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### 2011 AHC Training Programs

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2011 AHC Training Program

**ICH Quality by Design (Q8, Q9, Q10)**

- **Date**: October 4-5, 2011
- **Title**: Official Integrated Implementation Training Workshops
- **Venue**: Grand Hilton Hotel, Seoul
- **513 participants** from APEC and Non-APEC region, including
  - 9 experts invited as speakers & chairs, 6 AHC supported trainees, 40 foreign attendees, 450 domestic attendees.
  - Speakers: FDA, PMDA, AFSSAPS (5 countries), ICH Q-IWG, Pharmaceutical industry experts.
2011 AHC Training Program

ICH Quality by Design (Q8, Q9, Q10)

Programs

- How Q8/Q9/Q10 work in a life cycle approach
  - Case Study: Product Development, Regulatory Assessment, Implementation and the Pharmaceutical Quality System Consideration, Inspection at a manufacturing site

- Discussions
  - Design space, Control Strategy, Pharmaceutical Quality System, Quality Risk Management

- Panel Discussion, Q&A
More discussions
- For Design Space, Control Strategy and Regulatory Process development in QbD implementation.

More practical cases
- Q-IWG’s message: generally understandable.
- But more practical cases are needed, particularly on Design Space Development

More Clear definition on linkages with cGMP
- Linkages among Control strategy, Pharmaceutical quality system and cGMP.
- Control strategy cannot replace cGMP
More cooperation & communication
- More cooperation among developers and regulators for greater understanding
- Communication with senior executives on risk and benefit in implementing pharmaceutical quality system

Forming an atmosphere where regulators and businesses can trust each other.

Well managed knowledge management system can reduce time in searching good information during difficult times.
2011 AHC Training Program

**ICH Quality by Design (Q8, Q9, Q10)**

**Major Achievement**

- **Good Chance** to get information directly by ICH-IWG members
  - Practical discussions were available from experts.

- **Establishment of Expert network** among regulators and industries
  - Seek ways how to implement the guidelines in APEC region
2011 AHC Training Program

Multi-regional Clinical Trial Tokyo Workshop

- Date: November 1-2, 2011
- Title: 2011 APEC Multi-regional Clinical Trials Tokyo Workshop
- Venue: Hitotsubashi Memorial Hall, Tokyo
- Co-hosted by: MHLW, PMDA, SRSM, AHC
- Supported by: JPMA

Highlighting Korea, China and Japan Tripartite Symposium

- Highlighting Korea, China and Japan Tripartite Symposium
- Co-hosted by: MHLW, PMDA, SRSM, AHC
- Supported by: JPMA
2011 AHC Training Program

Multi-regional Clinical Trial Tokyo Workshop

Programs
- Briefing on Director General level Meeting
- Study Design
- Importance of Asia in the global drug development strategy
- Oncology case study
- Panel discussion

Participants
- 400 attendees from 9 countries including
- 23 invited speakers and chairs, 7 AHC supported foreign trainees, and 370 Japanese attendees
CHN-JPN-KOR Tripartite Cooperation

Director General Level Meeting on Pharmaceutical Affairs

- 2008. Apr. : Tokyo, Japan
- 2009. Dec. : Beijing, China
- 2010. Nov. : Seoul, Korea
- 2011. Oct. : Tokyo, Japan

- Information exchange focusing on clinical trials
- Multi-regional clinical trial guidelines
- Joint research projects on ethnic factors

<KOR>

INFORMATION EXCHANGE FOCUSING ON CLINICAL TRIALS

<JPN>

JOINT RESEARCH PROJECTS ON ETHNIC FACTORS

<CHN>

MULTI-REGIONAL CLINICAL TRIAL GUIDELINES
2011 AHC Training Program

**Multi-regional Clinical Trial Tokyo**

**Major Achievement**

- **Strengthening cooperative relationship**
  - Building networks and basis for future cooperation with MRCT experts from FDA, EMA, and several regions
  - Capacity building of regulators from APEC region and beyond, including developing countries in the area of MRCT

- **Greater sharing** and distribution of training materials via AHC website
  - Facilitates future training of other regions.
# 2012 AHC Training Programs

## Education & Training: AHC Workshop plans for 2012

Workshop Agendas were discussed at RHSC meeting & endorsed in principle.

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<td>March or April</td>
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<td>Pharmacovigilance</td>
<td>TBD</td>
<td>Seoul</td>
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<td>Combination Products</td>
<td>TBD</td>
<td>TBD</td>
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Future Plans

- Importance of synergy effect created through close cooperation
- Expanding the opportunities to work together with other initiatives
Thank You for your attention!

If you have any comments or questions, please contact us at ahckorea@khidi.or.kr

For more information please visit our website at www.apec-ahc.org