Quality excellence: The next frontier for the Indian pharmaceutical industry

Indian Pharmaceutical Alliance
QUALITY means doing the right thing when no one is looking

Henry Ford
Indian pharma is a significant contributor to global public health

- 60% of global vaccine production
- 30%+ annual UNICEF supply globally
- 60%+ of global supply of ARV drugs
- 40-70% of WHO demand for DPT & BCG
- 90% of WHO demand for measles vaccine
Indian pharma has been able to deliver this impact due to its **distinctive capabilities**

1. **Manufacturing capabilities**
   - Highest number of US FDA-registered facilities outside US (379 facilities)
   - 1400+ WHO GMP certified plants; 800+ UK MHRA certified sites

2. **Product development capabilities**
   - 37% of total ANDA approvals
   - 22% of the approvals in specialty generics

3. **Process innovation capabilities**
   - One of the world leaders in efficient and cost competitive API manufacturing
Quality in pharma has been an increasing concern, both globally and in India.

1. Between 2008 and 2014, the number of product recalls and warning letters to pharma companies globally tripled.

2. At least one pharma facility worldwide has entered into a consent decree every year since 2008 globally.

3. 30% of quality related warning letters are attributed to India.

4. 10% of OAI inspections and 4% of drug recalls in last 5 years are from India.
Indian companies in other sectors have continuously received recognition for **Quality excellence**

**Sector specific accolades**

<table>
<thead>
<tr>
<th>Sample sector</th>
<th>Player</th>
<th>Award</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steel</td>
<td>Tata Steel</td>
<td>▪ Deming Grand prize</td>
<td>2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ A320 best operational excellence</td>
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<tr>
<td>Auto components</td>
<td>Rane</td>
<td>▪ Deming Grand Prize</td>
<td>2013</td>
</tr>
<tr>
<td>Infra-structure</td>
<td>Delhi IGI</td>
<td>▪ #1 airport by size</td>
<td>2014</td>
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<td></td>
<td></td>
<td>▪ #5 airport by region (Asia Pacific)</td>
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</tr>
<tr>
<td>Aviation</td>
<td>IndiGo</td>
<td>▪ A320 best operational excellence</td>
<td>2014</td>
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Indian pharma could achieve quality excellence by focusing on six improvement areas

1. Establishing robust and seamless data management and documentation
2. Ensuring effective and robust investigations
3. Aligning management systems with increasing operational complexity
4. Expanding and upskilling talent pool
5. Embedding quality into product development and technology transfer
6. Building a culture of quality across the organization
Pharmaceutical companies need to take a holistic approach by building ‘Quality’ into three systems.

- Build managerial capability to lead quality and a culture of quality on the frontline.
- Build quality across product lifecycle and across the value stream.
- Capture and mitigate emerging risks early through predictive metrics and robust continuous improvement systems.
Potential steps for key stakeholders – individual companies

- Evaluate and **upgrade QMS**
- Embed quality **across product lifecycle**

- Embed a **culture of quality**
- Strengthen the **organization** with specialist roles
- Develop robust **capability building infrastructure**

- Harmonize **metrics driving accountability and collaboration**
- Adopt **predictive metrics** over and above output metrics
- Scale up **governance systems**
## Potential steps for key stakeholders - IPA

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
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<tbody>
<tr>
<td>1</td>
<td>Create guidelines</td>
</tr>
<tr>
<td></td>
<td>• Implementation oriented guidelines e.g. data reliability</td>
</tr>
<tr>
<td></td>
<td>• Multiple sources of insight – industry, regulators and experts</td>
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<tr>
<td>2</td>
<td>Facilitate creation of best practices</td>
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<tr>
<td></td>
<td>• Harmonized metrics – define and measure</td>
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<tr>
<td></td>
<td>• Creation of best practices on key quality processes</td>
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<tr>
<td>3</td>
<td>Evolve strong pool of talent</td>
</tr>
<tr>
<td></td>
<td>• Industry academia collaboration to ensure up to date curricula</td>
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<td></td>
<td>• Learning modules</td>
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</table>
Potential steps for key stakeholders –
**Government and regulators**

- **Guide companies and industry bodies** by providing feedback on guidelines, benchmarks and training modules under development

- Continue to **engage in periodic dialogue** to clarify industry’s understanding of guidelines, clauses and metrics
The IPA has already **begun the journey** towards quality excellence.
IPA commits to being **conduit of change** in the industry

**The start of a long journey ...**

Over next 5 years IPA will work to:

- Create **targeted guidelines** and best practices
- **Measure and benchmark** Indian pharmaceutical quality with the rest of the world and track progress
- Expand the skill and capability of **quality talent** for Indian pharmaceutical companies

IPA will develop a 5 year plan, with clear intermediate milestones over the next 12 months. IPA will also review progress annually and further refine the plan periodically.
Thank You
Management commitment to ‘Quality’

REMEmber, QUALity Is our top priority.

QUESTION: IS IT more important than safety?

Ooh... i forgot about that one.

QUESTION: IS QUALITY more important than obeying the law?

wELL, probably not.

If we could maximize shareholder value by selling lower quality items...

...wouldn’t we have a fiduciary responsibility to do it?

Hmm

I’m sure it’s in the top four.

What if we had to lie to achieve quality?
Indian pharma industry’s contribution to affordable healthcare

90% +
Drugs approved by US FDA for PEPFAR

33% +
Of all medicines dispensed in US by all generics. Significant contribution by India

USD 254 bn
Health system savings in US by all generics.

“Millions will die if India cannot produce new HIV/AIDS medicines in the future – it is a matter of life and death.”
— UNAIDS

“Generic medicines have saved the US health system USD 1.7 trillion from 2005 to 2014.”
— CDER, FDA
The Indian pharmaceutical industry has one of the largest number of manufacturing plants of international standards.

- **379** US FDA registered plants
- **1400+** WHO GMP certified sites
- **800+** UK MHRA certified sites
- **250+** EDQM approved plants
- **270+** PMDA (Japan) accredited sites
Evolution of the Indian pharmaceutical industry

Local capabilities

- API manufacturing
- Tablets
- Capsules
- Injectable
- Inhalers
- Controlled substances
- Patches
- Nasal, derma, ophthalmic, oral contraceptives, NDDS...

Strong technical capabilities

- Complex generics, complex technology platforms, NDDS

New entities

- Biologics
- NMEs/NCEs

# of DMF filings¹

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<tbody>
<tr>
<td># of DMF filings</td>
<td>22</td>
<td>112</td>
<td>3,400+</td>
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¹ Includes active Type II DMF filings
Inspections of Indian Pharma manufacturing sites by US FDA

Number of inspections went up in 2015

- Avg. 2011–14: 102
- 2015: 135

Proportion of OAI + VAI decisions has remained the same

- Share of global total 2011–14: 6% OAI, 11% VAI

OAI + VAI inspections

- Avg. 2011–14: *%
Regulatory actions on Indian pharma manufacturing sites by US FDA

- Warning letters: 102 (~2%)
- OAI inspections: 296 (~10%)
- Drug recalls: 6,604 (~4%)
Outstanding ‘Quality’ creates disproportionate upside

Intent to purchase
~1 million responses in surveys
Industry studies suggest, culture drives 30% of ‘Quality’ outcomes.
Indian players have been able to build a culture of quality and discipline.

- #1 ranked airport worldwide: Delhi International Airport; in the top 3 for 4 years in a row.
- Mumbai and Delhi airports are among the Top 5 airports in Asia-Pacific in terms of Airport Service Quality (ASQ).

- 10th best in cumulative air accidents record; ahead of US, UK, and France.
- Top 3 in Asia with a customer satisfaction score of 8/10.

- Indigo Airline won the Best Operational Excellence Award among 311 airlines; Top 10 in on-time performance in Asia-Pacific.

- Leaders in hospitality globally: Oberoi Group and Taj Hotels.
- Have properties ranked in Top 10 by Travel and Leisure magazine.
Management system — Build right leading metrics to **predict and correct** future quality challenges

**Pyramid of leading quality indicators**

**Correlation coefficients between quality metrics**
(Perfect correlation = 1.00)

- Consent decrees
- Warning letters
- 483s

<table>
<thead>
<tr>
<th>Yield rate</th>
<th>Human errors</th>
<th>Standard processes</th>
</tr>
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<tbody>
<tr>
<td>0.56</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.71</td>
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<td></td>
</tr>
<tr>
<td>0.91</td>
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</tbody>
</table>

- Regulatory actions
- # of recalls
- Complaints rate
- Rejects rate
- Deviation rate

Severe quality outcomes
Quality outcomes
Leading metrics
Contrary to popular perception, it is possible to measure quality culture.

**Capabilities**

- Patient focus
- Training
- Problem solving
- Recognition
- Metrics
- Knowledge
- Continuous improvement
- Dialogue
- Coaching
- Censibility
- Awareness
- Ethics
- Openness

SOURCE: POBOS Quality survey
Certain imperatives arise for all key stakeholders, individual companies, IPA and regulatory bodies.

1. **Pharma companies**
   - Diagnose and identify challenges
   - Prioritize based on risk
   - Design and implement solutions, both corrective and preventive

2. **Indian Pharmaceutical alliance**
   - Facilitate industry-wide collaboration, like creation of best practices and guidelines
   - Develop training content and industry-wide mechanisms

3. **Government and regulators**
   - Support the industry by providing inputs and feedback on initiatives by industry to ensure quality
   - Create platform for dialogue with pharmaceutical companies on regulations