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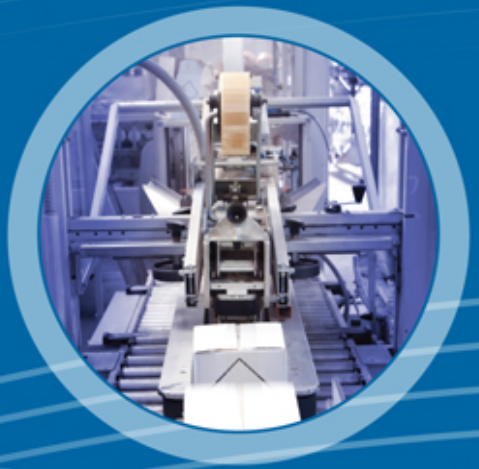
ICH Q7 Chapter 17: Agents, Brokers, Traders, Distributors, Repackers, and Relabellers (ABTDRR)



PDA - PIC/S ICH Q7 Training

Content

- **Applicability** *(17.1)*
- **Traceability of Distributed APIs and Intermediates** *(17.2)*
- **Quality Management** *(17.3)*
- **Repackaging, Relabelling and Holding of APIs and Intermediates** *(17.4)*
- **Stability** *(17.5)*
- **Transfer of Information** *(17.6)*
- **Handling of Complaints and Recalls** *(17.7)*
- **Handling of Returns** *(17.8)*

To simplify this presentation

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  Agents, *negotiates contracts of purchase and sale*

  Brokers, *mediates between a buyer and seller*

  Traders, *buys and sells*

  Distributors, *procures, imports, holds, supplies and/or exports a commodity*

  With whom ever companies are dealing in regards to distribution of APIs

  Repackers and

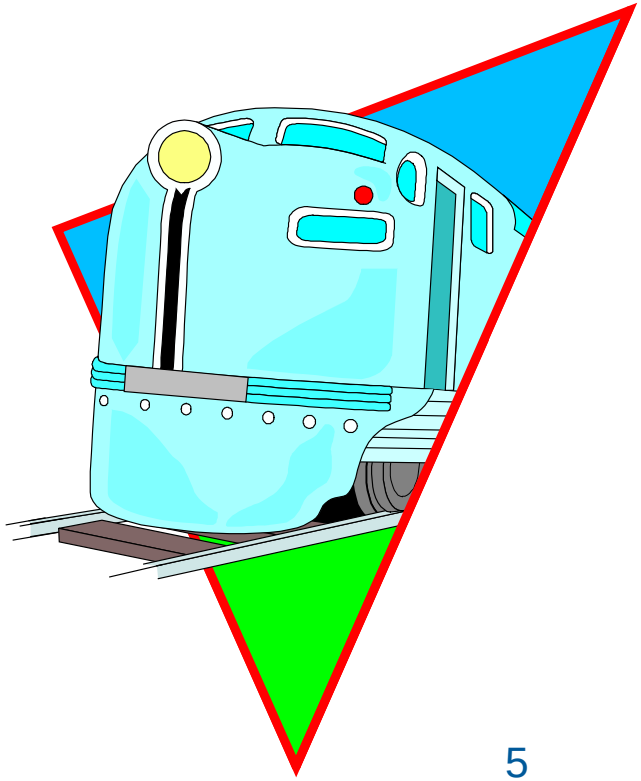
  Relabellers

  will hereafter be referred to as ABTDRR

17.1 Applicability

- **Applies to any party other than the original manufacturer who may** *(17.10)*
  - Trade and/or take possession
  - Repack
  - Relabel
  - Manipulate
  - Distribute or
  - Store

  an API or an intermediate



17.1 Applicability

- **ABTDRR should comply with relevant GMPs as defined in ICH Q7 when involved in manufacturing activities**
  - ◆ *Take possession of material, with or without storage, Receipt of material, Re-packing, Re-labeling,*
- **Specific consideration to**
  - Preventing cross-contamination
  - Responsibility for sharing information
  - Preventing products deterioration
  - Maintaining traceability ◆ (critical requirement)

Distribution of 'API starting material'

- **'This section applies to any party other than the original manufacturer who may trade and/or take possession, repack, relabel, manipulate, distribute or store an API or intermediate' *(17.10)***

Type of Manufacturing	Application of this Guide to steps (shown in grey) used in this type of manufacturing				
Chemical Manufacturing	Production of the API Starting Material	Introduction of the API Starting Material into process	Production of Intermediate(s)	Isolation and purification	Physical processing, and packaging
API derived from	Collection of	Cutting, mixing	Introduction of	Isolation and	Physical

- *Chapter 17 applies to the distribution of APIs and intermediates but not to 'API starting materials'*

Similarities with Contract Manufacturers?

Contract Manufacturer	ABTDRR
A manufacturer performing some aspect of manufacturing ***on behalf*** of the original manufacturer	Any party other than the original manufacturer that may trade and/or take possession ….

17.2 Supply Chain Traceability

- **Documents to be retained and available** *(17.20)*
  - Identity and address of original manufacturer
  - Purchase orders and transportation documents
  - Receipt documents
  - Name or designation of API or intermediate
  - Manufacturer's Batch number
  - Distribution and relevant transportation documents and records
  - All authentic Certificates of Analysis
  - Retest or expiry date

- *Today traceability may be referenced as 'pedigree' locally*
- *ABTDRR must not withhold the identity of the original manufacturing sites (including the original CoA, see 11.44)*

17.3 Quality Management

- **Effective system of managing quality is to be established, documented and implemented** *(17.30)*
  - As specified in Section 17.2 (traceability)
  - Commensurate to the activities performed
    - *Through the chapter 2 reference in chapter 17.30, a wide range of Q7 requirements do apply to ABDTRR, such as training, release, change control, computerised systems, contracted activities, etc..*
    - *ABDTRR need to have appropriate level of technical skills for the type of activities undertaken (3.10)*

17.4 Repackaging, Relabeling & Holding

- **Performed under appropriate GMP as stipulated in this guide** *(17.40)*
  - *Activities consisting of repackaging, relabelling or dividing-up of active substance batches are manufacturing activities and have to follow Q7!*
- **Avoid mix-ups, loss of identity or purity** *(17.40)*
  - *Full traceability has to be maintained between original and repack material*
  - *Appropriate identity testing, as necessary*
  - *There need to be appropriate steps in place to maintain the integrity of the repackaging operations*
- **Appropriate environmental conditions** *(17.41)* to avoid contamination

17.5 Stability

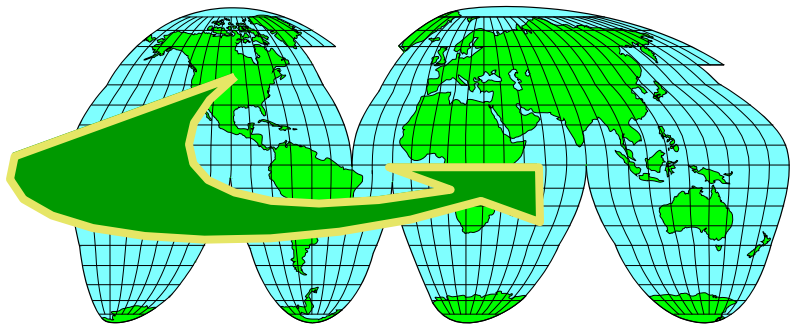
- **Studies to justify assigned expiration or retest dates should be conducted if API or intermediate is repackaged in a different type of container than that used by the API manufacturer** *(17.50)*

  - *Different types of container = different container closure system and/or different types of material (same type of containers e.g. other color, other size)*
  - *A stability study is required when the change of packaging may impact the quality attributes of the substance, such as a different container closure system or a different type of material*

17.6 Transfer of Information

- **ABTDRR should transfer all quality or regulatory information from** *(17.60)*
  - Manufacturer to customer
  - Customer to manufacturer

- *This requirement includes the authentic Certificate of Analysis of the original manufacturer*



17.6 Transfer of Information

- **Provide the name of the original manufacturer and batch number to customer** *(17.61)*
- **Provide identity of original manufacturer to regulatory authorities upon request** *(17.62)*
  - Original manufacturer can respond to regulatory authority
  - Directly
  - Through authorized agents

- *The CoA format should comply with requirements of chapters 11.41, 11.42 and 11.43 and 17.63*
- *Where the analysis has been carried out by a third party, the CoA should show its name, address and telephone, and reference the name of the original manufacturer. In case a new CoA is issued, a copy of the original CoA should be attached (17.63, 11.44 and 11.43)*

17.6 Transfer of Information

- **Where the analysis has been carried out by a third party, the CoA should show**
  - its name,
  - address and
  - telephone, and
  - reference the name of the original manufacturer.
- **In case a new CoA is issued, a copy of the original CoA should be attached** *(17.63, 11.44 and 11.43)*

17.7 Complaints and Recalls

- **ABTDRR should maintain records of *received* complaints and recalls as specified in Section 15** *(17.70)*
- **If warranted ABTDRR should review complaint with original manufacturer to determine any further action with customers and/or regulatory authority** *(17.71)*

17.7 Complaints and Recalls

- **Investigation into cause conducted and documented by appropriate party** *(17.71)*
- **For complaints referred to original manufacturer, record maintained by ABTDRR should include any response received from the original manufacturer** *(17.72)*

See also for the same procedures Chapter 15.10 and 15.11

Key Messages

- **Agents, Brokers, Traders, Distributors, Repackers and Relabellers (ABTDRR) have to follow ICH Q7 requirements, if the respective operations are performed**
- **Provide the name of the original manufacturer and batch number to customer and regulatory authorities according to the local procedures**

ICH Q7 QaA *Clarification of Uncertainties*

1. What does ICH Q7 mean by ‘Agents, brokers, traders, distributors, repackers, or relabellers’?
2. Could a distributor of an API engage a contract manufacturer for production steps?
3. Is it acceptable to replace the original label, which contains the information of the original manufacturer?
4. Who is considered to be the original manufacturer of the API for purposes of the Certificate of Analysis (CoA)?

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