of the Delphi Study
3. Methodology and Background of the Delphi Study
4. Key Outcomes of the Delphi Study
5. Overview of the Selected Projections
6. Detailed Results of the Delphi Study
7. Contact
Goals of the Delphi Study

Operational Excellence in the Indian pharma industry

- Paint a more solid picture of the most likely developments in regards to Operational Excellence in the Indian pharma industry
- Facilitate the discussion between experts from different backgrounds
- Provide practitioners with exclusive industry intelligence
- Make a valuable contribution in order to strengthen the future competitiveness of the Indian pharma industry
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## Methodology of the Delphi Study

**Definition of Relevant Projections**
- Definition of projections in regards to the development of OPEX within the Indian pharma industry **based on literature review**
- Modification of projections based on **interviews with industry experts**
- Definition of **10 final projections** and starting of the real-time online Delphi study

**Initial Assessment of Projections**
- Industry experts assess the projections on the **Delphi online platform**
- Every expert gives **quantitative estimates** for each projection with regard to:
  - Probability to come true
  - Importance/Impact on the future development
- In addition experts can add **qualitative arguments** for their decisions

**Reconsideration of Initial Assessment**
- After the first round, each expert is able to see the assessment as well as the arguments of the other participants
- The experts are thus able to **reconsider their own assessment** based on the reasoning of the other participants
- **Iterative process** until each expert has reached his final assessment

**Evaluation of the Delphi Study**
- **Consolidation of quantitative & qualitative results** with focus on:
  - Probability to come true
  - Importance/Impact on the future development
  - Consensus among the participants
- **Summary of the key outcomes** for each projection
- **Citation of key comments** of the expert panel

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**Delphi Study with 70 participants to assess the current and future state in regards to Operational Excellence in the Indian pharma industry**
Background of the Delphi Study

Terminology, key facts, and platform

Terminology

- **Probability**
  - Measures the expected probability of each projection to come true
  - Metric scale (0-100%)

- **Consensus**
  - Measured using the interquartile range (IQR)
  - The IQR is the measure of dispersion for the median and consists of the middle 50% of the observations

- **Importance/Impact**
  - Measures the importance/impact on the future development of the Indian pharma industry
  - 5 point Likert Scale

Real-Time Online Delphi Platform

Key Facts

- **No. of Participants**
  - 70 experts answered all questions

- **No. of Comments**
  - 539 comments by participants
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Key Outcomes of the Delphi Study

Operational Excellence in the Indian pharma industry

- The considerable number of participants (70 experts answered all questions) confirms that OPEX has great significance for the Indian pharma industry.

- Although there is strong dissent among the respondents of the Delphi study, overall the expert panel estimates all defined projections likely to come true (average 63%).

- Moreover the expert panel rates the impact of these projections on the future development of the Indian pharma industry as very high (average 4.4 on a likert scale).

- These results exhibit that the Indian pharma industry is on the right path to align with global standards and thus to increase its overall competitiveness.
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Overview of the Selected Projections

Ten projections to assess the most likely developments in the Indian pharma industry

1. In 2018, more than 90% of the Indian domestic pharma companies strive beyond compliance and aim for real Operational Excellence.

2. In 2018, the internal quality systems of more than 90% of the Indian domestic pharma companies are designed to ensure continuous improvement.

3. In 2018, Operational Excellence is understood on management as well as on shop floor level and recognized as competitive advantage for the Indian domestic pharma companies.

4. In 2018, product quality has replaced costs as main competitive advantage for more than 90% of the Indian domestic pharma companies.

5. In 2018, the new product pipeline of the most advanced Indian domestic companies competes with the pipeline of established western companies in major pharma markets outside India.

6. In 2018, the Indian domestic pharma industry is recognized as a reliable partner by international pharma companies in terms of product supply on time in the right quality and quantity.

7. In 2018, globally leading regulatory authorities do not perceive Indian domestic pharma companies as potential risks of the global pharmaceutical supply chain.

8. In 2018, the level of qualification (directly related to the production of drugs) on the shop floor in Indian domestic pharma companies is as high as the level in Europe.

9. In 2018, Indian domestic pharma companies are not cited by the US FDA for fake data.

10. In 2018, the management of domestic pharma companies has established a failure culture in which failures are seen as a chance to improve.
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Projection 1

*OPEX Implementation Level*
Projection 1 – Results of Expert Panel

**OPEX implementation level**

**Description**

In 2018, more than 90% of the Indian domestic pharma companies strive beyond compliance and aim for real Operational Excellence

**Key Conclusions**

- The industry experts rate the probability of reaching this objective as 63%, with approximately 2 of 4 experts rating the likelihood somewhere between 41% and 80%.
- Although there is strong dissent among the participants on this projection, its impact on the future development is seen on a very high level (4.5).
- Some experts see a lack of commitment from Top Management and most of the companies putting efforts towards OPEX only when being forced to.
- On the other hand experts opine, that a high focus is set on OPEX and that Indian pharma companies believe that this will help them to increase their competitiveness within the highly competitive global market.
Projection 1 – Key Comments of Expert Panel

**OPEX implementation level**

**Description**

In 2018, more than 90% of the Indian domestic pharma companies strive beyond compliance and aim for real Operational Excellence

**Low Probability**

- “90% is a way to high number.”
- “I audit many Indian pharma companies and I don’t see any efforts towards OPEX.”
- “Lack of commitment from Top Management regarding integrity.”
- “Typically they don’t do it unless forced to.”
- “Still some of the companies don’t have a focus on OPEX and other related areas.”
- “Many of domestic pharma companies are not even aware of the OPEX initiatives. It will take time to understand and employ resources to carry this forward.”
- “Cost effectiveness, lack of progressive vision, old generation business and resistance to change current profitable model.”
- “Most of Indian pharma companies are in the SME sector and operate domestically. There is no incentive for them to aim for real OPEX. It will be great if they can reach at least compliance level.”

**High Probability**

- “Operational Excellence will help to increase competitiveness.”
- “As the world market is becoming more competitive, everyone has to upgrade to better standards as part of survival and growth strategy.”
- “Perception of quality standards is changing in peoples minds and companies can survive and grow only with Operational Excellence.”
- “OPEX will define market position and market share and mere compliance will only let me stay in business (not excel).”
- “We generate too much waste and overdoing things many times without questioning why. Science driven approaches are lacking.”
- “My belief is that extremely high focus on compliance might have lead to built up of waste in the processes, which needs to be tackled.”
- “Top 20 pharma companies will be investing over $8 Billion in the next few years on facilities, equipment, R&D and high-end compliance consulting services primarily driven by the series of US FDA and EU-GMP observations.”

**Results (Statistical Group)**

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<tr>
<th>Probability in %</th>
<th>Consensus</th>
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Likely Strong Dissent High
Projection 2

Goals and Design of Internal Quality Systems
Projection 2 – Results of Expert Panel

Goals and design of internal quality systems

Description

In 2018, the internal quality systems of more than 90% of the Indian domestic pharma companies are designed to ensure continuous improvement.

Key Conclusions

- From the perspective of the expert panel it seems likely (64%) that in 2018, the internal quality systems of most of the Indian pharma companies will be designed to ensure CI, but still there is strong dissent among the participants.
- The experts rate the impact of this projection on the future development of the Indian pharma industry as very high (4.6).
- Several experts say that the Indian QMS are in place to ensure passing US FDA inspections, not CI, and that a quality culture needs to be built up.
- However most of the participants opine that the cost of non-compliance is becoming more evident to most of the Indian pharma companies and that in long term, quality will sustain the business and thus there is a strong need for CI.

CI: Continuous improvement
Projection 2 – Key Comments of Expert Panel

Goals and design of internal quality systems

Description

In 2018, the internal quality systems of more than 90% of the Indian domestic pharma companies are designed to ensure continuous improvement.

Results (Statistical Group)

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</table>

Low Probability

- “Professionalism is lacking. Quality culture needs to be built up.”
- “Indian QMS are in place to ensure passing US FDA scrutinies, not CI.”
- “There may still be many small companies which may not have access to CI methodologies or leadership trained in applying these.”
- “Level of statistical know-how is low in the pharma sector - their primary focus is on keeping the system in a corrective action mode.”
- “It is the attitude of the Indian pharma entrepreneurs to play short cuts and work for short term benefits. As such they have low value for the quality systems. For them only ultimate results count and they work to meet the basic requirements and are not willing to surpass or excel.”
- “The low retail prices due to DPCO will not allow them to spend money on improving quality systems.”
- “Large numbers are involved only in getting their products manufactured and selling it. Professionalism is at back seat.”

High Probability

- “The cost of non-compliance with increasing regulatory standards is becoming evident to most Indian pharma companies.”
- “Majorities of companies will be working in regulated market and hence CI will be required in addition to compliance.”
- “Companies have realized that in long term, quality will sustain the business and there is need for CI.”
- “Global status of Indian pharma industry will necessitate excellence and improvement including in response to regulatory guidelines.”
- “With increased audit transparencies between various regulatory authorities it will be important for everyone to upgrade their internal standards as part of CI. Better tools are available to find deviations and this will influence the approach towards quality.”
- “It is easier to say so then reality. But, most of the export oriented companies will have to opt for CI. However there is also need to develop trained & skilled workforce for successful implementation.”

CI: Continuous improvement
Projection 3

OPEX Recognized as Competitive Advantage
Projection 3 – Results of Expert Panel

*OPEX recognized as competitive advantage*

Description

In 2018, Operational Excellence is understood on management as well as on shop floor level and recognized as competitive advantage for the Indian domestic pharma companies.

Key Conclusions

- According to the expert panel the projection of OPEX being recognized as competitive advantage is likely to come true, with more than 3 of 4 participants of the study expecting a high likelihood (66%).
- Following the results of the two previous projections, the participants estimate the impact on a high level (4.4).
- On one hand experts believe that very few companies really understand the concept of OPEX and that it would be difficult to achieve awareness at all levels as many of the employees are not aware or trained on these aspects.
- On the other site experts opine that Indian pharma companies are recognizing that to continue export business the key driver is compliance and OPEX and investments will be decided based on long-term operational and compliance objectives.

Results (Statistical Group)

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Probability (Detailed)

Share of Expert Panel, in %

- 0-20: 11
- 21-40: 29
- 41-60: 37
- 61-80: 20
- 81-100: 0
Projection 3 – Key Comments of Expert Panel

OPEX recognized as competitive advantage

Description

In 2018, Operational Excellence is understood on management as well as on shop floor level and recognized as competitive advantage for the Indian domestic pharma companies

Low Probability

- “Very few domestic companies understand Operational Excellence”
- “Operational Excellence is not necessarily a competitive advantage.”
- “The concept of Operational Excellence is not that easy to be understood. Most of the people who run the domestic pharma industry do not understand this concept as on today. Even if they are trained it will take time to change their mind set. Going to shop floor is a dream for Indian pharma industry.”
- “Less knowledge and expertise available in OPEX domain. this also may have some influence on capital expenditure budget.”
- “It would be difficult to achieve awareness at all levels as many of the employees are not aware or trained on these aspects.”
- “It also depends on the attitude & culture of Top Management.”
- “Time for training is not made available”
- “Worker level education is the missing link”

High Probability

- “Cost competitiveness and excellent quality is the key to success in current/ future scenario. Hence requires involvement of one and all.”
- “Top Management is recognizing that to continue export business the key driver is compliance and OPEX and investments will be decided based on long-term operational and compliance objectives.”
- “Any business is a teamwork and involves management as well as shop floor. In the present scenario of all costs going up, the efforts have to be concentrated on understanding and implementing the Operational Excellence measures. This is vital for survival.”
- “An OPEX program in any organization is a Top Management driven program. Hence success of the program depend all upon how Top Management support OPEX initiatives in the organization.”
- “Understanding Operational Excellence at shop floor level needs continuous interactions and motivations”
- “While it is understood at some levels, it is still not grown as culture.”

Results (Statistical Group)

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Projection 4

*Product Quality Understood as Competitive Advantage*
Projection 4 – Results of Expert Panel

Product quality understood as competitive advantage

Description

In 2018, product quality has replaced costs as main competitive advantage for more than 90% of the Indian domestic pharma companies.

Key Conclusions

- There is strong dissent among the participants of the study in regards to the projection of product quality replacing costs as main competitive advantage for Indian pharma companies.
- Nevertheless most of the experts expect the projection to come true (61%) and they attach a high importance to it (4.2).
- Several experts say that most of the Indian pharma companies have a cost based strategy and changing this paradigm in a price conscious market like India, with low health coverage, constitutes really a difficult task.
- However the majority of the experts opine that product quality is the only way to survive on the global market, especially against the background of the growing demand for high quality drugs and the globally increasing regulatory scrutiny.

Results (Statistical Group)

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Probability (Detailed)

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<th>Share of Expert Panel, in %</th>
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Projection 4 – Key Comments of Expert Panel

Product quality understood as competitive advantage

Description

In 2018, product quality has replaced costs as main competitive advantage for more than 90% of the Indian domestic pharma companies

Results (Statistical Group)

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Low Probability

- “The costs will always be the most important criteria.”
- “Most of the domestic pharma companies have a cost based strategy. Changing this paradigm is really a difficult task in India.”
- “In a price conscious market like India, with low health coverage, pricing is important. The common perception of Indian consumer is that quality of medicines in India is "good enough".”
- “DPCO controls, cost competitiveness with very low operating margins among domestic players is a concern area.”
- “It depends on the culture & attitude of Top Management - is it for quality or quantity?”
- “Indian pharma companies survive on their cost competitive edge and this commercial reason had been the main driver so far for the rapid growth of the industry. Quality comes at a cost which was not accounted for. This additional investment will make the companies no longer competitive - cost-wise.”

High Probability

- “Product quality will be a competitive advantage especially with the strong competitors on the market.”
- “Yes, quality is the only way to survive from global market as end users get well educated about the usage of the products.”
- “Main reason Indian pharma companies have got global respect is due to complete focus on quality as cost is any way lower, but key is to deliver world class quality consistently.”
- “With increased regulatory scrutiny, quality will be top priority for every company in the area of exports and simultaneously there are likely to be more stringent regulations by Indian government.”
- “With awareness of QBD concepts, pharmacovigilance and economics there will be increasing demand for quality to achieve more safety.”
- “There is a growing demand for goods with high quality which have to meet international standards. Hence, the quality takes precedence over cost advantage in international business for pharma goods.”
Projection 5

Product Competitiveness of Indian Pharma Companies
Projection 5 – Results of Expert Panel

*Product competitiveness of Indian pharma companies*

**Description**

In 2018, the new product pipeline of the most advanced Indian domestic companies competes with the pipeline of established western pharma companies in major pharma markets outside India.

**Key Conclusions**

- There is strong dissent among the expert panel with regard to the projection of Indian pharma companies having a new product pipeline that is able to compete with the pipeline of established western pharma companies.
- The experts seem to be relatively undecided as the probability is estimated at 53% and no value range really stands out. The assessed impact of this projection has an average value of 4.1.
- As new product pipelines require huge investments and the development of new molecules is a lengthy and risky process multiple experts don’t expect this projection to come true.
- On the other hand many participants see India as a future hub for many new molecules. As a fast growing economy India will be increasingly showing presence in research based companies that will be at par with western companies.

**Results (Statistical Group)**

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**Probability (Detailed)**

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Projection 5 – Key Comments of Expert Panel

Product competitiveness of Indian pharma companies

Description

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Likely          Strong Dissent        High

Low Probability

- “No as major pharma companies deal with generic market. New product pipeline requires huge investment and management will.”
- “The scale of Indian pharma in 4 years will still not be at the level that they can compete on research on molecules.”
- “Indian pharma companies lack financial muscle and/ or mindset on the development of new molecules.”
- “Drug discovery is lengthy, expensive & risky. IPM does not have the skill set and deep pockets to develop rich product pipeline”
- “There is hardly any real R&D taking place in Indian companies. Unlike the western pharma companies, which invest around 10% of their profits in the research of new drugs, Indian pharma companies in general are happy to copy the new products of the multinationals.”
- “It is unlikely due to high investment requirements. However, Indian domestic pharma companies have initiated such projects and some successes can be expected.”

High Probability

- India is a developing hub for many new molecules.”
- “Indian companies are exploring and slowly graduating to be in the group of NCE innovators, or partnering for growth.”
- “R&D in Indian pharma industry is getting spruced up so we might touch that figure”
- “Indian pharma companies have the talent pool, but it needs to be utilized more ethically which will be a good sign for future.”
- “India is a growing economy and it will be increasingly showing presence in research based companies.”
- “Advanced Indian pharma companies are already at par with the generic products of established western pharma companies and will further align closer in 2018. The key drivers to new product pipelines are poor margins from domestic sales, increased speed/ automation of patent and regulatory filings and approvals as well as new facilities resulting from the investments as answered for projection 1.”
Projection 6

*International Reputation of the Indian Pharma Industry*
Projection 6 – Results of Expert Panel
International reputation of the Indian pharma industry

Description

In 2018, the Indian domestic pharma industry is recognized as a reliable partner by international pharma companies in terms of product supply on time in the right quality and quantity.

Key Conclusions

- According to the expert panel the projection of Indian pharma companies being recognized as a reliable partner by global partners is likely to come true, with more than 3 of 4 experts estimating a high probability (68%).
- Moreover the participants evaluate this projection as highly important, as the impact on the future development of the Indian pharma industry exhibits a value of 4.4.
- One part of the expert panel expects only a few companies to achieve this by 2018. To reach the level of western companies in regards to quality compliance a longer period is foreseen.
- The majority of participants opine that India is already a major player and that India is expected to retain its position because of its quality drugs supply at competitive costs (India has the highest number of US FDA approved manufacturing facilities).

Results (Statistical Group)

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<td>68</td>
<td>30</td>
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Likely  Strong Dissent  High

Probability (Detailed)

Share of Expert Panel, in %

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<th>Probability, in %</th>
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<th>21-40</th>
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<td>11</td>
<td>27</td>
<td>37</td>
<td>21</td>
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</tr>
</tbody>
</table>
Projection 6 – Key Comments of Expert Panel

International reputation of the Indian pharma industry

**Description**

In 2018, the Indian domestic pharma industry is recognized as a reliable partner by international pharma companies in terms of product supply on time in the right quality and quantity.

**Low Probability**

- “By 2018 almost all of the top 20 Indian pharma companies will be either on a warning letter, enforcement actions, etc., which will account for loss of sales in mega terms. US FDA/EU-GMP are already working on managing drug shortage issues, meaning that they expect more enforcement actions. To bring back the Operational Excellence and quality compliance culture at par with western companies a minimum period of 10 years is foreseen (2024).”
- “Only a few (3-5) companies will achieve this by 2018 - ongoing GMP remediation expected due to US FDA and MHRA warning letters.”
- “Indian pharma companies are yet to meet these expectations of international pharma companies and the current trend does not provide that confidence, especially the regulatory compliance.”
- The big question comes as to who will authorize the scrapping of old, non-compliant investments and agree on fresh investments which meet or exceed the operational quality compliance objectives.”

**High Probability**

- “With focus on quality and overall quality culture in the country improving, I expect a very high percent of companies being regarded as reliable partners.”
- “IPM has matured and has the highest number of US FDA approved manufacturing facilities, ANDAs, DMFs and FTFs outside US which shows its competence level.”
- “India is already a major player and is expected to retain its position because of its quality medicines supply at competitive cost.”
- “More and more international pharma companies are starting their operations in India or they are partnering with Indian companies to expand their supply chain. We can see upward trend in the same with increase in quality & other aspects of products from India.”
- “The good ones are doing it and thus India has achieved high exports to so many countries. Quality is a issue though, and hanky panky by whatever the companies has to stop.”

**Results (Statistical Group)**

<table>
<thead>
<tr>
<th>Probability</th>
<th>Consensus</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>68 in %</td>
<td>30</td>
<td>4.4</td>
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</tbody>
</table>

Likely Strong Dissent High
Projection 7

Indian Pharma Industry Not Perceived as a Risk
Projection 7 – Results of Expert Panel

*Indian pharma industry not perceived as a risk*

**Description**

In 2018, globally leading regulatory authorities do not perceive Indian domestic pharma companies as potential risks of the global pharmaceutical supply chain.

**Key Conclusions**

- While there is moderate dissent among the experts whether globally leading regulatory authorities will not perceive Indian pharma companies as potential risks, overall the panel rates the projection as likely (59%).
- Furthermore the participants rate the impact of this projection on the future of the Indian pharma industry as high (4.5).
- Few experts don’t expect much improvement in the near future and regard Indian pharma companies as potential regulatory risks in future as well. Unless drastic steps are taken, they don’t expect the situation to improve, but to deteriorate.
- On the other hand approximately 3 of 4 participants opine that although bad events in the past will have an impact, CI and quality supply will give confidence to leading regulatory authorities about capabilities of Indian companies.

**Results (Statistical Group)**

<table>
<thead>
<tr>
<th>Probability in %</th>
<th>Consensus</th>
<th>Impact</th>
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<tbody>
<tr>
<td>59</td>
<td>25</td>
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</tr>
<tr>
<td>Likely</td>
<td>Moderate Dissent</td>
<td>High</td>
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</tbody>
</table>

**Probability (Detailed)**

[Bar chart showing the distribution of expert opinions across different probability ranges.]
Projection 7 – Key Comments of Expert Panel

Indian pharma industry not perceived as a risk

Description

In 2018, globally leading regulatory authorities do not perceive Indian domestic pharma companies as potential risks of the global pharmaceutical supply chain.

Low Probability

- “Bad events in the past will still have an impact.”
- “The current regulatory issues faced by Indian pharma companies prove that they will be potential regulatory risks in future as well. Not much improvement expected in the near future.”
- “Unless drastic steps are taken, the situation shall deteriorate.”
- “By 2018 global leading regulatory authorities will be sharing databases, information, expectations and audit observations in real time and enforcements will be rapid and concerted efforts. This will be primarily driven by analytic tools currently developed by US FDA/EU-GMP, which will focus on India and other developing countries. Perceptions of data falsifications will be an all-time high and will result in more sanctions. This will result in a surge back of the western companies margins as they gain more profits due to sales as their price point competitions are no longer viable and found as risk for the supply chain.”

High Probability

- “Continual improvement and quality supply will give confidence to global regulatory authorities about capabilities of Indian companies.”
- “In spite of NTB/TBT efforts the affordable access to quality generics will drive the supply chain”
- “It depends on how management empowers QA/QC departments.”
- “Concerns from leading RAs would keep lowering from current level as Indian pharma companies become ready to accept the feedback and improve. RA and industry need to work as partners in growth.”
- “Though bad events in the past will still have an impact, continuous improvement and quality supply will give confidence to global regulatory authorities about capabilities of Indian companies.”
- “If the compliance is improved and training is done religiously, this is not at all difficult for Indian pharma companies.”
- “IPM has to overcome its challenge about data integrity and GMP compliance. If this is achieved, it can be globally competitive.”

Results (Statistical Group)

<table>
<thead>
<tr>
<th>Probability in %</th>
<th>Consensus</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>59</td>
<td>Moderate Dissent</td>
<td>High</td>
</tr>
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</table>
Projection 8

Level of Qualification on Shop Floor Level
In 2018, the level of qualification (directly related to the production of drugs) on the shop floor in Indian domestic pharma companies is as high as the level in Europe.

**Key Conclusions**

- The expert panel shows moderate consensus on the projection of Indian domestic pharma companies reaching the level of qualification on shop floor level of western companies, overall the panel estimates the projection likely to occur (67%).
- More than half of the respondents rate the probability greater than 61% and see this projection having a high impact (4.3).
- Few experts opine that it will take a lot of time to build up the corresponding education systems. Unless shop floor operators acquire professional skills the desired level cannot be achieved.
- On the other hand most of the participants are of the opinion that there is already a change seen in terms of reaching this goal. India has a high availability to qualified workers and one of the best education standards in the world, nevertheless the education should be supplemented by practical exposure.
# Projection 8 – Key Comments of Expert Panel

## Level of qualification on shop floor level

### Description

In 2018, the level of qualification (directly related to the production of drugs) on the shop floor in Indian domestic pharma companies is as high as the level in Europe.

### Low Probability

- “Shop floor operators learn on the job. This has to be complimented with professional skills and behavioural modification training. Unless this lacunae is corrected the desired level cannot be achieved.”
- “It will take a lot of time to build up the corresponding education systems.”
- “The contract employee concept that lowers the level in everything shall be prohibited in Indian pharma, as mindset to treat employee and work quality have a direct link. Hence existing level is lower compare to Europe. The direct work on shop floor is practically done by majority of contract employees (low paid, low educated).”
- “Indian pharma industry needs to hire professionals with pharmacy background in production and related areas to improve quality and process adherence. At the current speed it is unlikely to change drastically in the next few years, however in long term the Indian industry needs to rely heavily on trained pharma professionals.”

### High Probability

- “There is already a change seen in terms of reaching this goal.”
- “Probably this is possible, if the focus on training shop floor people is improved to a high level. It seems to be a possible task.”
- “With respect to availability of qualified persons, India would have the biggest pool of talents”
- “India has one of the best education standards in the world, the only thing is that this education has to be supplemented by practical exposure to make qualifications more job oriented.”
- “Easy availability of qualified graduates and post graduates and increased penetration of private educational institutions. This is reinforced by emphasis on training and skill development by GOI.”
- “Shop floor operations will be a key driver for the foreseen improvements in OPEX and quality compliance. Large investments in trainings, systems implementations, compliance applications, etc. will be key drivers towards improving the level of qualification.”

### Results (Statistical Group)

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<th>Probability in %</th>
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Likely Moderate Consensus High
Projection 9

No Fake Data Provided by Indian Pharma Companies
Projection 9 – Results of Expert Panel

No fake data provided by Indian pharma companies

Description

In 2018, Indian domestic pharma companies are not cited by the US FDA for fake data

Key Conclusions

- Although there is strong dissent among the experts, overall the panel rates the probability of Indian pharma companies not being cited by the US FDA as likely (65%).
- Moreover, the respondents of the study rate the impact of this projection on the future development of the Indian pharma industry as high (4.4).
- One part of the participants state that the actual status is not expected to change significantly until 2018, unless there is a drastic cultural change and improvement in the moral values of the Indian society.
- The majority of experts opine that especially with the US FDA putting pressure on Indian pharma companies and increasing the number of inspections, the current scenario is definitely going to improve towards ensuring data integrity.

Results (Statistical Group)

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<tr>
<th>Probability in %</th>
<th>Consensus</th>
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Probability (Detailed)

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<th>Probability, in %</th>
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</table>
Projection 9 – Key Comments of Expert Panel

No fake data provided by Indian pharma companies

Description

In 2018, Indian domestic pharma companies are not cited by the US FDA for fake data

Low Probability

- “As fake data is a matter of habit and habit takes long time to change.”
- “It seems to be difficult to achieve this level in just 4 years. It may take about 5-7 years. Here they have to do lot of hard work and sincere efforts.”
- “The status is not expected to change significantly until 2018, unless there is drastic cultural change and improvement in the moral values of the society.”
- “This will depend on the management’s willingness to implement proper quality systems Companies which are looking for export to the USA have to enforce this practice from top down to meet the requirement of the US FDA.”
- “This is an utopian statement which will not happen as data falsification issues are not just about culture. The technical aspects to such issues can be modified. However, the controls need to be implemented with automated workflows for compliance.”

High Probability

- “Indian pharma companies are conscious and are working towards ensuring data integrity and single minded focus on compliance.”
- “Improvements with respect to expectations from the US FDA would be substantially grown by that time.”
- “With the consistent increase in US FDA interventions among Indian pharma companies, surprise visits, opening office and posting permanent staff in India, and also cases of huge financial punishment for data forging or not meeting compliances, current scenario is definitely going to improve a lot by 2018.”
- “With US putting pressure on IPR compliance amongst others, data integrity will be of paramount importance. Additional thrust on operational efficiency and total automation in future will ensure that the data is not faked.”
- “I am sure Indian companies will learn from their mistakes or other case studies and will take timely action/ control of the situation. The risk of ignoring alarm signs is very high.”

Results (Statistical Group)

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Likely | Strong Dissent | High
Projection 10

Establishment of a Failure Culture
Projection 10 – Results of Expert Panel

Establishment of a failure culture

Description

In 2018, the management of domestic pharma companies has established a failure culture in which failures are seen as a chance to improve.

Key Conclusions

- There is strong dissent among the expert panel regarding the projection, whether the management of Indian pharma companies will have established a failure culture in 2018.
- However the overall results show that this projection is likely to come true (59%) and that it will have a high impact on the future development of the Indian pharma industry (4.5).
- Several experts opine that this is a very high level of maturity in regards to quality culture and that to reach this state, a lot of cultural barriers would have to be overcome, not expecting this projection to come true within the next 4 years.
- On the other hand most of the participants are of the opinion, that this scenario is already seen today and that it will be more established in the future, as the entire culture and environment in India are making huge improvements.

Results (Statistical Group)

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Likely Strong Dissent High

Probability (Detailed)

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<td>81-100</td>
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Probability, in %
Projection 10 – Key Comments of Expert Panel

Establishment of a failure culture

Description

In 2018, the management of domestic pharma companies has established a failure culture in which failures are seen as a chance to improve.

Low Probability

- “Absolutely sarcastic.”
- “For this a lot of cultural barriers would have to be overcome.”
- “So far this aspect has not been addressed.”
- “This is a very high level of maturity in quality and I expect it to take some more time than only 4 years.”
- “It seems to be a remote opportunity for domestic companies. The situation prevailing is bad at present.”
- “Major Indian companies try to do the right thing the very first time... as failure may cost a huge punishment.”
- “This may not happen as most of the Indian pharma companies are family owned and are not professional. Not many pharma companies learn from the past mistakes. The culture here is to hire and fire.”
- “The attitude to have immediate financial returns on investment may not allow such attitude and there would be a lot of replacement for staff available.”

High Probability

- “This is seen today also and will be more established in future.”
- “The entire culture and environment shall improve by 2018.”
- “It is very much dependent on the willingness of Top Management to implement a culture of quality for system improvement and reduction in failures. Failure should not only be considered for improvement. However, systems need to be robust enough to avoid failures. Moreover, failure should always be taken as a challenge to make the system perfect.”
- “I agree with the statement made. However, this can result in either overspending for quality and losing the competitive edge - cost-wise and hence the evolved companies have to tread the tightrope of rapid investments in quality compliance tools and applications with steady focus on the ROI and engaging the best consultants without compromising on their purchasing and negotiation skills.”
- “Major pharma companies are on the path of growth which is not possible without improvements from failure.”

Results (Statistical Group)

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Likely Strong Dissent High
Overview of the Delphi Study Results

Assessment of the impact and probability for each projection to come true

1. In 2018, more than 90% of the Indian domestic pharma companies strive beyond compliance and aim for real Operational Excellence
2. In 2018, the internal quality systems of more than 90% of the Indian domestic pharma companies are designed to ensure continuous improvement
3. In 2018, Operational Excellence is understood on management as well as on shop floor level and recognized as competitive advantage for the Indian domestic pharma companies
4. In 2018, product quality has replaced costs as main competitive advantage for more than 90% of the Indian domestic pharma companies
5. In 2018, the new product pipeline of the most advanced Indian domestic companies competes with the pipeline of established western companies in major pharma markets outside India
6. In 2018, the Indian domestic pharma industry is recognized as a reliable partner by international pharma companies in terms of product supply on time in the right quality and quantity
7. In 2018, globally leading regulatory authorities do not perceive Indian domestic pharma companies as potential risks of the global pharmaceutical supply chain
8. In 2018, the level of qualification (directly related to the production of drugs) on the shop floor in Indian domestic pharma companies is as high as the level in Europe
9. In 2018, Indian domestic pharma companies are not cited by the US FDA for fake data
10. In 2018, the management of domestic pharma companies has established a failure culture in which failures are seen as a chance to improve

The results of the Delphi study exhibit a high importance/impact as well as a substantial probability for each projection to occur.
Agenda

1. Authors of the Delphi Study
2. Goals of the Delphi Study
3. Methodology and Background of the Delphi Study
4. Key Outcomes of the Delphi Study
5. Overview of the Selected Projections
6. Detailed Results of the Delphi Study
7. Contact
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