ICH-GCG ASEAN ICH Q8, Q9, Q10

Breakout: B
Control Strategy

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Disclaimer

General on this presentation

- Feedback from the facilitated discussions
- See it as a brainstorming from the breakout discussion

Breakout B Summary - Control Strategy

Are we clear with the key messages?

- IWG key messages generally accepted
  - No need for any additional terminology
  - To harmonize definitions for Process Control between Q6A and Q7
- Control Strategy is a life cycle approach. Needs to be maintained, revised according to further knowledge on the product and process.
- Control strategy and batch released should not be confused.

Breakout B Summary - Control Strategy

Practical concerns / Clarification required for practical harmonised implementation?

RTRT valid method to replace end product testing, both are acceptable but RTRT is a more scientific approach

- How do we describe RTRT in specification?
  - Relationship to Pharmacopoeial standards
- Certificate of Analysis / Certificate of Compliance
- Sampling plan
- Validity of RTRT across different configurations (e.g. NIR on blender)
- Foundation built during product development activities
  - Implementation for legacy drug substances and products?
- Method validation of PAT for RTRT vs for internal monitoring
- Harmonised approach to RTRT and avoidance of import testing

Breakout B Summary - Control Strategy

Practical concerns / Clarification required for practical harmonised implementation?

- **Importance of risk assessment**
  - How to perform: define in on-site SOPs
  - Output included in application files
  - How much information in an application file?

- **Description of control strategy for RTRT in a submission**
  - Revision of CTD Q-location issues?

Practical concerns / Clarification required for practical harmonised implementation?

- **Movement to new technologies**
  - Adoption by Industry
  - Acceptance by Regulators
  - Training
- **Harmonised guidances to facilitate and encourage innovation and adoption of new technology**
- **Continue dialogue between industry and regulators (Assessors and Inspectors)**

Breakout B Summary - Control Strategy

Practical concerns / Clarification required for practical harmonised implementation?

- **Control strategy and lifecycles**
  - How does Control Strategy evolve during lifecycle?
  - Maintenance and update of models
    - Clarification of role of Assessors and GMP Inspectors

- **Role of QTPP**
  - Good start to identify at an early stage critical quality attributes of the drugs substance and its potential impact on the drug product.
  - Dynamic nature of QTPP during development

Breakout B Summary - Control Strategy

Practical concerns / Clarification required for practical harmonised implementation?

- **Use of different control strategies for the same product can be accepted** e.g.
  - Fall-back testing for RTRT equipment failure
  - Different facilities
  - Approved for different countries

- **Is there a relationship between control strategy (Q8/Q9/Q10) and process validation?**