






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



PDA - PIC/S  
ICH Q7 Training 01/2014



*ICH Q7 Training*  
*Chapter 17: Agents, Brokers, Traders, Distributors, Repackers, & Relabellers*





## 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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## 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)**



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## To simplify this presentation



- **To simplify this presentation**
  - Agents**, *negotiates contracts of purchase and sale*
  - Brokers**, *sells or distributes something*
  - Traders**, *business is buying and selling*
  - Distributors**, *marketer of a commodity*
  - Repackers and**
  - Relabellers**

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

**will hereafter be referred to as**

**ABTDRR**

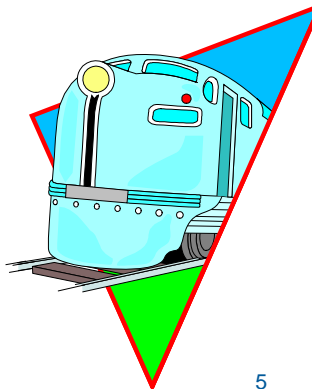
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## 17.1 Applicability

- **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 intermediate**



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## Why?

- **“*Manufacturing*” is defined to include all operations of**
  - ➡ Receipt of materials,
    - Production
  - ➡ Packaging and repackaging
  - ➡ Labelling and relabelling
    - Quality control
    - Release
  - ➡ Storage and distribution and
    - Related controls

The arrows indicate:  
some of the  
manufacturing activities  
may be performed by  
ABTDRR



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## 17.1 Applicability

- **ABTDRR should comply with relevant GMPs as defined in ICH Q7**
  - Where ABTDRR are involved and included in the manufacturing activities
- **Specific consideration to**
  - Preventing cross-contamination
  - Responsibility for sharing information
  - Preventing products deterioration
  - Maintaining traceability ◆ (critical requirement)

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## Distribution of 'API starting material'

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

- **No, it is not in scope of ICH Q7**  
*'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' (17.0)*


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## Similarities with Contract Manufacturers?

<div style="background-color: yellow; border: 1px solid black; border-radius: 10px; padding: 5px; display: inline-block; margin-bottom: 10px;"><b>Contract Manufacturer</b></div> <p><b>A manufacturer performing some aspect of manufacturing <i>on behalf</i> of the original manufacturer</b></p>	<div style="background-color: yellow; border: 1px solid black; border-radius: 10px; padding: 5px; display: inline-block; margin-bottom: 10px;"><b>ABTDRR</b></div> <p><b>Any party other than the original manufacturer that may trade and/or take possession ....</b></p>
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## 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)*

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## 17.3 Quality Management

- **Effective system of managing quality to be established, documented and implemented (17.30)**
  - As specified in Section 17.2 (traceability)
  - **According to the activities performed**
- ◆ *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, to avoid (17.40)**
  - Mix-ups, Loss of identity or purity
  - ◆ *Traceability has to be maintained between original and repack material (e.g. by appropriate identity testing)*
  - ◆ *There need to be appropriate steps in place to maintain the integrity of the repackaging operations*
- **Under appropriate environmental conditions to avoid contamination (17.41)**



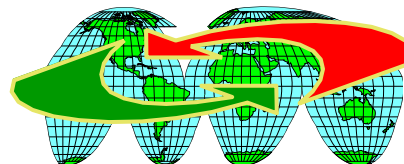
## 17.5 Stability

- **Studies to justify assigned expiration or retest dates should be conducted if API or intermediate is repackaged in a different type 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)*
  - ◆ *Stability studies under these condition have to maintain the original retest date*



## 17.6 Transfer of Information

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



## 17.7 Complaints and Recalls

- ABTDRR should maintain records of 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 (17.71)
  - Customers
  - Regulatory authority





## 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)



## Key Messages

- **Agents, Brokers, Traders, Distributors, Repackers and Relabellers (ABTDRR) have to **follow 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



## 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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