IPA Quality Forum – Reflections on the Journey so far

India Pharmaceutical Forum 2018

23rd Feb 2018
The IPA Quality forum was formed with a vision of helping the Indian pharma industry achieve excellence in quality.

**IPA QF Mission**

- Be the conduit of change through thought leadership, knowledge development, and best practice sharing
- Measure, benchmark, and publicise the achievements of the Indian Pharma Industry in Quality
- Expand the size and base of Quality talent in India
- Deepen, and strengthen the industry’s relationship with key stakeholders – both within and outside India
- Provide platforms for members and other stakeholders to interact and network

The IPA Quality forum was setup 3 years back, by a group of 6 founding member companies, and supported by McKinsey & Company as their knowledge partner.
The Industry has made progress over the last 3 years (1/2)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of USFDA inspections in India</th>
<th>Outcomes of these inspections</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>OAI</td>
</tr>
<tr>
<td>2014</td>
<td>173</td>
<td>21</td>
</tr>
<tr>
<td>2015</td>
<td>272</td>
<td>11</td>
</tr>
<tr>
<td>2016</td>
<td>271</td>
<td>10</td>
</tr>
<tr>
<td>2017</td>
<td>192</td>
<td>8</td>
</tr>
</tbody>
</table>

- India has 7% of the global USFDA approved manufacturing sites
- India’s share of inspections has come down and outcomes improved during 2017

1 FY14 taken as Oct 2013 to Sep 2014. Similarly for FY15,16 &17
SOURCE: CDER
The Industry has made progress over the last 3 years (2/2)

- Improvement in quality standards and regulatory outcomes over last 2 years
- Significant effort required to achieve sustainable excellence in quality

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>USFDA Warning letters for Non-US sites</strong>¹</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>39%</td>
<td>50%</td>
<td>43%</td>
<td>35%</td>
</tr>
<tr>
<td>China</td>
<td>22%</td>
<td>13%</td>
<td>43%</td>
<td>35%</td>
</tr>
<tr>
<td>RoW</td>
<td>39%</td>
<td>38%</td>
<td>29%</td>
<td>37%</td>
</tr>
<tr>
<td></td>
<td>2014</td>
<td>2015</td>
<td>2016</td>
<td>2017</td>
</tr>
<tr>
<td><strong>USFDA Import alerts for Non-US sites</strong>¹</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>35%</td>
<td>53%</td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td>China</td>
<td></td>
<td></td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>RoW</td>
<td>12%</td>
<td></td>
<td>20%</td>
<td></td>
</tr>
</tbody>
</table>

¹ Numbers shown for FY - FY14 taken as Oct 2013 to Sep 2014.; Similarly for FY15,16 &17

SOURCE: Web search
There has been a reduction in data-related errors; Gap in Investigations and root cause assessments is now a leading source of non-compliance.

<table>
<thead>
<tr>
<th>Nature of observations</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Others</td>
<td>10%</td>
<td>3%</td>
<td>17%</td>
</tr>
<tr>
<td>Facilities &amp; Infra</td>
<td>7%</td>
<td>14%</td>
<td>4%</td>
</tr>
<tr>
<td>Production systems</td>
<td>16%</td>
<td>11%</td>
<td>13%</td>
</tr>
<tr>
<td>Lab controls</td>
<td>8%</td>
<td>19%</td>
<td>17%</td>
</tr>
<tr>
<td>Investigations &amp; root cause assessment</td>
<td>18%</td>
<td>46%</td>
<td>28%</td>
</tr>
<tr>
<td>Data reliability &amp; Good documentation practices</td>
<td>41%</td>
<td>20%</td>
<td></td>
</tr>
</tbody>
</table>

- Failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans
- Failure to ensure that test procedures are scientifically sound
- Failure to adequately investigate
  - Deviations
  - OOS results
  - Invalidated OOS
  - Customer complaints
- Inadequate controls of computer & other data systems
- Gap in prevention of unauthorized access
- Incomplete data in lab records
- Incomplete data in batch production records

SOURCE: US FDA Warning letters & 483 observations available in public domain
Building Excellence in Quality is a 3-step journey

**Step 1: Achieve 100% compliance across key sites**
- Ensure key sites achieve full compliance vis-à-vis regulatory guidelines / expectations
- Complete ongoing remediation efforts in timely and effective manner
- Achieving 24X7 Audit Readiness

**Step 2: Put in place a robust Quality systems**
- Set-up the right quality system & processes
- Introduce quality metrics & benchmark with best-in-class
- Designing the right quality organization & governance model

**Indian pharma focus over the last 2-3 years**

**Step 3: Achieve sustained excellence in Quality**
1. Build a robust **Quality culture** across the network from top to bottom
2. Drive quality & productivity in an integrated manner
3. Develop capabilities to sustain quality excellence across all levels
4. Adopt next generation (Ops 4.0) tools to leverage Digital & Advanced Analytics

**Potential focus going forward**
IPA Quality Forum is now in its third year

- **Formation of IPA QF with 6 members**
- **IPA QF sub-groups formed; 1st wave of initiatives launched**
- **1st IPA Quality Conference**
- **Investigations guidelines finalized**
- **Quality culture survey & Change Leaders’ Forum launched**
- **IPA QF sub-groups formed; 1st wave of initiatives launched**
- **Quality metrics benchmarking pilot initiated**
- **2nd wave of initiatives launched**
- **2nd IPA Quality conference**
- **Data Reliability Guidelines finalized**
- **23, 24 Feb 17**
- **Process Validation guideline finalized**
- **23rd Feb 16**
- **Batch failure investigation guideline finalized**
- **22, 23 Feb 18**
- **3rd IPA Quality conference**
- **Good Documentation Practice guideline finalized**
- **Capability building sessions by USFDA across multiple cities in India**
IPA Quality Forum has approached Quality Excellence through 3 lenses

- **Operating System (OS)**
  - Setting up formal quality performance management tools supported by the right quality organisation to drive results
    - Quality metrics
    - Benchmarking
    - Strengthening quality governance & organization

- **Management Infrastructure (MI)**
  - Putting in place best-in-class-technical systems & processes which are core to the quality system
    - Data reliability
    - Product lifecycle management
    - Investigation of non-conformances (batch failures, market complaints)
    - Good Documentation practices

- **Mindsets & capabilities (MC)**
  - Creating a robust quality culture & capabilities from senior management to the shop floor level- building the right skills, mindsets, behaviours and ownership
    - Quality Culture
    - Building capabilities

Focus so far has been more on OS & MI
Going forward increased focus on MC
Extensive time and resources have been invested in this effort so far

Days of Quality Forum CEOs time: 50+

Days of senior Operations, R&D leadership time: 500+

Employees covered for culture & capability assessment: 25K+

Crore financial contribution for Quality Forum activities: 25+

Plants covered for the benchmarking exercises: 20+

Dedicated McKinsey team working with IPA QF for the last 2.5 years

SOURCE: IPA QF sub-groups
3 focus areas were outlined for IPA Quality forum last year

**A**
Continue to develop best practice guidelines for Indian pharmaceutical companies

**B**
Expand reach of Quality Forum activities within IPA QF members, and other IPA members

**C**
Driving capability building, and training at scale

Progress this year:
- Limited progress
- Very strong progress
Best-practices being deployed to further improve quality standards

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<tbody>
<tr>
<td>1</td>
<td>Design and deploy a comprehensive Production System to enable a consistent set of practices, standards &amp; tools across the network</td>
</tr>
<tr>
<td>2</td>
<td>Digital performance management by real-time tracking of process parameters &amp; leading metrics</td>
</tr>
<tr>
<td>3</td>
<td>Advanced analytics to improve product &amp; process robustness by reducing deviations/ OOS, improving yield etc.</td>
</tr>
<tr>
<td>4</td>
<td>Lean tools to drive efficiencies in Lab operations e.g., enhancing QC lab throughput, improving QA/ QC productivity</td>
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<tr>
<td>5</td>
<td>Building next-gen quality capabilities &amp; culture across the organization through experiential learning &amp; use of digital channels</td>
</tr>
</tbody>
</table>
Most production systems have 3 elements

WHAT: Vision or the end objective from production system

Vision
Safe operations, delivering high quality products on time at a competitive cost

1. Best-in-class Quality
2. High Safety levels
3. Cost excellence
4. Engg. excellence
5. People development & capability
6. Cont. Improvement

HOW: Focus elements as the main pillars

Compliance to regulations
Leadership development
People Empowerment
Alignment with company values

Fundamentals/Foundations: Contain essential non-negotiable elements
Focus areas for IPA Quality Forum next year

A. Publishing remaining best practice guidelines - Batch failure investigations and Market complaints handling

B. Launching middle management capability building pilot, followed by at scale implementation

C. Scaling up IPA QF interventions to other IPA members