IPA Quality Forum - Reflections on the journey so far

Conference document | 23rd Feb 2017
The IPA Quality forum was formed with a vision to help Indian Pharma Manufactures be the global benchmark in quality

Mission

- Be the conduit of change through thought leadership, knowledge development and best practice sharing
- Measure, benchmark and publicize the achievements of the Indian Pharma Industry in Quality
- Expand the skill and capability of Quality talent in India
- Deepen and strengthen the industry’s relationship with key stakeholders – both within India and globally!
- Provide platforms for members and other stakeholders to interact and network
Quality is never an accident. It is always the result of intelligent effort.

John Ruskin
We are adopting a comprehensive approach to design and drive our journey to build an industry leading quality position.
Building a distinctive Quality system - 6 core elements

1. Quality by design in product development
   - Designing products using QbD tools such as
     - Risk management
     - Design of experiments
     - Control strategies etc.

2. Robust technology transfer & feedback
   - Robust handover and codification of product/process knowledge from R&D to Operations
   - Ensure scalability by establishing linkage between product/process parameters and Quality attributes

3. World class supplier quality management
   - Stringent process capability and quality system requirements/checks at supplier
   - Collaborate with strategic suppliers to build their capability and improve process

4. Improve efficiency in operations
   - Improve productivity and asset utilization across manufacturing and quality, e.g.,
     - OEE improvement
     - Yield improvement
     - Batch disposition cycle time reduction

5. Proactive Quality Risk Management
   - Assess and control potential quality issues across lifecycle of legacy products
   - Reduce variabilities in key quality attributes by controlling process parameters, material attributes etc.
   - For example: Recall management, market complaint assessment etc.

6. Robust post-marketing processes
   - Improve performance/reduce variability on key post-marketing process that contribute to CoPQ
Building a distinctive Quality system - 4 key enablers

A. Strong shop-floor quality monitoring systems
   - Extensive measurements and data collection on shop-floor (e.g., CPPs) to aid real-time decision making
   - Machine learning/predictive analytics to enhance yields and accelerate root cause identification

B. Robust governance and performance management system
   - Streamlined and interconnected forums across levels (at site and above)
   - Prioritized set of metrics baselined and monitored to assess progress
   - Dashboards to provide timely and correct information across multiple sites/BUs

C. Problem solving discipline and capabilities
   - Organization-wide problem solving and problem prevention capabilities
   - Application of consistent & rigorous toolkit for innovation and continuous improvement
   - Ensuring root causes are found effectively and counter measures are adopted immediately

D. Expert group to resolve most complex issues
   - Dedicated cross-functional team of experts ("best of best")
     - Address most complex investigations
     - Coach/mentor other investigators and operations teams
Building a distinctive Quality system - 5 dimensions of quality culture

1. Right-First-Time performance mindset
2. Variability reduction
3. Focus on identifying root cause
4. Data driven decision making
5. Line ownership of quality, cost & delivery
The IPA Quality Forum is now in the second year of this journey

IPA QF sub-groups formed; members identified
Middle managers forum piloted
Peer review of best practices, metrics & guidelines
2nd wave of initiatives launched
2nd IPA Quality conference

May 15
Formation of IPA QF with 6 members

Jul 15
First wave of initiatives launched
Design activity initiated within sub-groups
1st IPA Quality Conference held

23rd Feb 16
Global expert and Regulator review of guidelines

23 & 24 Feb 17
Change leader’s forum piloted
We have made significant progress on last year’s focus themes

### Data reliability
- Developed a robust **data reliability guideline document**
  - **Incorporates and builds** on existing regulatory guidance from FDA, and other regulators such as MHRA, WHO
  - **Vetted by leading subject matter experts** and each of the member companies

### Metrics and best practices
- Aligned on a detailed definition of a **standard set of quality metrics** in-line with FDA draft guidance
- Collected data on these metrics at the pilot sites
- Collated best-practices for **investigations and process validation**

### Culture and capability
- Priority **technical training modules** developed as part of Quality Forum initiative (e.g., data reliability, investigations)
- **Quality Culture assessment done across** pilot sites
- Quality Change leadership forum implementation launched to drive behavioral change
Extensive time and resource investment has gone into the effort so far

- **35+** Days of Quality Forum CEOs time
- **300+** Days of senior Operations, R&D leadership time
- **15+** Quality Forum Workshops with working groups
- **15** Crore financial contribution for Quality Forum activities
- **12** Plants covered the benchmarking exercise

SOURCE: IPA QF sub-groups
A good start is half the race
Focus areas for the IPA Quality forum going forward

A. Sharing learnings and expanding the quality forum work to other IPA members

B. Enabling capability building and training at scale

C. Launching the next set of initiatives of IPA QF
   - Batch failure investigations
   - Market complaint investigation
   - Good documentation practices
Make a step jump in capability

1. Mapping skills to capabilities across levels
2. Connect classroom training to day-to-day workplace
3. Innovative delivery that goes beyond compliance
Next set of initiatives for the IPA QF going forward

4 Batch failure investigation
- Draft a detailed checklist for investigating batch failures
- Develop best practice SOPs
- Create a comprehensive guideline document for batch failure investigations

5 Complaints – Investigation & Review
- Compile best practices on complaints investigation and review
- Develop best practice SOPs
- Outline standardized approaches to situations outside SOP

6 Good documentation practices
- Document management across lifecycle (QC reports, batch records)
- Simplification – eliminate duplication and rationalize SOPs
- Minimizing human intervention in data capture through IT coverage, Automation etc.
BACKUPS
### Key takeaways from last year’s conference

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<tr>
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<th>Key Takeaway</th>
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<tr>
<td><strong>1</strong></td>
<td>Increasingly reward good performers and challenge poor performers</td>
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<tr>
<td><strong>2</strong></td>
<td>Greater differentiation between poor &amp; great quality systems through enhanced surveillance and risk-based inspection approaches</td>
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<td><strong>3</strong></td>
<td>Indian regulators should play a key role in improving industry-wide quality</td>
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<td><strong>4</strong></td>
<td>Metrics and data-based analysis will be used to separate good and bad performers</td>
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<td><strong>5</strong></td>
<td>Quality Culture and role modeling by the senior management to get “Quality outcome”</td>
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**SOURCE:** IPA Quality Conference, 2016