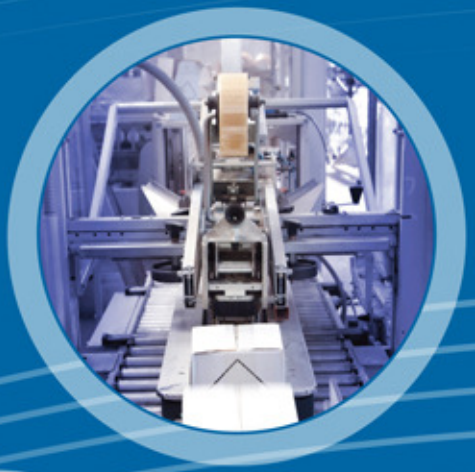
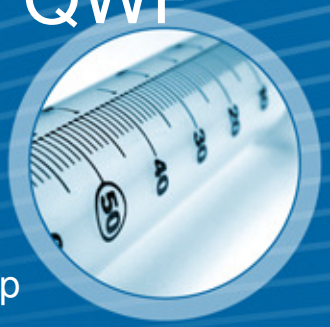
Connecting People, Science and Regulation®

Joint Regulators-Industry Quality by Design Workshop

Introduction and Goals of the Workshop





Jean-Louis ROBERT
Chair CHMP-CVMP QWP

Joint Regulators/Industry QbD Workshop
28-29 January 2014 London, UK

Pharmaceutical Development a History

1989 Development Pharmaceutics (EU)

1999 Revision of Development Pharmaceutics (EU)

1998 Discussion on CTD-Q

Initial proposal → Pharmaceutical Development under Regional Requirement!

Reminder: EU: dossier structure (before CTD)

1. Composition
2. Development Pharmaceutics
3. .....

2005: Pharmaceutical Development

Quality by Design – Paradigm Change

"Develop a harmonised pharmaceutical ***quality system*** applicable across the ***lifecycle*** of the product emphasizing an integrated approach to quality ***risk management*** and ***science***."

Brussels July 2003

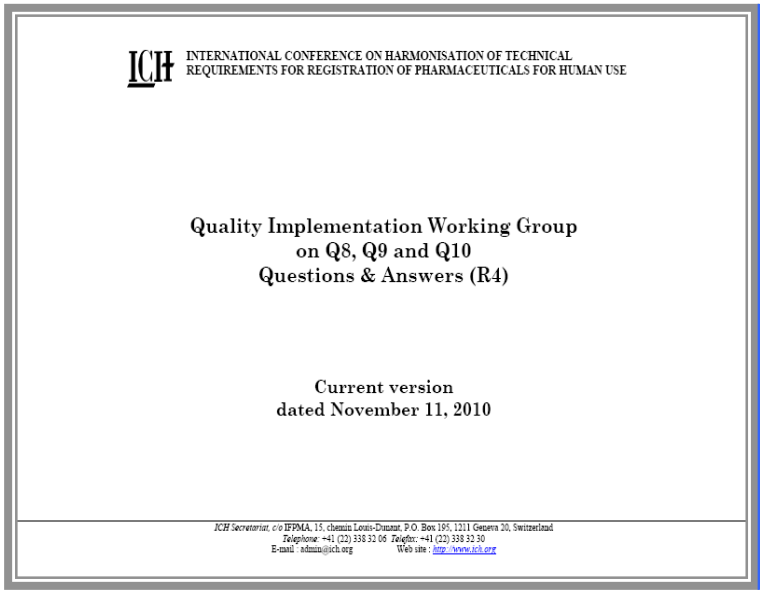
Achievements

- Q8 (R2): pharmaceutical Development
  - Principles, concepts, opportunities
- Q9: Quality Risk Management
  - Proactive approach
- Q10: Pharmaceutical Quality System
  - Based on ISO standards but including the lifecycle
- Q11: Development and manufacturing of APIs
  - Q8 (R2) for APIs

"Application including QbD: A Leaning process

From 2009 to 2011

ICH – Quality IWG implementation support


ICH INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

Quality Implementation Working Group
on Q8, Q9 and Q10
Questions & Answers (R4)

Current version
dated November 11, 2010

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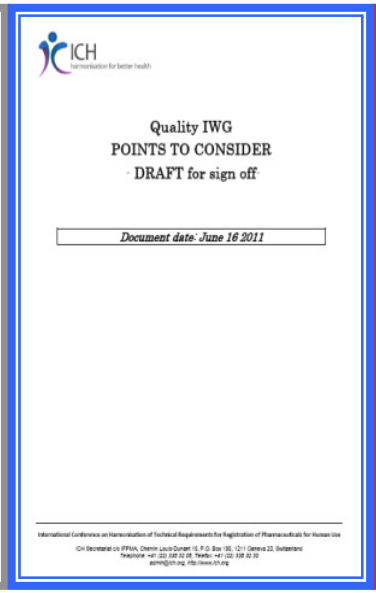
ICH

Quality IWG
POINTS TO CONSIDER
DRAFT for sign off

Document date: June 16 2011

'Questions and Answers' **'Points to consider'** **'Training & Workshop'**

http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

Quality by Design – Paradigm Change

- Quality must be mainly built in and it will not only improve by additional testing and inspection
- Better utilization of modern science throughout product lifecycle
- QRM is a key enabler throughout product lifecycle
- Robust PQS with appropriate knowledge management assures quality throughout product life cycle.
- An integrated approach to development, manufacturing and quality for both industry and regulators

Quality by Design – Paradigm Change

- Understanding of Quality by Design as in Q8(R2)
  - A more systematic approach to development may include, for example, incorporation of prior *knowledge*, results of experimental studies using *design of experiments, use of quality risk management,* and *use of knowledge management* (see ICH Q10) throughout the *lifecycle* of product.
  - Science is no longer isolated; it is living across the lifecycle of the product/process within a Quality Management System.

Current Status (1)

- A lot of progress in the recent past
  - More science based applications
  - More scientific understanding (DoE)
    - More robust manufacturing processes
  - More emphasis on
    - Control Strategy
- Opportunities:
  - Real Time Release Testing
  - Manufacturing flexibility (Design Space)

Current Status (2)

- However a lot of complaints (Regulators and Industry)
  - More science but more questions !?!
  - Level of data/information requested or submitted in an application not really clarified.
  - Quality of information submitted.
  - Reason for a more systematic or QbD approach if no benefit at the end.
  - Is the term QbD unclear or not sometimes misused?
  - Terminology!

ICH Informal Quality Discussion Group

- Forum for promoting QbD topics
- Identified QbD topics so far

  (not a priority list, no decision taken):
  - Revision of Q6A/B
  - CTD-Q location
  - Life-Cycle Management
  - Process Validation
  - Continuous Manufacturing
  - QbD Analytical Methods/Analytical Validation
  - Quality Glossary
- Training

Scope of Workshop

- Workshop based on real cases
- Survey/Wrap up of what has been achieved so far
- Experience gained so far
- Promotion of common understanding
- Identify bottlenecks/obstacles to QbD
- Identify next steps
- International harmonisation: participation of FDA/MHLW-PMDA

Future Challenges

- QbD for biologicals: more discussion needed!?
- QbD for more "complex" type of products.
- How can we further promote this paradigm?
- International harmonisation: what about regions outside ICH?

Thank you

- Organising Committee
- Presenters: Industry and Regulators
- PDA
- EMA for hosting