Implementation of ICH Q8, Q9, Q10

ICH Q-IWG Integrated Training Programme

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

Disclaimer

The information within this presentation is based on the ICH Q-IWG members expertise and experience, and represents the views of the ICH Q-IWG members for the purposes of a training workshop.

ICH: 20 years process (1)

- **Start in 1990 (Brussels)**
- **Objective of ICH:**
  Technical and scientific harmonisation between Japan, Europe and USA.
- **Scope:**
  New chemical entities and biotechnology derived products
- **Sponsors:**
  - Regulators: EU, FDA, MHLW
  - Industry: EFPIA, JPMA, PhRMA
- **Observers:**
  - EFTA, Health Canada, WHO
- **Steering Committee**

ICH: 20 years process (2)

- 1990: Pharmacopoeial Discussion Group
  - EP, JP, USP, WHO
- 1997: Interested Parties: IGPA, WSMI
- 1999: Global Cooperation Group
  - 2004 RHIs: APEC, ASEAN, GCC, PANDRH, GCG
  - 2008 DRAs: Australia, Brazil, China, India, Russia, Singapore, South Korea
  - 2008: DoH: Chinese Taipeh
- 2003: Quality New Paradigm
- 2006: Biotech Industry
- **2010: ICH Training: Implementation Q8, Q9, Q10**

Achieved so far (1)

- **Areas**
  - Quality, Safety, Efficacy
  - Multidisciplinary areas, MedDRA, e-submission,…..
- **Initial ICH Quality topics**
  - Scientific/technical guidelines mostly:
    Stability, Method Validation, Impurities, Specifications, Q5 series (Biological)
  - System oriented: GMP for APIs
  - Structure: Common Technical Document

Quality: A New Paradigm

'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)**

- Q8: Pharmaceutical Development
- Q8 (R2): Pharmaceutical Development Revision
- Q9: Quality Risk Management
- Q10: Pharmaceutical Quality System
- Q11: Development and Manufacture of Drug Substances (chemical/biological entities): in progress.

Quality: A New Paradigm

Main message

Science is no longer isolated; it is living across the lifecycle of the product/process within a Quality Management System

Quality: A New Paradigm

The new paradigm emphasize:

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

Implementation WG on Q8, Q9, Q10

- Task of IWG Q8, Q9, Q10:
  - "….due primarily to departure from the traditional approaches to quality guidance, proper implementation of these concepts is provided by bringing clarity, further explanation and removing ambiguities and uncertainties".
  - Technical issues & related documentation:
  - Additional implementation issues: influence on existing ICH guidelines;
  - Communication and training
- Unique training programme for industry and regulators (assessors and inspectors) in the three regions:
  - Tallinn June 2-4, 2010
  - Washington October 6-8, 2010
  - Tokyo October 25-27, 2010

Structure of Tallinn Training

- **Plenary presentations**
  - Lifecycle of a drug product
  - Development, Assessment, Manufacturing, Inspection
- **Breakout sessions**
  - Design Space
  - Control Strategy
  - Pharmaceutical Quality System
  - Quality Risk Management
- **Conclusions and next steps**

Training on Implementation of Q8, Q9, Q10

- Training based on a case study.
- Integrated implementation of Q8, Q9, Q10 and application to drug products and related operations
- Opportunity for open dialogue between Regulators and Industry.
- Feedback from the workshops will be used to further facilitate the understanding and implementation of ICH Q8, Q9 and Q10.

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