APEC Harmonization Centre Report

Purpose: Information
Submitted by: AHC
Contents

Overview of 2011 Activities

Planning 2012 Projects
Overview of 2011 Activities

hosted/co-hosted 4 international workshops
• Asia Regulatory Conference
  - Asia’s Role in Global Drug Development
• AHC Workshop on Medical Devices:
  - Implementation of GHTF Documents
• AHC Quality by Design Workshop
• MRCT Tokyo Workshop

invited regulators (27 delegates, 7 economies)

AHC website updated and shared training materials & video recordings

worked in collaboration with other initiatives

Planning 2012 Projects

• Four International Workshops
  - Biosimilars
  - Pharmaco-vigilance
  - Pharmaceutical Supply Chain
  - Combination Product

2012
Biosimilars Workshop

**VENUE**
Grand Hilton Seoul Hotel, Seoul, Korea

**DATE**
April 3rd – 5th, 2012

**OVERVIEW**
- about 35 experts invited as speakers, panels and chairs
- 8 delegates invited from APEC travel-eligible member economies
- more than 350 participants have registered on-line

**OBJECTIVES**
- To promote active discussion and participation among participating stakeholders to further promoting the harmonization of regulatory standards for biosimilars and to promote trade among APEC economies by ensuring quality and consistency of biosimilars.
- To facilitate the convergence on requirements for biosimilars throughout the APEC region and provide consistency and certainty with patients, health care providers, and biosimilars developers.

Biosimilars Workshop Program

- Current Status of Biosimilar Global Regulatory Framework
- Biosimilar Regulation & Guideline Update
- Issues and Challenges in Developing Biosimilars (Case-study)
- Regulatory Harmonization on Biosimilar
- Regulators Meeting and Manufacturing Site Tour
Pharmacovigilance Workshop

- Date: June 2012
- Location: Seoul, Korea
- Objective:
  - To compare different regulations on the adverse drug reaction (ADR) within the APEC region
  - To search for the most effective way to harmonize these diverse regulations.
- Contents
  - Importance of Pharmacovigilance
  - Sharing experience of Pharmacovigilance
  - Current status and gaps of Pharmacovigilance system in APEC economies

Combination Product Workshop

- Date: November 2nd, 2012
- Location: Chinese Taipei
- Objectives: to implement regulatory framework on the pharmaceutical and medical device

Pharmaceutical Supply Chain Workshop

- Date: September or October 2012
- Location: Seoul, Korea
- Objectives: to promote safety management on the pharmaceutical supply chain and counterfeit drugs
THANK YOU FOR YOUR ATTENTION!

SEND YOUR ADDITIONAL COMMENTS OR QUESTIONS TO AHC SECRETARIAT
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