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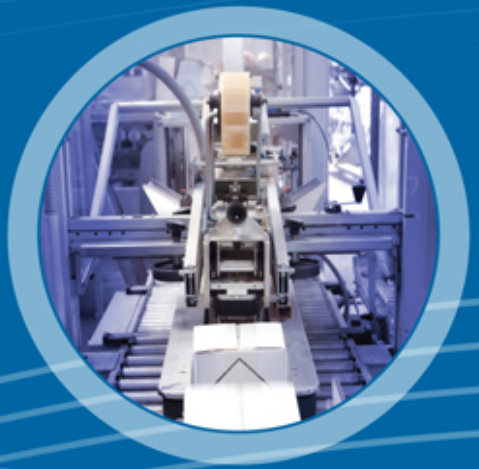
ICH Q7 Chapter 9:
Packaging & Labelling



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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

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

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*

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*

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)

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**

ICH Q7 QaA *Clarification of Uncertainties*

- No Question

ICH Q7 Q&A, 2015


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