

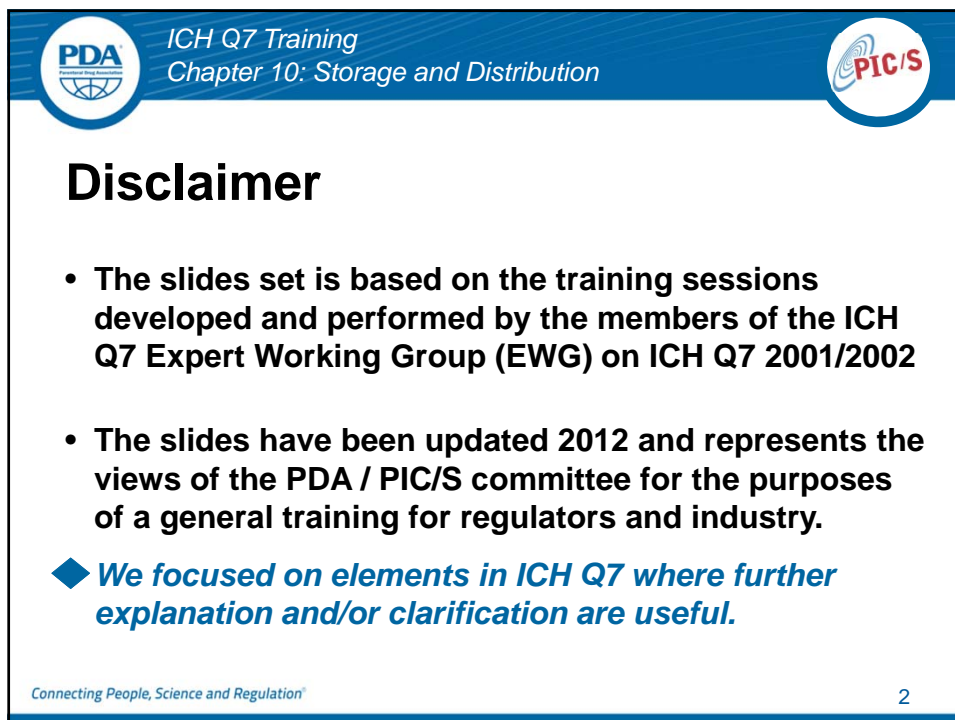
The slide features a blue background with white diagonal lines. In the top left corner is the PDA logo with the tagline "Connecting People, Science and Regulation". In the top right corner is the PIC/S logo. The main title "ICH Q7 Chapter 10: Storage & Distribution" is centered in white. To the right of the title are three circular images: a pharmaceutical production line, a scientist in a lab coat and mask, and a close-up of a syringe. At the bottom left, the text "PDA - PIC/S" and "ICH Q7 Training 01/2014" is displayed.

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PIC/S

ICH Q7 Chapter 10: Storage & Distribution

PDA - PIC/S
ICH Q7 Training 01/2014



The slide has a blue header with the PDA logo on the left and the PIC/S logo on the right. The header text reads "ICH Q7 Training" and "Chapter 10: Storage and Distribution". The main content is a disclaimer in black text, with a blue diamond icon preceding the final sentence. The footer contains the PDA tagline and the number "2".

PDA
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ICH Q7 Training
Chapter 10: Storage and Distribution

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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

- **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*

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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


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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)**

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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

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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**

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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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