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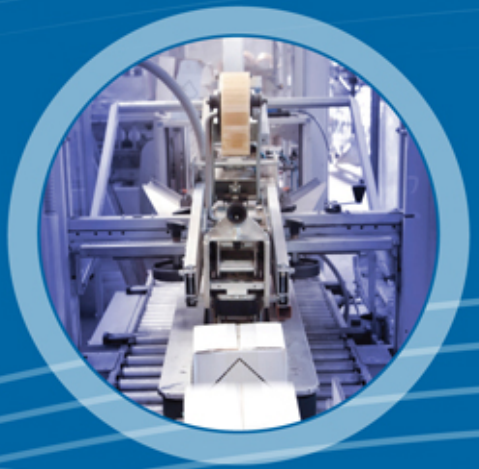
ICH Q7 Chapter 15:
Complaints & Recalls



PDA - PIC/S ICH Q7 Training

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

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)*

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*

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)**

ICH Q7 QaA *Clarification of Uncertainties*

1. Can quality defects of released APIs that are identified by another entity belonging to the same company be handled outside of the API manufacturer's complaint procedure?
2. Must a quality related return, at the request of the API manufacturing site, from another site within the same company be recorded as a 'recall'?

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