

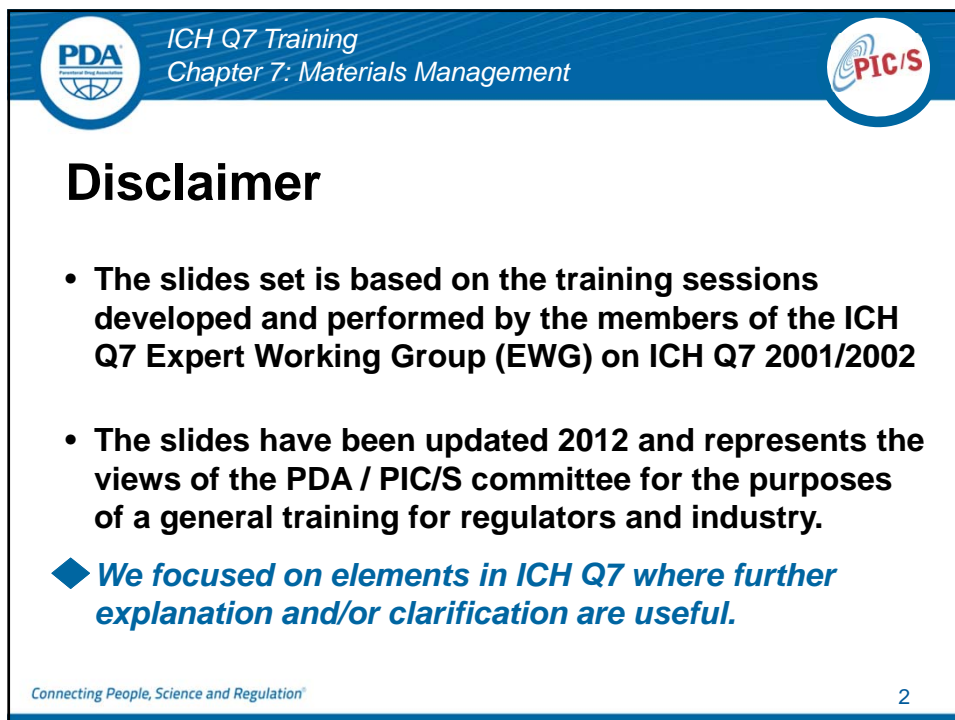
The slide features a blue background with white diagonal lines. In the top left is the PDA logo with the tagline "Connecting People, Science and Regulation". In the top right is the PIC/S logo. The main title "ICH Q7 Chapter 7: Materials Management" is centered in white. Below the title are three circular 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".

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# ICH Q7 Chapter 7: Materials Management

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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 text "ICH Q7 Training Chapter 7: Materials Management" is centered in the header. 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 statement about focusing on elements needing further explanation. At the bottom left is the PDA tagline, and at the bottom right is the number "2".

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Chapter 7: Materials Management



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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.*

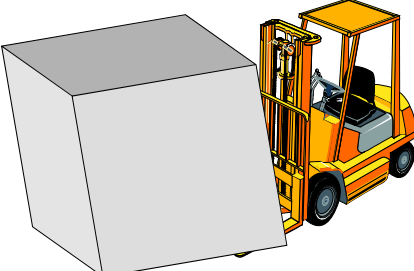
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## Content

- **General Controls (7.1)**
- **Receipt & Quarantine (7.2)**
- **Sampling & Testing of Materials (7.3)**
- **Storage (7.4)**
- **Re-evaluation (7.5)**




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## Definition

- **Material**
  - Denotes raw materials, process aids, intermediates, APIs, packaging and labeling materials
- **Raw material**
  - Denotes starting materials, reagents, solvents used in production of APIs or intermediates

◆ ICH Q11 defines what to file as 'API starting material'. This is the starting point for GMP according ICH Q7




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## Definition

- **Reagent**
  - Denotes materials that participate in reaction
- **Solvent**
  - Denotes inorganic or organic liquid used as vehicle for preparation of solutions or suspensions in production of APIs or intermediates
  - ◆ *Some materials can have different classes depending on the use e.g. a solvent can also be an API-starting material (e.g. Ethylene dichloride, Acetonitrile). The 'worst case' have to be applied.*




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## Definition

- **Process aid**
  - Denotes materials (excluding solvents) used as aid in production of APIs or intermediates that do not participate in reaction (e.g. filter aid, activated carbon)
- **Packaging material**
  - Denotes any material intended to protect an API or intermediate during storage and transport



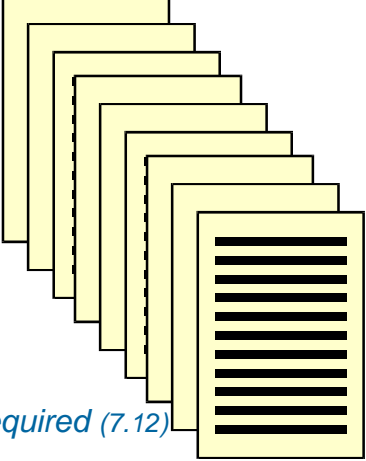
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**7.1 Materials Management General**

- **Written Procedures (7.10)**
  - Receipt
  - Identification
  - Quarantine
  - Storage
  - Handling
  - Sampling
  - Testing
  - Approval / rejection
- ◆ *A list of approved suppliers is required (7.12)*



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**7.1 Materials Management General**

- **Suppliers approved by the quality unit (7.12)**
  - ◆ *Approval by the purchasing department is not regarded adequate*
- **System for evaluating suppliers of *critical* materials (7.11)**
  - ◆ *API starting material, building blocks and solvencies used in the final stage at leased are regarded as 'critical material'*
  - ◆ *Also not mandatory this evaluation should usually include and be based on audits by or on behalf of the company*
  - ◆ *This right should be in the contract*

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## 7.1 Materials Management General

- **Specifications for materials (7.12)**
  - ◆ *There should be an agreement that the supplier and company uses all-times the same specification and implement a periodic review*
  - ◆ *On certainty API-starting materials the root of synthesis should be defined and agreed (re: impurity profile)*
- **Name & address of manufacturer known (for materials supplied through intermediaries) (7.13)**
- **Change control for changing source of critical raw materials (see also Section 13) (7.14)**
  - ◆ *Critical is defined for all material affecting the quality of the API*



## 7.2 Receipt & Quarantine

- **Each container (or group of containers) visually examined (7.20)**
  - Labeling, damage, seals, tampering
  - ◆ *'Container' which are used for transportation and/or storage*
  - ◆ *Any inconsistencies should be investigated*
- **Held under quarantine until sampled, examined / tested & released (7.20)**
  - Including mixing into existing stock (e.g. solvents (7.21))
- **Unless appropriate system to allow use under quarantine (2.17)**
  - ◆ *Quarantine: Status of materials isolated physically or by other means pending a decision on their subsequent approval or rejection*



## 7.2 Receipt & Quarantine

- If material delivered in non-dedicated tankers (7.22)...



## 7.2 Receipt & Quarantine

- .... assurance of no cross-contamination from tanker (7.22)

- Certificate of cleaning
- Testing for trace impurities
- Audit of supplier / transporter



One or more

- ◆ *Using certificates of cleaning should be preferably supported by an audit of the transport company or an alternative type of assessment giving adequate confidence of the validity of the certificate*







## 7.2 Receipt & Quarantine





- Large storage containers, manifolds, filling & discharge lines appropriately identified (7.23)
- Each container (or grouping) assigned code, batch or receipt number (7.24)
- System to identify status of each batch (7.24)
  - ◆ *A system should be in place to ensure the status of the different containers of each batch is clear. This may depend on how the batch is used in productions*



## 7.3 Sampling & Testing




- One ID test, at least (7.30)
  - With supplier Certificate of Analysis (CoA) for other tests
  - With system to evaluate suppliers
  - ◆ *There are exceptions (7.32)*
- Supplier Approval (7.31)
  - Adequate evidence that material consistently meets specifications
  - Full analyses on at least 3 batches before reduced testing
  - Full analysis at appropriate intervals versus CoA
  - Reliability of CoA checked at regular intervals
  - ◆ *This can be assessed based using Quality Risk Management principles and may be consider annual full analysis*



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## 7.3 Sampling & Testing



- **No testing necessary for processing aids, hazardous or highly toxic, special materials, transfers within company control if (7.32)**
  - CoA shows conformance to specs
  - Visual examination of containers/labels
  - Recording of batch numbers
  - Lack of on-site testing justified & documented



◆ *Proper documentation and justification is needed for other exceptions*




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## 7.3 Sampling & Testing

- **About Samples (7.33)**
  - Representative
    - ◆ *This may require mixing or warming before sampling*
  - Methods specify
    - Number of containers
    - Part of container
    - Amount of material
  - Sampling plan based on
    - Material criticality
    - Material variability
    - Quality history
    - Quantity analyzed



◆ **Normally there should be a statistically bases for the sampling plan**

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## 7.3 Sampling & Testing

- **Sampled at defined locations & by procedures to prevent contamination (7.34)**
- **Sampled containers resealed & marked (7.35)**



## 7.4 Storage of Materials



- **Stored / handled to prevent degradation, contamination & cross-contamination (7.40)**
  - ◆ *Small quantities (e.g. tailings) are often stored separately. The controlling should be equivalent to the main batch.*
- **Stored off floor, suitably spaced for cleaning / inspection (7.41)**

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## 7.4 Storage of Materials

- **Materials should be stored under conditions and for a period that have no adverse affect on their quality. (7.42)**
  - ◆ *Storage facilities should be temperature and humidity mapped in worst case seasonal conditions*
- **Materials should normally be controlled so that the oldest stock is used first. (7.42)**
  - ◆ *Normally first expiry first out (FEFO)*


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## 7.4 Storage of Materials

- **Outside storage in suitable containers o.k. if labels remain legible and containers cleaned before opening / use (7.43)**
  - ◆ *Assessment of the suitability of the labels to remain legible over time (e.g. influence of sunlight, rain)*
  - ◆ *Containers with out side storage should be sealed*
- **Rejects identified and controlled (7.44)**

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## 7.5 Re-evaluation

- **Re-evaluation as appropriate to determine suitability for use (7.50)**
  - Time
  - Conditions
- ◆ *Any material that is desired to be used beyond the re-test date should be typically fully tested before use*
- ◆ *Clarify with the manufacturer really means of the date given for a batch: 're-test date' or 'expiry date'*

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## Key Messages

- **Be clear on the categorisation of the material**
  - Material, raw material, reagent, solvent, process aid, packaging material, API starting material
- **General needs**
  - Specification
  - Evaluating, approval and change control of suppliers of *critical* materials
  - Receipt, quarantine and re-use procedures
  - Sampling and Testing (ID test at least)
- **Storage of Materials**
  - Prevent degradation, contamination & cross-contamination

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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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