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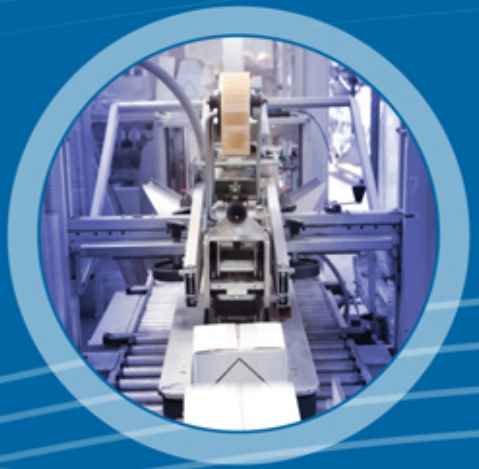
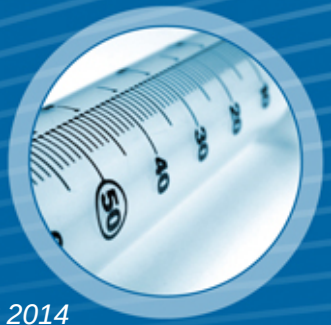
ICH Q7 Chapter 13:
Change Control





PDA - PIC/S ICH Q7 Training

Change Control

- **Formal system to evaluate all changes that may affect the production and control of the intermediate or API** *(13.10)*
- **Including changes to** *(13.11)*
  - Raw materials
  - Specifications
  - Analytical methods
  - Facilities
  - Support systems
  - Equipment
  - Process steps
  - Labelling and packaging materials
  - Computer hardware

Anything else what has potential impact on the API / intermediate quality or the regulatory dossier need to follow a change control procedure

Change Control

- **ICH Q7 describe the Change Control activities linked to GMP and Quality System elements**
- **ICH Q10 describe the Change Management:**
  - **ICH Q10:** 'Innovation, continual improvement, the outputs of process performance and product quality monitoring and CAPA drive change' (ICH Q10: 3.2.3)
  - A life cycle activity

Table III: Application of Change Management System throughout the Product Lifecycle

Pharmaceutical Development	Technology Transfer	Commercial Manufacturing	Product Discontinuation
Change is an inherent part of the development process and should be documented; the formality of the change management process should be consistent with the stage of pharmaceutical development.	The change management system should provide management and documentation of adjustments made to the process during technology transfer activities.	A formal change management system should be in place for commercial manufacturing. Oversight by the quality unit should provide assurance of appropriate science and risk based assessments.	Any changes after product discontinuation should go through an appropriate change management system.

Change Control

- **See regarding Change Management:**
  - Changes **WILL** happen throughout the product lifecycle
    - Proactively due to business or technical reasons (e.g. new supplier, batch size change, new equipment)
    - Reactively driven as part of CAPA (e.g. Due to deviations, OOS, batch rejections)
  - The Quality Management System must include a robust change management system
    - Use of knowledge and Quality Risk Management

Based on ICH Q-IWG training: Manufacturing implementation & PQS

Change Control

- **Any proposals for GMP relevant change should be** *(13.12)*
  - Drafted, reviewed and approved by the appropriate organisational units
  - Approved by the quality unit(s)

- *Any maintenance change (incl. exact replacements = 'like for like' changes) needs to be assessed and documented in the engineering records at least.*
- *It is practice to allow like for like changes without going through the full change control. This procedure must be approved by QA.*

Change Control

- **The potential for impact of the proposed change on the quality of the intermediate or API should be evaluated** *(13.13)*
  - *It is good practice to consider* failure *modes that result from the covered change*
  - *- Consider proposed cumulative changes and previously initiated changes as these may have a greater impact than a single minor change*
- **May be useful to establish a classification system for changes depending on nature and extent of change** *(13.13)*

Change Control

- **Use scientific judgement to determine need for additional testing and validation studies when justifying a change to validated process** *(13.13)*
- **Ensure all documents affected by the changes are revised** *(13.14)*
- **Evaluate the first batches produced or tested under the change** *(13.15)*

Change Control

- **Effect of critical changes to API stability may need to be evaluated** *(13.16)*
- **If necessary, samples of intermediate or API produced by modified process can be placed on** *(13.16)*
  - Accelerated stability
  - Stability monitoring program

Change Control

- **In general the customers should be notified of changes from established production and process control procedures that can impact the quality of the API** *(according 13.17)*
  - *In some cases this may be conducted by an agent, distributer or repacker*
  - *The customer is responsible for defining what changes they expect to be informed of and this should be defined in a procedure e.g. in a quality / technical type agreement*

Key Messages

- **ICH Q7 describes the change control activities linked to GMP and the change management element of the Quality Management System (see ICH Q10)**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