IPA Quality Forum –
Launch of best practice document
Investigation of Market complaints
IPA Sub-group on Handling of Market Complaints

**Context and objective(s)**

- **Promoting thought leadership** is among top 3 focus areas of IPA Quality Forum
- Handling of market complaints was identified as one of 8 areas for developing and sharing best practices across companies
- **Effort was initiated in 2017** with 6 representatives from member companies of IPA Quality Forum

**Team members**

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<tr>
<th>Team member</th>
<th>Company</th>
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<tr>
<td>Avinash Joshi</td>
<td>Cadila Healthcare</td>
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<td>Indrajit Bose</td>
<td>Lupin Ltd</td>
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<td>Jigar Marfatia</td>
<td>Sun Pharma</td>
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<td>Shiney Joy</td>
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<td>Dilkesh Shah</td>
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<td>Rama-krishna V</td>
<td>Dr. Reddy's</td>
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Document created by the subgroup in order to develop and share a harmonized set of ‘best-practices’ with the broader pharma community; 4 key imperatives

- **‘Need of the hour’ for quality and compliance**
  - Product complaint handling system is second most cited 483, with 326 EIR observations, which was 3% of overall EIR observations¹

- **Standardized set of best practices needed across companies**
  - While, guidance documents from various regulatory agencies are available online, the interpretation and implementation of each (through the QMS) was largely at the discretion of respective companies

- **Latest thinking across agencies need to be understood**
  - Several best-practices have been made available by agencies over the years; this effort was taken up to represent agencies’ most current thinking on this topic²

- **Need for adopting a risk-based approach across companies**
  - Help pharma community choose a risk based approach towards addressing market complaints, through a harmonized best-practice document for handling market complaints

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1. USFDA’s 2016 enforcement statistics; 2 [https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs](https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs)
This best-practice document is a culmination of efforts from multiple sources.

Benchmarking of best practices across organizations

Available guidance from various regulatory authorities

Review by independent external expert(s)

Over last 2 years, the team has got together through multiple calls, in person meetings, and emails.
The document covers best practices across the ‘life-cycle’ of a market complaint; i.e. from receipt to closure of complaints.

- **Receipt of complaint**
  - Defines process to be followed once complaint is received

- **Categorization of complaint**
  - Categorisation of complaints in critical, major or minor

- **Regulatory notification**
  - Process to raise Alert notification or field action report

- **Investigation**
  - Historical review of product
  - Health Hazard Evaluation
  - Risk assessment

- **Receipt & handling of samples**
  - Process for receipt and handling of samples

- **Closure of complaints**
  - Process to close the complaint

The best practice document additionally provides process for trending of complaints, management review, record keeping and quality metrics data.
The document also shares 4 sets of read-to-deploy templates

1. Trending of market complaints
2. Risk assessment
3. Query template
4. Dosage form wise investigation checklist