Connecting People, Science and Regulation

ICH Q7 Chapter 15:
Complaints & Recalls

PDA - PIC/S
ICH Q7 Training 01/2014

Disclaimer

- **The slides set is based on the training sessions developed and performed by the members of the ICH Q7 Expert Working Group (EWG) on ICH Q7 2001/2002**
- **The slides have been updated 2012 and represents the views of the PDA / PIC/S committee for the purposes of a general training for regulators and industry.**

◆ ***We focused on elements in ICH Q7 where further explanation and/or clarification is useful.***

Complaints & Recalls

- **All quality related complaints recorded and investigated according to written procedure** *(15.10)*
- **Complaint records retained to evaluate** *(15.12)*
  - Trends
  - Frequencies
  - Severity

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Complaint

- **Complaint records *(15.11)***
  - Name/address of complainant
  - Name/phone of submitter
  - Nature of complaint includes batch number
  - Date received
  - Action initially taken include what/when/who
    - *A root cause investigation should be performed and recorded*
  - Follow up action
  - Response to originator
  - Final decision on batch
    - *All these documents have to be easily available to have the full picture*

Recall - For clarification

- *A recall is any withdrawal of an API (not a dosage form) from the supply chain having left the control of the manufacturer*
- *If the API did not enter the market as a drug (medicinal) product the authorities normally not need to be informed (consider local regulations)*

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Recalls

- **Written procedure should describe**
  - When recall should be considered *(15.13)*
  - Who involved in evaluating information *(15.14)*
  - How recall initiated *(15.14)*
  - Who should be informed of recall *(15.14)*
  - How recalled material is treated *and traced (15.14)*
- *It is helpful to describe reconciliation procedures*

Recalls

- **Serious or potentially life-threatening situation – local / national / international authorities informed** *(15.15)*
  - *Communication channels should be considered (e.g. health authorities, traders, senior management, business, country affiliates)*
  - *In case of limited experience it has been shown beneficial to simulate a recall situation in order to verify the system to be effective*

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Key Messages

- **Investigations are recorded**
- **Corrective actions and preventive actions should be implemented (effective CAPA system)**
- **The system must be confirmed to be efficient and meet timelines**
- **Authorities are informed appropriately by the marketing authorisation holder (following local requirements)**

Acknowledgement

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