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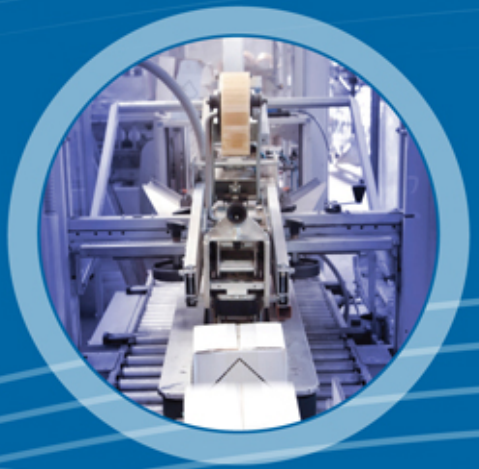
ICH Q7 Chapter 10:
Storage & Distribution



PDA - PIC/S ICH Q7 Training

Content

- **Warehousing** *(10.1)*
- **Distribution of APIs & Intermediates** *(10.2)*

10.1 Warehousing

- **Facilities for storage under appropriate conditions** *(10.10)* e.g. temperature, humidity
  - *There should be solid stability data to justify not performing temperature control and monitoring*
  - *Storage facilities should be temperature and humidity mapped in worst case seasonal conditions*
  - *Sampling points should be representative*
  - *A definition of 'room temperature' should be available*
  - *Consider controlled access to the warehouse*

10.1 Warehousing

- **Records maintained, if conditions critical** *(10.10)*
- **Separate storage areas for temporary storage of quarantined, rejected, returned, recalled material** *(10.11)*
  - Unless alternative system in place

◆ *Alternative systems such as electronic segregation could be considered adequate*

10.2 Distribution of APIs and Intermediates

- **APIs and intermediates only released for distribution to third parties after release by Quality Unit** *(10.20)*
- **APIs may be transferred under quarantine to unit under company's control if** *(10.20)*
  - Authorized by quality unit
  - With appropriate controls & documentation
  - *There are local regulatory requirements not allowing shipment under quarantine in some countries*

10.2 Distribution of APIs and Intermediates

- **Transported in a manner not adversely affecting API / intermediate** *(10.21)*
  - *Manufactures should understand the challenges caused by the shipping route e.g.*
    - Exposure to direct sunlight while awaiting air/sea fleet
    - Container at the top of container ship
    - Airplane: can get to -50˚ C if not pressurised
    - Foil used to protect against rain

10.2 Distribution of APIs and Intermediates

- **Special transport / storage conditions on label, if any** *(10.22)*
  - *Labels should ideally state the maximum and minimum of temperature for storage / transport (options for harmonisation)*
- **Manufacturer ensure transporter contractor knows and follows appropriate conditions** *(10.23)*
- **System in place to permit recall** *(10.24)*

Related documents

- **Good Distribution Practice requirement include guidance to handle APIs e.g.**
  WHO: API certification Schemes

Starting materials

- Control and safe trade of starting materials for pharmaceutical products
- Good trade and distribution practices for pharmaceutical starting materials [pdf 83kb]
  Annex 2, WHO Technical Report Series 917, 2003
- WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation [pdf 100kb]
  Annex 3, WHO Technical Report Series 917, 2003

Storage

- Guide to good storage practices for pharmaceuticals [pdf 632kb]
  Annex 9, WHO Technical Report Series 908, 2003
- Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products (jointly with the Expert Committee on Biological Standardization)
  Annex 9, WHO Technical Report Series 961, 2011

Best practices:
PDA Technical Reports No. 39, 53

Key Messages

- **Awareness of the storage and transport conditions over the supply chain**
- **Storage and transport under appropriate conditions and oversight**
- **When? Where? the material is**
- **Distribution of APIs and Intermediates requires approval by the Quality Unit**

ICH Q7 QaA *Clarification of Uncertainties*

1. What is meant by ‘APIs and intermediates can be transferred under quarantine to another unit under the company’s control when...’ and is this applicable to contract manufacturers?

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