APEC LSIF
ICH Quality Guidelines
Workshop Results

COEX, Seoul Korea
September 13~14, 2007

APEC Life Science Innovation Forum
Korea Health Industry Development Institute
ICH Q8, Q9 & Q10 Workshop

Participants

- Held in September 13~14, COEX Seoul, Korea; coincides with BIO Korea 2007

- More than 200 people from 17 countries participated in the workshop each day (add up to 400 participants)
  - Participants were from Korea, EU, US, Canada, Australia, China, Japan, Thailand, Mexico, Peru, Chile, Vietnam, Indonesia, and etc.
  - 18 eminent speakers and moderators from regulatory and industry side spoke at the workshop
ICH Q8, Q9 & Q10 Workshop

Key Messages (1)

- Workshop provided a better understanding of the ICH Quality guidelines and their implementation.

- ICH guidelines serve to formalize practices and concepts which ensures pharmaceutical quality and harmonizes regulatory expectations.

- ICH guidelines describe an acceptable approach to complying with regulations.

- Concepts and approaches described in Q8,9,10 must be considered together.
ICH Q8, Q9 & Q10 Workshop

Key Messages (2)

- Challenges of harmonization are:
  - Industry/regulatory preparedness
  - Divergent regulations and interpretations
  - Lack of harmonized terminology

- Requires more information sharing and cooperation between industry-regulator and between regulators to translate concepts and goals into reality
Workshop judged to be a great success

- APEC LSIF and various industry and regulatory bodies rated a high value on this workshop regarding well organized process and contents, and fruitful outcome

- The press and journals of Korea showed high interest in this workshop and wanted to see what’s following up

- Participants were satisfied with finding the information they wanted and expected further events