



Connecting People, Science and Regulation®



ICH Q7 Chapter 3: Personnel



PDA - PIC/S ICH Q7 Training

© PIC/S and Parenteral Drug Association (PDA), July 2015

Reproduction prohibited for commercial purposes. Reproduction for internal use is authorised, provided that the source is acknowledged.

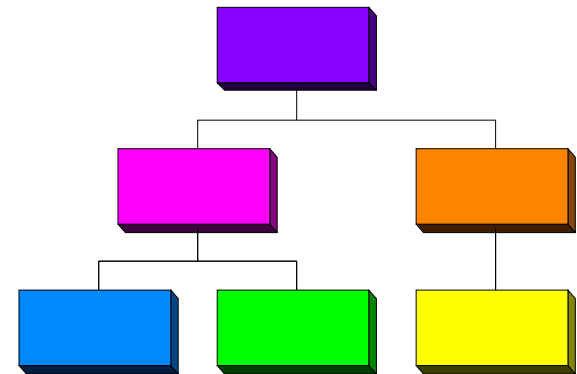


Content

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

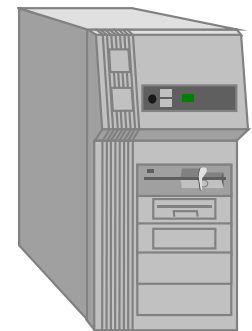
3.1 Personnel Qualifications

- 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*



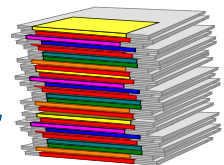
3.1 Qualifications: Training

- **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*
 - ◆ *Training of responsible senior/upper management in the area of GMP and quality matters should be conducted.*



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



3.2 Hygiene

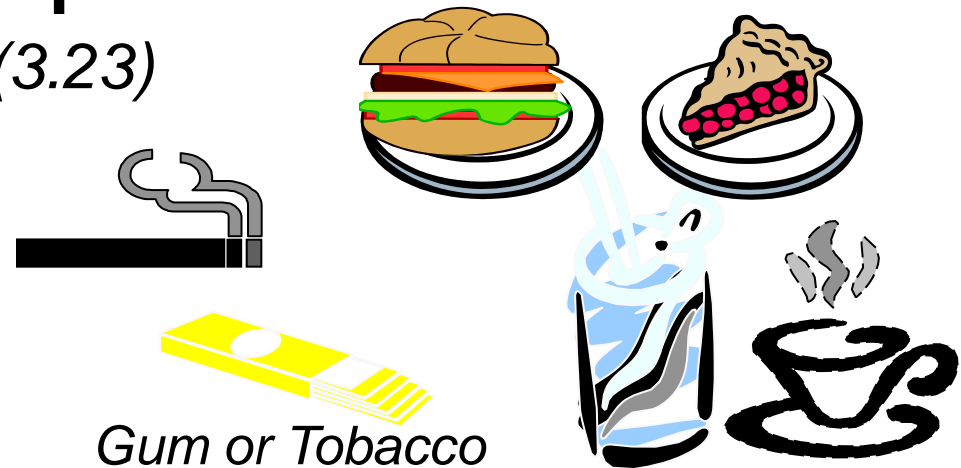
- **Avoid direct contact with intermediates and APIs (3.22)**
- ◆ *Consider risk of contamination of the product (and the health risk; outside the scope of ICH Q7)*



3.2 Hygiene

- **Designated areas separate from manufacturing for (3.23)**

- Smoking
- Eating
- Drinking
- Chewing
- Storage of food

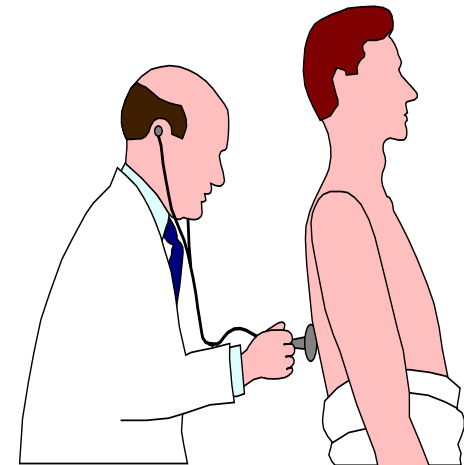


- ◆ *This also applies to the area of laboratories*

- ◆ *Normally working clothes should be changed to perform these activities (also refers to risk of cross-contamination)*

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**



ICH Q7 QaA *Clarification of Uncertainties*

1. What is the intent of the statement in [ICH Q7, 3.12] ‘training should be periodically assessed’?
2. Does ICH Q7 expect the use of a consultant and can a company delegate tasks and/or responsibility to a consultant?

