

Inaugural Address

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President Indian Pharmaceutical Alliance

5th INDIA
PHARMACEUTICAL
FORUM 2020



3 big focus areas for the IPA Quality Forum so far



1



Thought leadership: i.e. knowledge development, and best practice sharing

2



Capability-building at scale

3

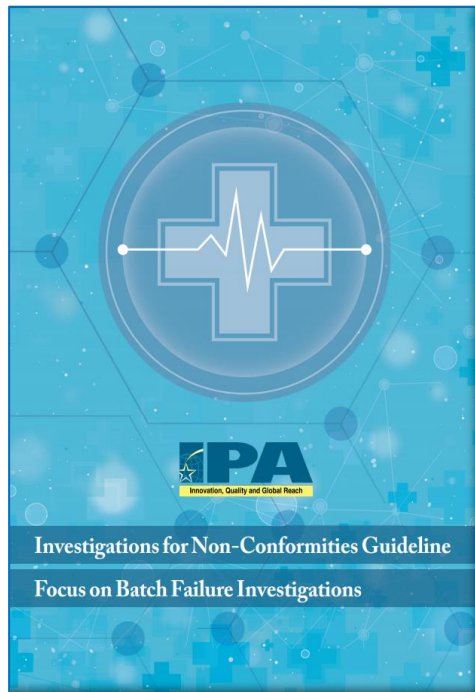


Collaboration with different stakeholders including regulators



1 Big focus area #1 Thought Leadership: To share best practices with the industry

Investigations for Non-Conformities Guideline: Focus on Batch Failure Investigations – released in the 4th India Pharmaceutical Forum 2019

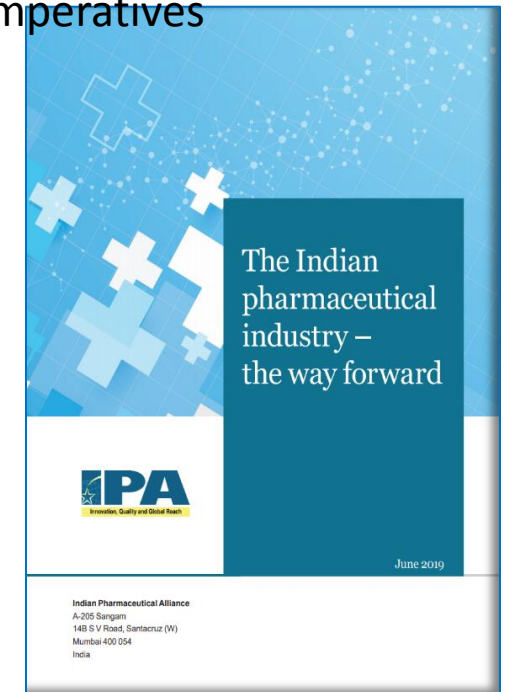


Other best-practices released in previous years

- Good Documentation Practice (GDP) guidelines
- Process validation guidelines
- Data reliability guidelines



Position paper on the way forward for Indian Pharma industry; Vision 2030, opportunities and challenges, key actions and imperatives



2 Big focus area #2 Capability Building: Through various forums convened through the year

PA conference, Feb 2019



Advanced GMP workshops, Nov 2019



Workshop on Recent Amendments in Drugs & Cosmetics Act



2 Big focus area #2 Capability Building: In it's forums, IPA has covered a variety of topics by regulators, industry speakers and reputed third parties

Broad set of topics covered over the last 3 years across various IPA QF forums ...

NOT EXHAUSTIVE

- Building Effective Pharma Quality Management Systems
- Driving Sustainable Cultural Transformation
- Continuous manufacturing – current trends
- Leveraging Automation in Pharmaceutical Operations for Continuous Improvement
- Disruptive Technologies in Pharma Operations
- Digitalized pharma world: cybersecurity best-practices
- Data Integrity: New PDA Technical Reports on DI in the Laboratory, Manufacturing, and QMS Systems
- Building Integrated Capabilities for Quality Excellence
- QBD in Analytical Development
- Validation of Analytical Methods
- Robust Technology Transfer
- CGMPs Aspects of NCE Development for Early Phase INDs: CMC Perspective
- Inspection of Sterile Dosage forms: recent trends
- Excipients Risk Management: New PDA Technical Report
- Building Quality Metrics



... delivered by speakers from regulatory agencies (e.g., USFDA, CDSCO, EMA), industry experts, and reputed third parties

3 Big focus area #3: collaboration with regulatory agencies

Recent developments in Indian regulations

- **New Drugs and Clinical Trial Rules (2019)** notified, to regulate import, manufacture, sale of drugs, to ensure safety, efficacy & quality
- **Post Market Surveillance conducted; national drugs survey** to assess extent of spurious and not-of-standard quality drugs in country
- **Pharmacovigilance Programme of India (PvPI) instituted**, in collaboration with WHO; 250 Adverse Drugs Reaction (ADR) Monitoring Centres currently.
- **Comprehensive E-Governance program** launched for entire country; portals for on-line processing of drug applications, laboratory information management system (LIMS) for drug testing laboratories under CDSCO
- **New Drugs Controller General (India) appointed**
 - 19th International Conference on Drug Regulatory Authorities (ICDRA) will be hosted, by CDSCO India, in autumn 2020
 - Officials from CDSCO participated in ICH Meeting in 2019
 - CDSCO to participate in PICs program

IPA closely involved with CDSCO on 3 levels

- Capability building sessions across the country (advanced GMP)
- Workshops: Recent Amendments in Drugs & Cosmetics Rules for Effective Implementation, Assam
- Quarterly discussions for greater collaboration going forward

Going forward, there are 3 key priorities for the IPA in 2020

3 focus areas for IPA Quality Forum in 2020-21

1



Best practices

- Product robustness
- Analytical method development
- Investigations, RCA and CAPA
- Continuous thrust on culture transformation

2



Capability building

- Advanced GMP workshops
- Annual India Pharmaceutical Forum
- Share best-practices, including publications

3



Collaboration

- PDA
- ISPE
- US Pharmacopeia
- CDSCO – Central Drug Control Standards Organization
- Industry associations