






ICH Q7 Chapter 13: Change Control



PDA - PIC/S
ICH Q7 Training 01/2014



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Chapter 13: Change Control




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.*

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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
 - Equipment
 - Specifications
 - Process steps
 - Analytical methods
 - Labelling and packaging materials
 - Facilities
 - Computer hardware
 - Support systems

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

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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.

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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

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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.*



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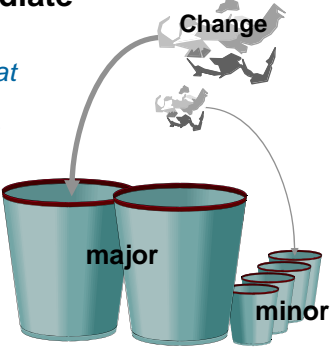
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- **The potential for impact of the proposed change on the quality of the intermediate or API should be evaluated (13.13)**
 - ◆ *It is good practice to consider failure modes that results from the covered change*
 - ◆ *Consider proposed cumulative 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)**



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- **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)**



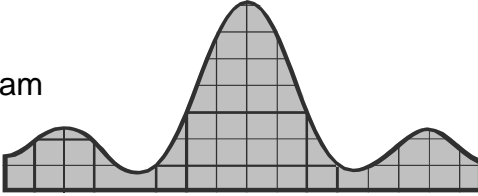
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- **Effect of critical changes to API stability may need to be evaluated (13.16)**
- **If necessary, samples of intermediate or API produced by modified process can be placed on (13.16)**
 - Accelerated stability
 - Stability monitoring program

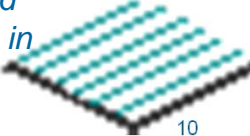


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- **In general the customers should be notified of changes from established production and process control procedures that can impact the quality of the API (according 13.17)**
 - ◆ *In some cases this may be conducted by an agent, distributor or repacker*
 - ◆ *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*



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Key Messages

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



Acknowledgement

- **This version represents an update of the 2001/2002 version by ICH Q7 EWG members organised in a joint initiative between PDA and PIC/S developed in 2012**
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