Connecting People, Science and Regulation

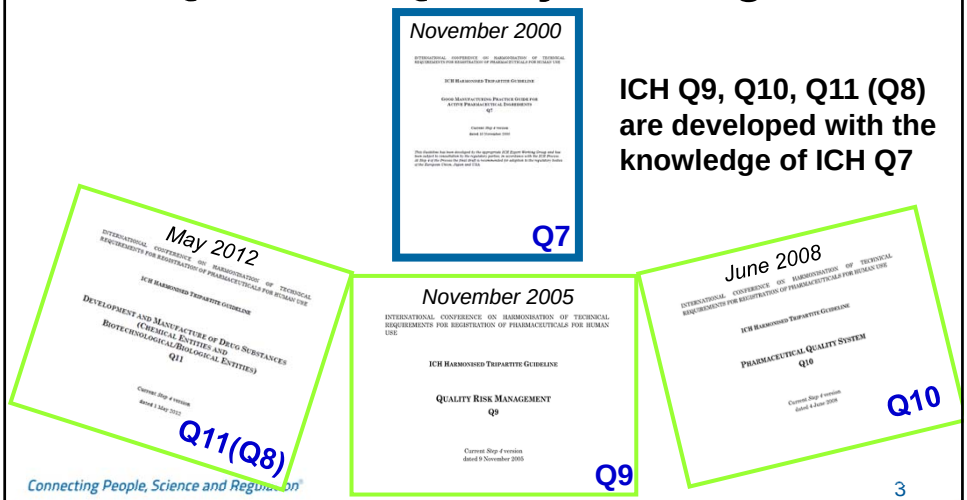
ICH Q7:
Link to the ICH Quality Paradigm

PDA - PIC/S
ICH Q7 Training 01/2014

Disclaimer

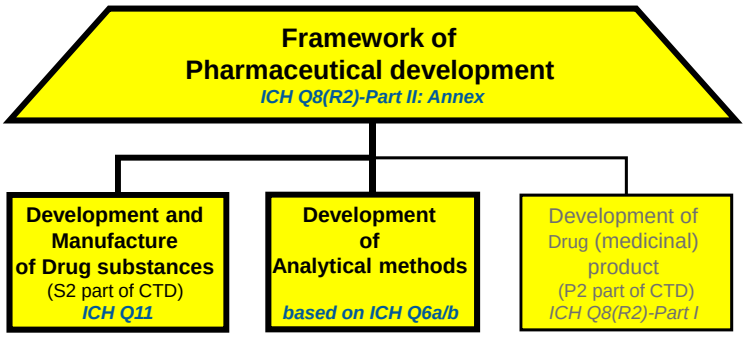
- **This slides have been developed by members of the ICH Q-IWG originally prepared and presented by Stephan Rönninger and Jacques Morenas**
- **These slides have been updated and represents the views of the PDA / PIC/S committee for the purposes of a general training for regulators and industry.**

ICH Q7 in the Quality Paradigm



ICH Q9, Q10, Q11 (Q8) are developed with the knowledge of ICH Q7

ICH Q7 and ICH Q11



- **Keep in mind: ICH Q7 does not address registration and filing requirements for APIs**

ICH Q7 and ICH Q11

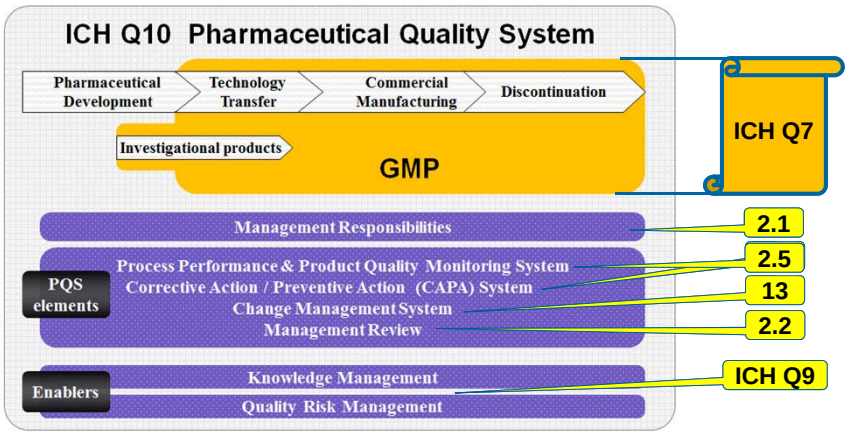
- **ICH Q11 defines the selection of starting materials and source materials for regulatory purpose**
  - 5.1 General Principles
  - 5.1.1 Selection of Starting Materials for Synthetic Drug Substances
  - 5.1.2 Selection of Starting Materials for Semi-synthetic Drug Substances
  - 5.1.3 Selection of Source Materials for Biotechnological/Biological Products
- **Based on this the approved regulatory dossier defines when GMP according to ICH Q7 has to start *at least***
  - *There is no need to file a change/variation of the 'API starting material' only because items from ICH Q7 are applied in earlier stages of production*

ICH Q7 and ICH Q10

'Regional GMP requirements, the ICH Q7 Guideline, "Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients", and ISO quality management system guidelines form the foundation for ICH Q10.'

(ICH Q10)

ICH Q7 and ICH Q10

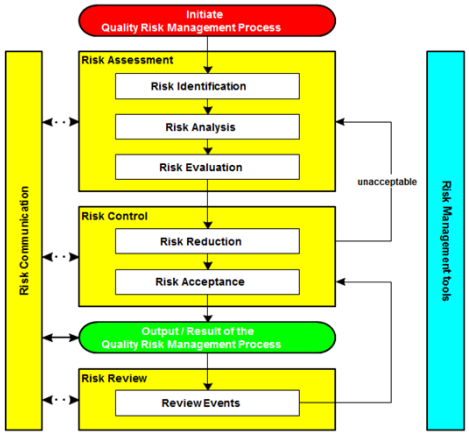


ICH Q7 and ICH Q9

GMPs for APIs is in the scope of ICH Q9

'This guideline provides principles and examples of tools for quality risk management can be applied to different aspects of pharmaceutical quality.'

'These aspects include … manufacturing, distribution, and the inspection… throughout the lifecycle of drug substances… biological and biotechnological products...'



ICH Q7 and ICH Q9

- **The annex II of ICH Q9 link to the elements of ICH Q7**

ICH Q7

2 Quality Management
3 Personnel
4 Buildings and Facilities
5 Process Equipment
6 Documentation and Records
7 Materials Management
8 Production and In-Process Controls
9 Packaging and Identification Labelling of APIs and Intermediates
10 Storage and Distribution
11 Laboratory Controls
12 Validation
13 Change Control
14 Rejection and Reuse of Materials
15 Complaints and Recalls
16 Contract Manufacturers (including Laboratories)
17 Agents, Brokers, Traders, Distributors, Repackers, and Relabellers

ICH Q9

Annex II: Potential Applications for Quality Risk Management

II.1 Quality Risk Management as Part of Integrated Quality Management
II.4 Quality Risk Management for Facilities, Equipment and Utilities
II.5 Quality Risk Management as Part of Materials Management
II.6 Quality Risk Management as Part of Production
II.7 Quality Risk Management as Part of Laboratory Control and Stability Studies
II.8 Quality Risk Management as Part of Packaging and Labelling

ICH Q7 Training
ICH Q7 Linked to the ICH Quality Paradigm

ICH Q7 along the product life cycle

Pharmaceutical Development → Technology Transfer → Commercial Manufacturing → Product Discontinuation

- **Whole ICH Q7 describe GMPs for API's applicable over the life cycle for small molecules and Biotech products**
- **To address specific needs ICH Q7 provides more details on**

18 Specific Guidance f. APIs Manufactured by Cell Culture/Fermentation
18.1 General
18.2 Cell Bank Maintenance and Recordkeeping
18.3 Cell Culture/Fermentation
18.4 Harvesting, Isolation, and Purification
18.5 Viral Removal/Inactivation Steps

19 APIs for Use in Clinical Trials
19.1 General
19.2 Quality
19.3 Equipment and Facilities
19.4 Control of Raw Materials
19.5 Production
19.6 Validation
19.7 Changes
19.8 Laboratory Controls
19.9 Documentation

ICH Q7 along End-to-End Quality

API starting material → **API Production & Purification (up stream/ down stream)** → **API Distribution**

API Starting Material	Manufacturing		Distribution
ICH Q7: Definitions	Ch 4: Building and Facilities	Ch 7: Materials Management	Ch 9: Packaging and Identification Labeling
ICH Q11: Selection of starting material	Ch 5: Process and Equipment	Ch 8: Production and In Process Controls	Ch 10: Storage and Distribution
	Ch 6: Documentation and Records	Ch 14: Rejections and Reuse	Ch 17: Agents, Brokers, Traders, Distributors, Repackers, and Relabellers

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ICH Q7 Linked to the ICH Quality Paradigm

ICH Q7 along End-to-End Quality

API starting material → **API Production & Purification (up stream/ down stream)** → **API Distribution**

API Starting Material	Manufacturing		Distribution
1 Introduction 1.3 Scope ICH Q7 Definition API Starting Material A raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. ICH Q11 5 Selection of Starting Materials and Source Materials 5.1 General Principles 5.1.1 Selection of Starting Materials for Synthetic Drug Substances 5.1.2 Selection of Starting Materials for Semi-synthetic Drug Substances 5.1.3 Selection of Source Materials for Biotechnological/Biological Products	4 Buildings and Facilities 4.1 Design and Construction 4.2 Utilities 4.3 Water 4.4 Containment 4.5 Lighting 4.6 Sewage and Refuse 4.7 Sanitation and Maintenance 5 Process Equipment 5.1 Design and Construction 5.2 Equipment Maintenance and Cleaning 5.3 Calibration 5.4 Computerized Systems 6 Documentation and Records 6.1 Documentation System and Specifications 6.2 Equipment Cleaning and Use Record 6.3 Records of Raw Materials, Intermediates, API Labelling and Packaging Materials 6.4 Master Production Instructions (Master Production and Control Records) 6.5 Batch Production Records (Batch Production and Control Records) 6.6 Laboratory Control Records 6.7 Batch Production Record Review	7 Materials Management 7.1 General Controls 7.2 Receipt and Quarantine 7.3 Sampling and Testing of Incoming Production Materials 7.4 Storage 7.5 Re-evaluation 8 Production and In-Process Controls 8.1 Production Operations 8.2 Time Limits 8.3 In-process Sampling and Controls 8.4 Blending Batches of Intermediates or APIs 8.5 Contamination Control 14 Rejection and Reuse of Materials 14.1 Rejection 14.2 Reprocessing 14.3 Reworking 14.4 Recovery of Materials and Solvents 14.5 Returns	9 Packaging and Identification Labelling of APIs and Intermediates 9.1 General 9.2 Packaging Materials 9.3 Label Issuance and Control 9.4 Packaging and Labelling Operations 10 Storage and Distribution 10.1 Warehousing Procedures 10.2 Distribution Procedures 17 Agents, Brokers, Traders, Distributors, Repackers, and Relabellers 17.1 Applicability 17.2 Traceability of Distributed APIs and Intermediates 17.3 Quality Management 17.4 Repackaging, Relabelling and Holding of APIs and Intermediates 17.5 Stability 17.6 Transfer of Information 17.7 Handling of Complaints and Recalls 17.8 Handling of Returns

ICH Q7 & Quality System items

2 Quality Management
2.1 Principles
2.2 Responsibilities of the Quality Unit(s)
2.3 Responsibility for Production Activities
2.4 Internal Audits (Self-Inspection)
2.5 Product Quality Review

3 Personnel
3.1 Personnel Qualifications
3.2 Personnel Hygiene
3.3 Consultants

11 Laboratory Controls
11.1 General Controls
11.2 Testing of Intermediates and APIs
11.3 Validation of Analytical Procedures
11.4 Certificates of Analysis
11.5 Stability Monitoring of APIs
11.6 Expiry and Retest Dating
11.7 Reserve/Retention Samples

12 Validation
12.1 Validation Policy
12.2 Validation Documentation
12.3 Qualification
12.4 Approaches to Process Validation
12.5 Process Validation Program
12.6 Periodic Review of Validated Systems
12.7 Cleaning Validation
12.8 Validation of Analytical Methods

13 Change Control

15 Complaints and Recalls

16 Contract Manufacturers (including Laboratories)

ICH Q7 Training
ICH Q7 Linked to the ICH Quality Paradigm

Key message

ICH Q7 is linked to the ICH paradigm

- **ICH Q9**
  - Applies to APIs
- **ICH Q10**
  - ICH Q7 as foundation
- **ICH Q11 (Q8)**
  - Addresses development, registration and filing requirements for APIs

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)
  - Jacques Morenas