

FDA's Pharmaceutical Quality Initiatives – Implementation of a Modern Risk-based Approach  
Co-sponsored with AAPS, ISPE, & FDA  
February 28, 2007 to March 2, 2007

## Breakout Session : ICH & International Activities (E)

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## Breakout Session Outline

- Issues Discussed
- Shared Understanding & Agreements
- Remaining Challenges
- Recommendations
  - Strategies to implement agreed-upon issues
  - Proposals to resolve remaining challenges

## Issues Discussed

- Best ways to ensure consistent implementation of new ICH approaches in the regions
- Need for further clarification beyond ICH Q8?
- Need for a Q8-type drug substance guideline?
- Need to update older ICH Q guidelines?
- Revision of QOS to become a knowledge rich review tool?

## Shared Understanding and Agreements

- Globally consistent implementation of Q8/9/10 is essential to prevent deharmonisation
- Need for "hands-on" examples (e.g. case-studies, feed-back from FDA pilot program) to help implement ICH concepts. However, needs to cover all ICH regions and beyond. Harmonised glossary key to success.
- Need for high-level guidance, case law etc. rather than examples that could be considered prescriptive. Could be done through non-commercial, non-profit organisations.

## Shared Understanding and Agreements

- Need to describe QbD-concepts for API, but not necessarily a top priority given limited resources
- Need to keep existing guidelines updated to accommodate new concepts, but also need to cover traditional approaches
- Focus on defining the content for QbD information to be included in the dossier "Delight the reviewer", but less important whether information goes into module 3 or in QOS

## Remaining Challenges (1)

- Harmonisation of terminology (e.g. critical/non-critical, QbD, control strategy....)
- A global implementation of new ICH Q concepts providing sufficient technical clarification (less guidance not constraining innovation, more examples).
- How to embrace optionality in revising old guidelines (new concepts vs. traditional approaches)

## Remaining Challenges (2)

- Overcoming the tradition of data-review to knowledge review
- Consistency in regional requirements for biotech drug substances
- Strong interest in a globally harmonised regulatory agreement

## Recommendations (1)

Strategies to implement agreed-upon issues

- Organise joint training sessions for industry and regulators with international participation
- Consider “roll-out” similar to Q7 exercise
- Elaboration of case-studies by non-profit organisations; global sharing of information

## Recommendations (2)

Strategies to implement agreed-upon issues

- Consider brief update of Q 8 to include high-level guidance on QbD concepts for API
- Include “opening clause” in Q8 to enable deviation from existing guidelines when using new concepts (e.g. specifications)

## Recommendations (1)

Proposals to resolve remaining challenges

- Consider building agreed terminology into Q8(R)
- Need for biotech/chemical experts to agree on direction for API guidance
- Agree on long-term ICH quality vision

## Recommendations (2)

Proposals to resolve remaining challenges

- Industry and regulators to collaborate to determine the right information and the right format that will facilitate science and risk-based regulatory decision making without the need for detailed data review
- Industry and regulators to work through scientific organisations in order to build a knowledge base on QbD and quality risk management