

APEC Harmonization Center Workshop

Official Integrated Implementation Training Workshops for ICH Q8, Q9 and Q10 - presented by AHC & ICH

Overview

- DATE : October 4 (Tue) ~ 5 (Wed)
- VENUE : Grand Ballroom & Emerald Hall,
Grand Hilton Hotel, Seoul, Republic of Korea
- Hosted by : *KFDA in cooperation with ICH*
- Organized by : KHIDI

Introduction

APEC Harmonization Center (AHC) and International Conference on Harmonization (ICH) are to hold a workshop on ICH QbD Guidelines which will take place in Seoul, Republic of Korea on October 4-5, 2011.

The main purpose of the workshop is to focus on promoting accurate understanding on ICH QbD so that the economies in the region can endeavor to reach regulatory convergence in the pharmaceutical sector.

Program

- How Q8 / Q9 / Q10 work in a life cycle approach
 - Case Study-Product Development,
 - Case Study-Regulatory Assessment
 - Case Study-Implementation and PQS considerations
 - Case Study-Inspections at a manufacturing site
- Breakout Discussions
 - Design Space
 - Control Strategy
 - Pharmaceutical Quality System
 - Quality Risk Management
- Report from each workshop including addressing Q&A
- Panel Discussion and Q & A



Travel & Accommodation will be provided to APEC travel-eligible economies by invitation. Further information will soon be provided

Additional Information



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