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# ICH Q7 Chapter 16: Contract Manufacture



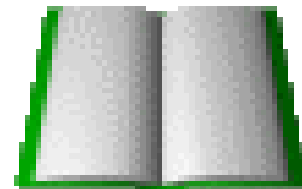
PDA - PIC/S ICH Q7 Training

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# 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)



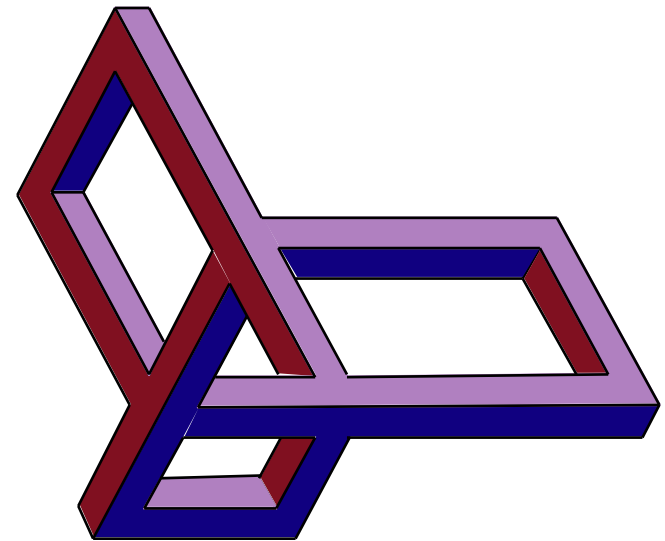
# Contract Manufacturers (ICH Q10)

- **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

# 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**



## ICH Q7 QaA *Clarification of Uncertainties*

- Does ICH Q7 preclude a contract manufacturer's independent quality unit from performing the main responsibilities in [ICH Q7, 2.22]?
- Which outsourced activities are covered by ICH Q7?
- What is meant by 'where subcontracting is allowed' [ICH Q7, 16.14]?

