

APEC Harmonization Center Updates

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ICH-GCG, Seville, Spain

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Contents

I

2011 AHC Training Program

II

2012 AHC Training Program

III

Future Plan



2011 AHC Training Programs



Topics	Sponsors	Dates
Asia's Role in Global Drug Development	AHC, DIA, IFPMA	Apr. 26-28
Medical Devices: GHTF Implementation	AHC, AHWP	Jul. 4-5
Pharmaceutical Quality: QbD	AHC	Oct. 4-5
Multi-regional Clinical Trial	MHLW, PMDA, SRSM, AHC	Nov. 1-2



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



ICH QUALITY BY DESIGN (Q8, Q9, Q10)

Recommendations(1)

- **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



ICH QUALITY BY DESIGN (Q8, Q9, Q10)

Recommendations(2)

- **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



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 TRIALS TOKYO ***WORKSHOP***

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



**2011 APEC
Multi-Regional Clinical Trials
TOKYO Workshop**

2011年 APEC 多地域共同臨床試験 東京ワークショップ

Highlighting KOREA, CHINA AND JAPAN TRIPARTITE SYMPOSIUM
日中韓薬事関係局長会合の結果をふまえて

平成 23 年 11 月 1 日 (火) 10:00-17:50 / 11 月 2 日 (水) 9:30-17:40
November 1 (Tue) 2011 November 2 (Wed) 2011

一層記念講堂 Hitotsubashi Memorial Hall
1 階 - 0003 目黒区平和館一階 2-1-2 学術会館ビル 2 階 電話: 03-4333-6000
National Center of Science Building 51-C, Hitotsubashi, Chiyodaku, 101-0003 Tokyo/Japan Tel: +81-3-4333-6000

Symposium	シンポジウム
・ Korea, China, Japan Director-Generals meeting report ・ Importance of Asia in global development strategy ・ Study Design of MRCTs ・ Case Studies in Oncology ・ Panel Discussion	・ 日中韓薬事関係局長会合報告 ・ 国際開発戦略におけるアジアの重要性 ・ 多地域共同臨床試験のデザイン ・ ケーススタディ (がん系) ・ パネルディスカッション
Organized by	主催
Ministry of Health, Labour and Welfare (MHLW) Pharmaceuticals and Medical Devices Agency (PMDA) Society for Regulatory Science of Medical Products (SRSM) APEC Harmonization Center (AHC)	厚生労働省 特許庁 一般社団法人医薬品医療機器総合機構 一般社団法人レギュラトリーサイエンス学会 APEC ハーモナイゼーションセンター
Supported by	協賛
Japan Pharmaceutical Manufacturers Association (JPMA)	日本製薬工業協会

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URL: <http://www.srsm.or.jp/>



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**

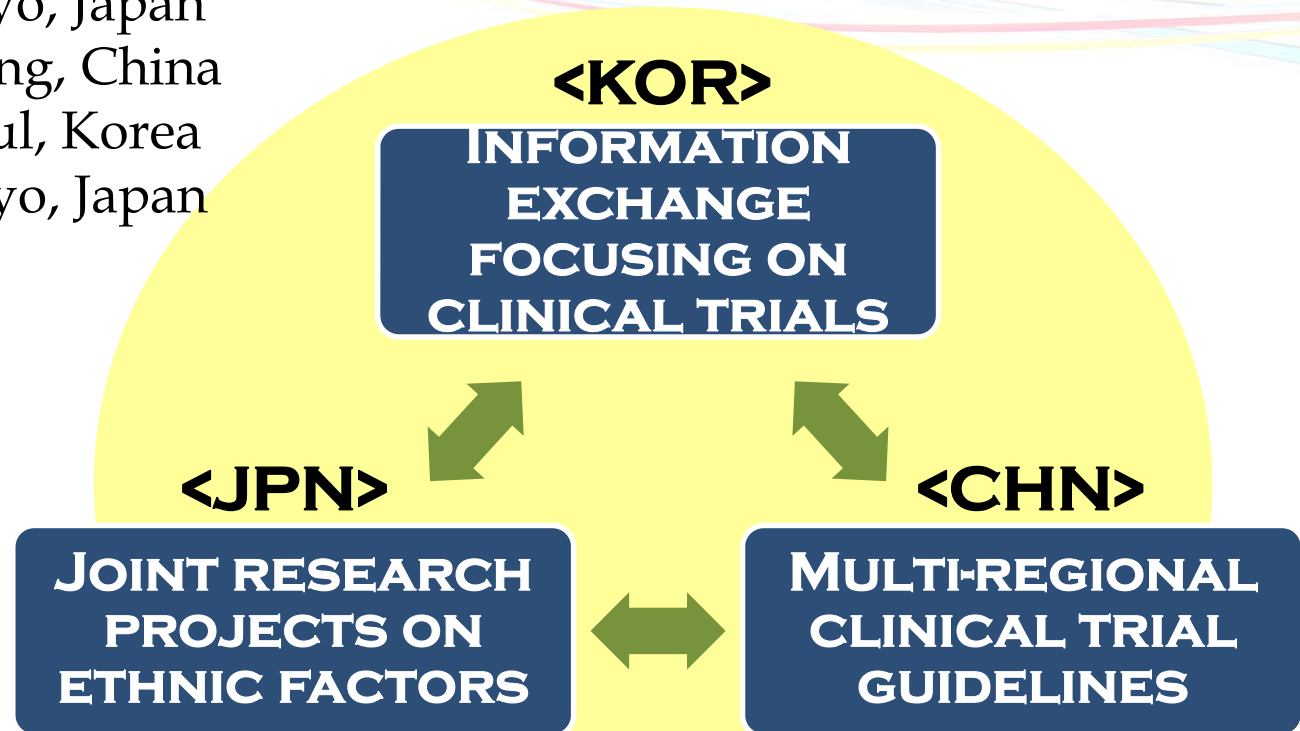
- **400 attendees from 9 countries** including
- **23 invited speakers** and chairs, 7 AHC supported foreign trainees, and 370 Japanese attendees



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



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.

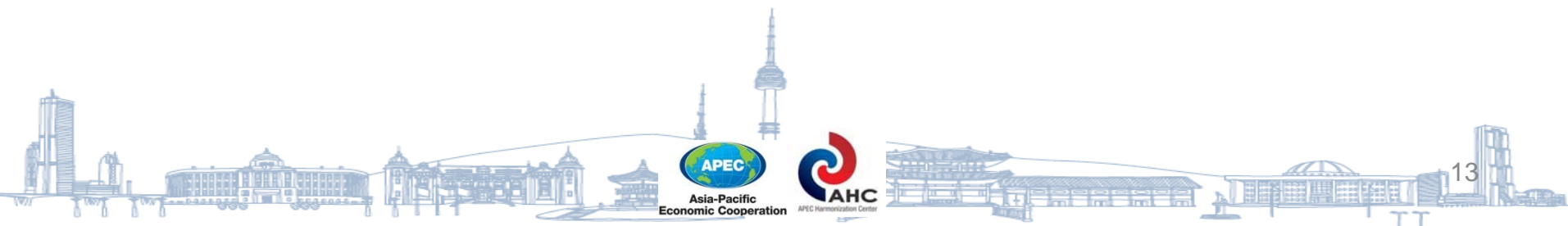


2012 AHC Training Programs

• Education & Training : AHC Workshop plans for 2012

Workshop Agendas were discussed at RHSC meeting & endorsed in principle

Topic	Dates Proposed	Location
Biosimilars	March or April	Seoul
Pharmacovigilance	TBD	Seoul
Combination Products	TBD	TBD



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

