






**ICH Q7 Chapter 9:
Packaging & Labelling**



PDA - PIC/S
ICH Q7 Training 01/2014



ICH Q7 Training
Chapter 9: Packaging and Labelling




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 are useful.*

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Content


- **General** (9.1)
- **Packaging Materials** (9.2)
- **Label Issuance & Control** (9.3)
- **Packaging & Labeling Operations** (9.4)

Packaging Material:


Any material intended to protect an intermediate or API during storage and transport

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9.1 General

- **Written procedures** (9.10)
 - Receipt
 - Identification
 - Quarantine
 - Sampling
 - Examination/testing
 - Release
 - Handling
- **Conform to specifications** (9.11)
- **Records for each shipment** (9.12)
 - Receipt
 - Examination / Testing
 - Acceptance / Rejection

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9.2 Packaging Materials

- **Adequate protection against deterioration or contamination of the intermediate or API (9.20)**
 - During transportation and recommended storage.
- **Not reactive, additive, absorptive (9.21)**
 - So as to alter API / intermediate beyond specifications
- **Clean (9.21)**
- **Sanitized if indicated by nature of material (9.21)**
 - ◆ *The primary packaging material should be handled in a way that it will not compromise the quality of the product*



9.2 Packaging Materials

- **Re-used containers cleaned according to documented procedure (9.22)**
 - ◆ *Also when containers are re-used for the same products (dedicated containers) a cleaning procedure should be agreed between the parties*
 - ◆ *Remember to keep the cleaning records*
- **All previous labels removed or defaced (9.22)**





9.3 Label Issuance & Control

- **Limited access to label storage areas** (9.30)
- **Procedures to reconcile quantities** (9.31)
 - Discrepancies investigated / approved by quality
- **Excess batch labels / printing destroyed** (9.32)
 - ◆ *Purpose: make sure that the excess labels are not misused*
- **Returned labels maintained/stored in manner to prevent mix-ups** (9.32)
- **Obsolete/out-dated labels destroyed** (9.33)



9.3 Label Issuance & Control

- **Printing devices controlled** (9.34)
 - To ensure all imprinting conforms
- **Printed labels issued examined for ID and conformity to specifications in master production record** (9.34)
 - Results documented in batch records
- **Representative printed label in batch records** (9.36)
 - If intended to be made commercially available
- ◆ *In some cases where secondary packaging is used an extra label on the primary packaging provide additional traceability assurance*
- ◆ *Additional transportation labels may be applied (e.g. safety)*
- ◆ *Transport stickers shall not replace labeling*



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9.4 Packaging Operations

- **During storage and transport**
 - Documented procedures to ensure correct packaging and labels used (9.40)
 - Labeling operations designed to prevent mix-ups (9.41)
 - Physical or spatial separation from other intermediates / APIs

◆ Consider impact of impregnated pallets used

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9.4 Label Information

- **General (9.42)**
 - Name or identifying code
 - Batch number
 - Storage conditions, if critical to assure quality
- **If transferred outside control of material management system (9.43)**
 - Manufacturer name & address
 - Quantity
 - Special transport conditions
 - Special legal requirements
 - Expiry / Retest date (in the Certificate of Analysis (CoA) as well)

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9.4 Packaging & Labeling Operations

- **Facilities inspected immediately before use (9.44)**
 - Ensure materials not needed for next operation removed
 - Documented in batch records, log, or other
 - ◆ *Called 'line clearance' in drug product manufacturing*
- **Correct labeling of packaged / labeled APIs / Intermediates examination (9.45)**
 - Part of the packaging operations
 - Documented in batch records



9.4 Packaging & Labeling Operations

- **Intermediate / API transported outside of manufacturer control (9.46)**
 - Sealed
 - If seal breached or missing, recipient will be alerted to possibility of contents altered
 - ◆ *The standard of security seals should be tamper evident and have an identifier (e.g. name / logo of the company)*
 - ◆ *The customer should be aware of the type of seal used*





Key Messages

- **There is a high risk if these processes are not under control**
 - There can be misconceptions on the use of materials
 - Mix up of material with different customer specification
 - Repackaging, Relabeling operations
- **The activity should also be under the scrutiny of the quality unit**



Acknowledgement

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