

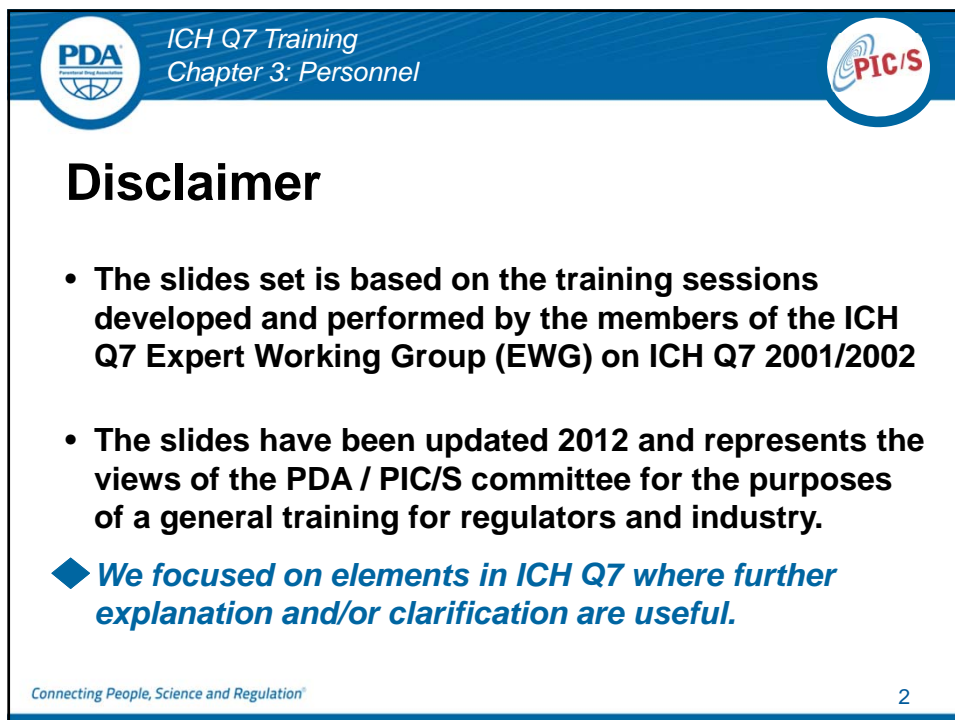
The slide features a blue background with white wavy lines. In the top left is the PDA logo with the tagline "Connecting People, Science and Regulation". In the top right is the PIC/S logo. The main title "ICH Q7 Chapter 3: Personnel" is centered in white. Below the title are three circular images: a laboratory machine, a person in a lab coat and mask, and a close-up of a syringe. At the bottom left, it says "PDA - PIC/S ICH Q7 Training 01/2014".

PDA  
Connecting People, Science and Regulation

PIC/S

## ICH Q7 Chapter 3: Personnel

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 Chapter 3: Personnel". The main content is on a white background with a blue border. It starts with the word "Disclaimer" in bold. There are three bullet points: the first is about the training sessions, the second is about the 2012 update, and the third is a blue diamond icon followed by a sentence in italics. At the bottom left is the PDA tagline, and at the bottom right is the number "2".

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ICH Q7 Training  
Chapter 3: Personnel

PIC/S

## 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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PDA ICH Q7 Training Chapter 3: Personnel PIC/S

## Content

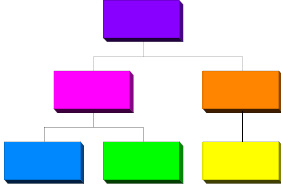

- **Personnel Qualifications (3.1)**
- **Personnel Hygiene (3.2)**
- **Consultants (3.3)**

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PDA ICH Q7 Training Chapter 3: Personnel PIC/S

## 3.1 Personnel Qualifications

- **Adequate number of personnel (3.10)**
- **Qualified by education, training, and / or experience (3.10)**
- **Responsibilities of personnel should be specified in writing (3.11)**
  - ◆ *Job descriptions should represent the current responsibilities and ideally be signed by the employee*

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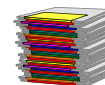
## 3.1 Qualifications: Training

- **Regularly conducted** (3.12)
  - ◆ *Different training at different levels in the organisation*
  - ◆ *Different levels according to the responsibility in a process*
- **By qualified individuals** (3.12)
  - ◆ *In some cases Web based training is also accepted if it includes an assessment*



## 3.1 Qualifications: Training

- **Covering particular operations performed and GMP** (3.12)
- **Records should be maintained** (3.12)
- **Training should be periodically assessed** (3.12)
  - ◆ *Preferably have predefined criteria on what the assessment includes*
  - ◆ *Consider to set refresher / re-training criteria / time limits*





## 3.2 Hygiene

- **Good sanitation and health habits (3.20)**



- **Clothing (3.21)**

- Clean
- Suitable for activity
- Additional protective apparel as appropriate



- ◆ *Objective protect the operator from the product and/or the product from the operator*
- ◆ *The level of gowning should be commensurate with the level of risk of the product / process*
- ◆ *Gowning requirements should be displayed and in different languages, if applicable*



## 3.2 Hygiene

- **Clothing suitable to activity**




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## 3.2 Hygiene

- **Avoid direct contact with intermediates and APIs (3.22)**

◆ *Consider risk of contamination and the health risk*

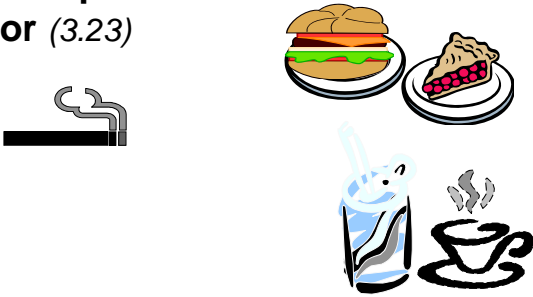


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## 3.2 Hygiene

- **Designated areas separate from manufacturing for (3.23)**
  - Smoking
  - Eating
  - Drinking
  - Chewing
  - Storage of food



◆ *This also applies to the area of laboratories*

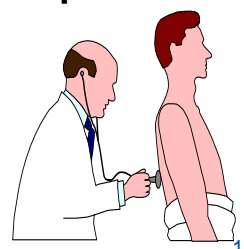
Gum or Tobacco

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## 3.2 Hygiene

- **Personnel with infectious disease or open lesions should not engage in activities that could compromise the quality of API (3.24)**
- **Until the condition is corrected or qualified medical personnel determine the person's inclusion would not jeopardize the safety or quality of the API (3.24)**



## 3.3 Consultants

- **Consultants should have sufficient education, training or experience (3.30)**
  - ◆ *Consultants have to have the same training as permanent staff for similar procedures*
  - ◆ *Same requirements should be established for temporary employees*
- **Record should be maintained of (3.31)**
  - Name
  - Address
  - Qualifications
  - Type of service provided



## Key Messages

- Requirements for tasks are described
- Every person has appropriate qualification
- Periodic training to be performed and assessed
- Hygiene should be established and maintained



## 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**
  - Stephan Rönninger (co-chair)
  - Mikael Le Bihan (co-chair)
  - Karl-Heinz Bender
  - Rosimeire Pereira Alves da Cruz
  - Graeme McKilligan
  - Jacques Morenas
  - Edwin Rivera
  - Georg Roessling
  - Lionel Viornerlywith input from members of the PIC/S Q7 expert cycle and other PDA volunteers

