Q11 Update

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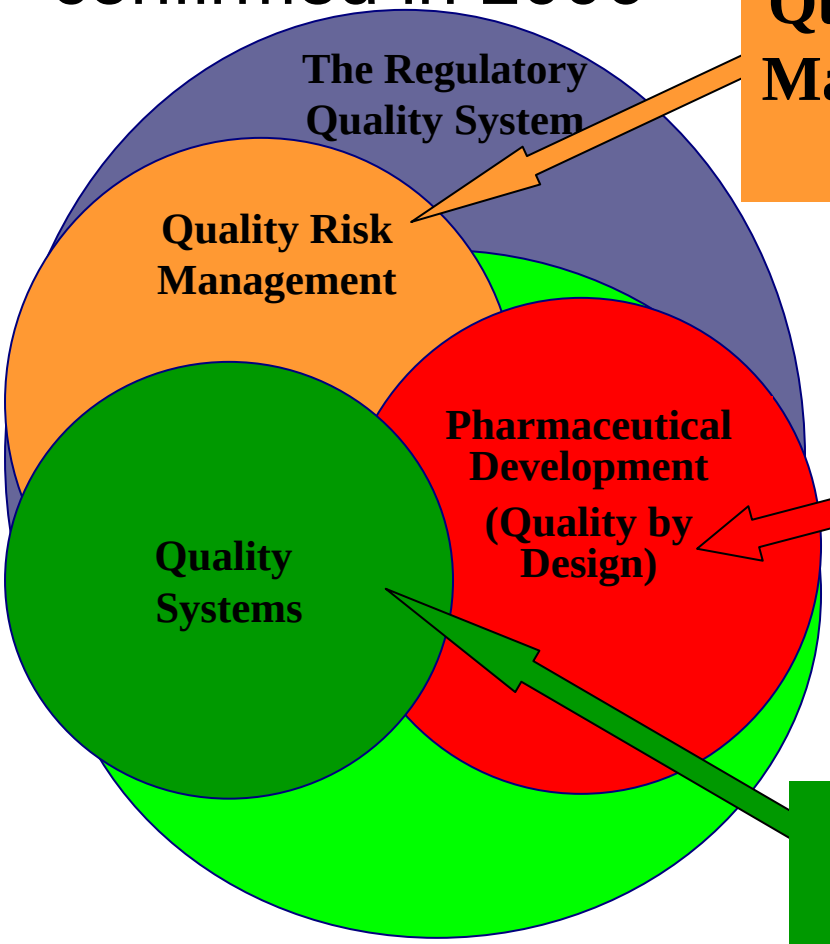
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

Content

- History of Concept Paper Development
- Review Concept Paper and Business Case
- EWG Activities

The Brussels 2003 agreement evolved and was confirmed in 2006



Quality Risk Management (Q9)

Pharmaceutical Development (Q8)

Quality Systems (Q10)

For companies with :

1. **Good design and control strategies**
2. **Good Risk Management strategies**
3. **Good Quality Systems**

Reduced intensity of Regulatory Oversight:

- **Reduction of submissions on changes/variations**
- **Inspection of quality systems**

ICH

Topics to be considered

- ***Drug substance guidance addressing chemical and biotech (similarities & differences), traditional and 'best scientific practices' for S2 of CTD***
- Clarity on terms and concepts (implementation of Q8, Q9, Q10)
- Q8 and Q10 EWGs to work together on high priority terms
- Guidance on content of an 'improved' QOS placing key information into QOS backed up by Mod 3.
- Updating of existing guidelines to accommodate technical advances

ICH Quality Roundtable, September 2007

Drug Substance Agreements and Understandings

- Principles of Q8, Q9, Q10 are applicable to chemical and biotech drug substances and drug products
- Broad spectrum of process and molecular complexity could impact implementation
- Principles provide significant opportunities (and challenges) for more complex molecules and processes
- Fundamentals of good product development need to be addressed regardless of ‘traditional’ or ‘new’ development paradigms
- Focus should be on enhancing the process for ensuring quality rather than specific terminology
- Lack of guidance on drug substance still a remaining gap

ICH Quality Roundtable,September 2007

Recommendations

Development of an ICH guideline on Development and Manufacture of the Drug Substance (Section ‘S2’ of CTD-Q)

- Follow process used by CTD-Q EWG where biotech & chemical experts work together and in parallel (if necessary)
- Core group (1-2/party + 1/observer) to develop concept paper and business case

Concept Paper Q11

Key Points

- Promote harmonisation of requirements
- …..High level technical guidance relevant to design, development and manufacture of drug substance as part of a total control strategy……
- Intended to provide guidance for drug substances as defined in Q6A and B
- Should identify similarities and differences for biologics and chemical entities

Concept Paper Q11

Issues to be resolved

- Selection of materials for manufacture of DS
- Control strategy
- Impurities and product related substances
- Process Robustness
- Scale Down models
- Critical Intermediates

Concept Paper Q11

Goals of Guideline

- Harmonise submissions
- Outline science based concepts
- Recommend approaches to demonstrating process and product understanding
- Address complexity of processes/products
- Accommodate different development approaches
- Address enhanced and systematic approaches to drug development.

Business Case for Q11

ICH-Q11
Proposal to Steering Committee
March 2008

- Problem statement
  - Different regional expectations
  - Difficult to harmonise technical information
- Expected Benefits
  - Cost of assessors time
  - Cost of submission preparation
  - Cost of preparing and reviewing answers to questions
  - Cost to managing regional documents

EWG Challenges

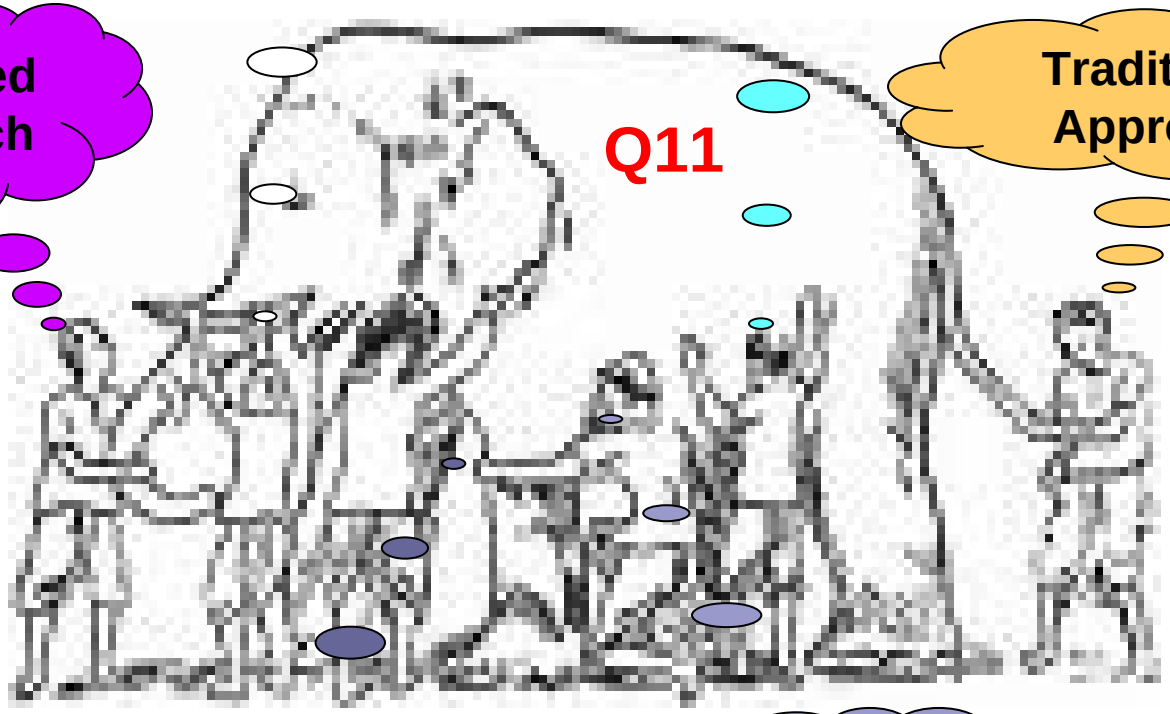
- Balance of Guidance
  - Complex vs Less complex molecules
  - Approach to Development
    - Empirical
    - Enhanced, QbD
  - Manufacturing
    - Validation
  - Level of Detail
    - Enough detail to be useful
    - Not so detailed to be prescriptive
- How far to reproduce from other Guidelines

Q11 Expectations?

Mfg Process

Control Strategy

Enhanced Approach



Traditional Approach

What goes In CTD

CQA's

ICH

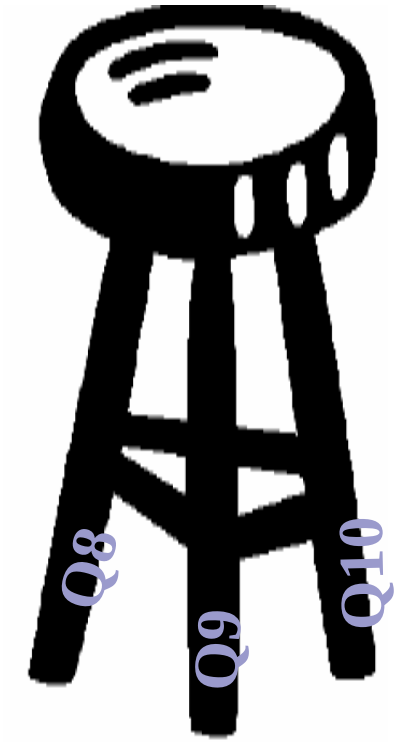
Outline Working Structure

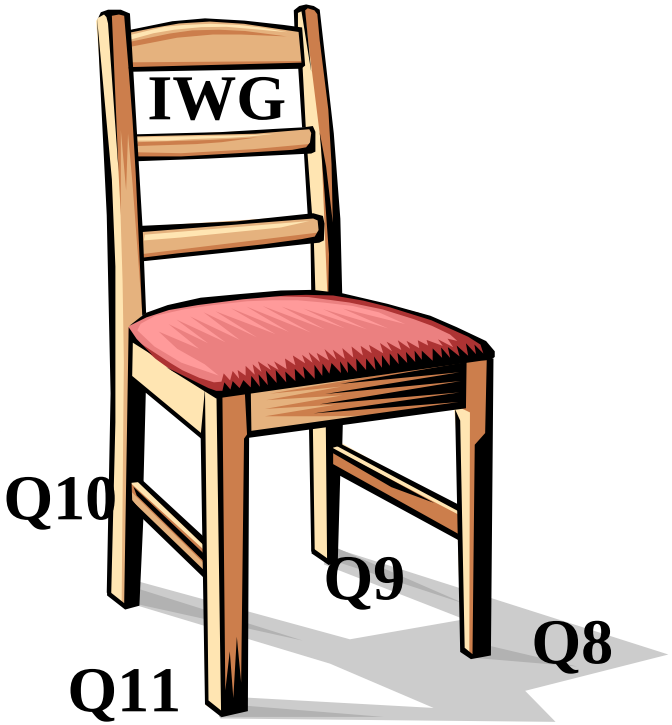
- Introduction
- Manufacturing Process Development
- Process Validation/Evaluation
- Controls
- Manufacturing Description

Questions/Topics Identified

- Critical Quality Attributes
- Control Strategy
- Defining Synthetic Starting materials
- Platform Technology
- Process Validation
  - Continuous Process Verification
  - Validation vs Verification
- Scale-Down Models

Value of Q11





Thank You

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