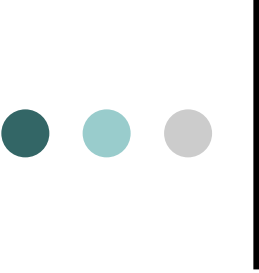




# **APEC LSIF** **ICH Quality Guidelines** ***Workshop Results***

COEX, Seoul Korea  
September 13~14, 2007

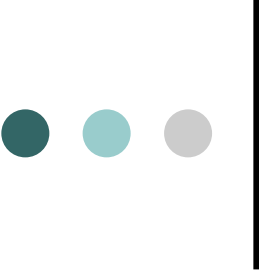
**APEC Life Science Innovation Forum**  
**Korea Health Industry Development Institute**



# ICH Q8, Q9 & Q10 Workshop

## *Participants*

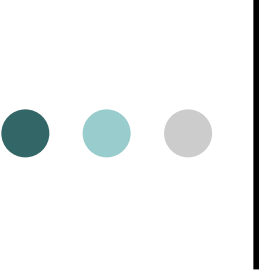
- Held in September 13~14, COEX Seoul, Korea; coincides with **BIO Korea 2007**
- More than 200 people from 17 countries participated in the workshop each day (add up to 400 participants)
  - Participants were from Korea, EU, US, Canada, Australia, China, Japan, Thailand, Mexico, Peru, Chile, Vietnam, 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