Connecting People, Science and Regulation

ICH Q7 Chapter 16:
Contract Manufacture

PDA - PIC/S
ICH Q7 Training 01/2014

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 is useful.***

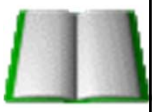
Definition

- **A manufacturer performing some aspect of manufacturing *on behalf of* the original manufacturer** *(Glossary)*
- **Involves agreement between two parties** *(16.12)*
  - Contract giver - manufacturer / owner
  - Contract acceptor - contractor (performs contracted service)

- *Contracting (and sub-contracting) of manufacturing has to be approved by QU (2.22.8) and should be described in the site master file and should be in the registration dossier*

Contract Manufacturers

- **Should comply with GMPs as defined in Q7** *(16.10)*
  - *Including Transport / Distribution (10.23)*
- **Written and approved contract or formal agreement**
  - Defining GMP responsibilities *(16.12)*
  - Permitting contract giver to audit to ensure GMP compliance *(16.13)*



Contract Manufacturers (ICH Q10)

- **Management of Outsourced Activities** *(ICH Q10, 2.7)*
  - Control and review of any outsourced activities and quality of purchased materials in responsibility of the pharmaceutical company *(ICH Q10, 2.7)*
  - These processes should incorporate quality risk management and include *(ICH Q10, 2.7)* :
    - Assessing prior to outsourcing operations
    - Defining the responsibilities and communication
    - Monitoring and review of the performance
    - Monitoring incoming ingredients and materials

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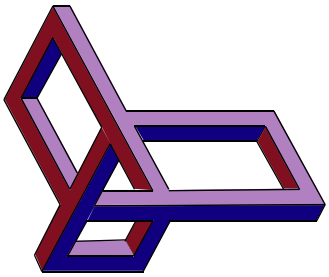
Contract Manufacturers

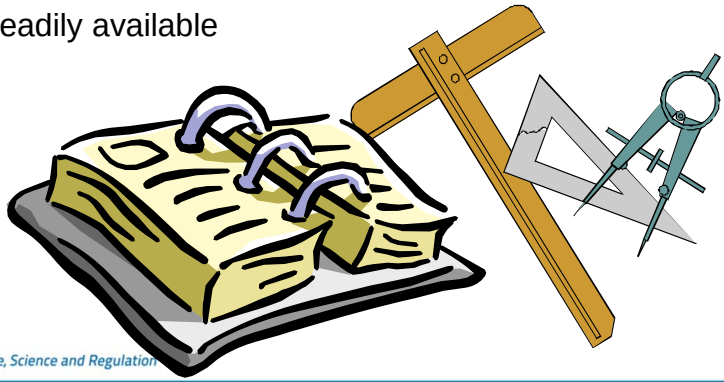
- **No changes in**
  - Process
  - Equipment
  - Test methods
  - Specifications
  - Sub-contracting *(16.14)*
  - Other contractual requirement



without approval by contract giver *(16.16)*

Contract Manufacturers

- **Original records should be** *(16.15)*
  - Kept at site where activity occurs
  - Readily available



Key Messages

- **On behalf of the original manufacturer contract manufacturers comply with GMPs as defined in Q7**
- **Changes must be under control by the contract giver and approved prior to implementation**
- **An appropriate knowledge exchange must be implemented**
- **Manufacturing contractors should be on the registration dossier; manufacturing authorization may be required according to local requirements**

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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