Indian Pharmaceutical Alliance: Quality Forum Update

Washington DC

29 June 2016

Objectives for today's meeting

Agenda

- **Recap** IPA Quality Forum's vision and objectives
- **Update** on progress and achievements since last meeting
- **Share** IPA Quality Forum's plan for going forward

Desired Outcomes

- Get FDA's feedback on the priorities and plans going forward
- Get inputs on agenda for the next **IPA Quality Conference**
- Determine other areas where FDA and IPA can partner to achieve priorities and align on modes of engagement
- Agree on touchpoints between the FDA and the IPA Quality Forum over the next year

Recap: We developed a joint Vision and Mission for the Quality Forum

Vision	▪ *Help Indian Pharma Manufacturers to be the global benchmark in Quality*
Mission	▪ Demonstrate true partnership to customers, patients and regulatory authorities by quality and reliability ▪ Be the conduit of change in the Industry through thought leadership, knowledge development, best practice sharing and membership engagement ▪ Measure, benchmark and share the achievements of the Indian Pharma Industry in Quality ▪ Expand the skill and capability of quality talent ▪ Deepen and strengthen the industry's relationship with key stakeholders – both within India as well as globally ▪ Provide platforms for members and other stakeholders to interact and network

Recap: Quality Forum was established to develop solutions and address quality challenges faced by the industry

Context for IPA

- The **IPA Quality Forum** was launched to address cross cutting challenges in quality
- Focus areas
  - In the near term, develop a pragmatic set of quality related interventions with the core group members
  - Scale up portfolio of initiatives and broaden participation to the other members of the IPA
  - Extend to non-IPA companies

Immediate priorities

- Ensuring **Data Reliability** guidelines are comprehensive and accurately interpreted/adopted
- Selecting right **Quality Metrics** and **Best Practices** to enable the companies to benchmark, diagnose and track improvements in quality performance
- Building **Capability** and the **Quality Culture** across the organization

Update: We have made significant progress in a short time on the near-term initiatives

Data Reliability

- Developed a robust draft D**ata 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 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
- Preparing pilot sites to collect data on these metrics
- Collating **Best Practices** for investigations and process validation

Culture and Capability

- Identified priority technical training modules to be developed as part of Quality Forum initiative (e.g., data reliability, investigations)
- Initiated process to conduct **Quality Culture** assessment across pilot sites
- Developed and piloted quality change leadership to drive **Behavioral Change**

Further details on subsequent slides

Update on Subgroup 1: Data Reliability

Key activities undertaken

- Formed dedicated group of executives across organizations to work on the topic
- Identified key areas requiring data reliability guidelines – core **Data Reliability** principles and six supporting areas (e.g., culture, capability, governance etc.)
- Developed draft guidelines based on existing regulatory guidelines on Data Reliability as well as internal **Best Practices** across companies
- Reviewed and refined data reliability guidelines with significant involvement of external experts

Progress and next steps

- **Progress:**

  Integrated set of implementation oriented guidelines on Data Reliability
  - Building on existing regulatory guidelines of FDA, MHRA, WHO, etc.
  - Incorporating elements of risk management, awareness and capability, culture, governance, systems and design of processes affecting data reliability
  - Providing practical guidance in addition to overall data reliability principles

- **Next steps for 6-9 months:**
  - Share guidelines for feedback from FDA and other regulators
  - Refine guidelines based on feedback
  - Keep document current as cGMP evolves in this area, e.g., from new regulatory guidelines (if any)

Update on Subgroup 2: Metrics and Best Practices

Key activities undertaken

- Formed dedicated group of executives across organizations to work on the topic

Metrics

- Created definitions and data collection modalities using FDA draft guidance document on metrics
- Identified the sites (combination of Formulations and API) for the pilot phase

Best Practices

- Developing Best Practices on select topics e.g., process validation, investigations, aseptic practices etc. through
  - Sharing good practices across companies to develop draft set of best practice guidelines
  - Brainstorming
  - Engaging with subject experts

Progress and next steps

Metrics

- **Progress:**
  - Full alignment on metrics, definitions and data collection methodology
  - Preparation in progress at pilot sites
- **Next steps for 6-9 months:**
  - Initiate data collection and benchmarking

Best Practices

- **Progress:**
  - Preparing draft Best Practice guidelines for process validation and investigations
- **Next steps for 6-9 months:**
  - Finalize Best Practice guidelines for the above mentioned two topics

Update on Subgroup 3: Culture and Capability

Key activities undertaken

- Formed dedicated group of executives across organizations to work on the topic

Capability

- Identified priority technical capabilities required for middle-management, e.g., investigations

Culture

- Developed **Quality Culture** assessment survey to be deployed across sites
- Designed **Behavioral Change** module for middle managers (Change Leader's Forum)

Progress and next steps

Capability

- **Progress:**
  - Developed outline and draft content for the technical capability modules
  - Initiated evaluation of electronic platforms to host modules for delivery
- **Next steps for 6-9 months:**
  - Finalize and share technical modules

Culture

- **Progress:**
  - Preparing sites for roll out of Quality Culture assessment survey
  - Piloted Behavior Change module at four companies
- **Next steps for 6-9 months:**
  - Launch Quality Culture survey followed by focused group discussions
  - Develop insights and key areas to address Quality Culture based on current state

Key priorities and plan for IPA Quality Forum

Immediate priority initiatives	▪ Publish guideline document on **Data Reliability** ▪ Share **Best Practices** on investigations and process validations ▪ Pilot **Quality Culture** assessment at IPA Quality Forum member companies ▪ Develop standard **Capability** building modules on Data Reliability, Investigations ▪ Streamline data collection for **Metrics** and initiate quality metrics pilot at selected sites
Additional initiatives	▪ Develop 5-year action plan for quality excellence with clear intermediate milestones and description of the end state

Highlights of the India Pharmaceutical Forum 2016

Active participation of Regulators, Government Academia and Industry

- Regulators:
  - FDA: Tom Cosgrove, Russel Wesdyk, Mathew Thomas
  - MHRA: Gerald Heddel, Mark Birse
  - EMA: Brendon Cuddy
  - CDSCO: G N Singh
- Government:
  - K L Sharma, Health Ministry
  - Central & State Drug Authorities
- Academia: Faculty of Pharmacy Colleges
- Industry: CEOs, Quality, Regulatory and Manufacturing Heads and Executives (~240)
- Closure meeting with Regulators and CEOs on key takeaways from the Conference

Key topics covered at the Conference

- **Topics**
  - Building a strong quality culture and line ownership
  - Quality metrics and Indian pharma
  - Demystifying data reliability
  - Way forward: Unlock the potential
- **Takeaways**
  - Quality will be a competitive advantage and good performers will be rewarded
  - Pharma at 2-3 sigma level lags Hi Tech and Automotive industries at 6 sigma
  - Industry-wide improvement needed
  - Metrics and data-based analysis will support risk-based inspections
  - Quality culture and role modeling by the senior management is critical

SOURCE: IPA-India.Org

Going forward

Continued Engagement of CEOs

- Half-Yearly Meetings with the FDA
- Interactive Meeting with Subject Experts
- Annual Quality Conference (India Pharmaceutical Forum 2017)

India Pharmaceutical Forum 2017:
Proposed agenda for discussion and feedback from FDA

Two-Day Conference: February 2017	
▪ **Tentative Dates**	▪ 23-24 February 2017 (Thursday/Friday)
▪ **Theme**	▪ *Towards Excellence in Quality*
▪ **Faculty**	▪ USFDA, EDQM, MHRA, WHO
▪ **Participants**	▪ Industry (CEOs, Quality, Regulatory and Manufacturing Heads and Executives) ▪ CDSCO ▪ Academia
▪ **Topics**	**Core Topics:** ▪ Data Reliability ▪ Metrics and Best Practices ▪ Culture and Capability **New Topics (Any Three):** ▪ Complaints - Investigation & Review ▪ Batch Failure Investigations ▪ Internal Auditing Systems ▪ Process Validation ▪ Aseptic Practices

THANK YOU

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