

APEC HARMONIZATION CENTER

update on progress and future work



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Sun Hee Lee, Ph.D.
Director General
Drug Evaluation Department
Korea Food and Drug Administration

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AHC – A Brief Overview

Vision & Activity



AHC Training Programs 2009-2010



Year	Main Topics	# of Participants	# of Economies
2009	Multi-Regional Clinical Trials	562	17
	Biosimilar	434	13
	GMP Validation (Pharmaceuticals)	458	Korea
2010	Pharmaceutical Supply Chain	287	10
	Multi-Regional Clinical Trials (Tripartite Symposium)	415	15
	Medical Devices	150	8

2010 AHC 3rd Training Programs

Medical Devices Workshop

- Date : **November 15-16, 2010**
- Title : **2010 AHC Workshop on Medical Devices**
 - Use of Clinical Evidence in the Medical Device Premarket Conformity Assessment Process
- **150 participants** from 8 economies
 - 15 experts invited as speakers
- **Key Agenda items**
 - Understanding and implementation of GHTF guidance on clinical evidence for premarket conformity assessment
 - Understanding the infrastructure needed to ensure a clinical trial is designed and conducted ethically and scientifically when it is required for premarket conformity assessment



Workshop Agendas were discussed at RHSC meeting & endorsed in principle

Topics	Sponsors	Proposed 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	Japan, AHC	NOV
Pharmacovigilance	AHC	2012

2011 AHC 1st Co-sponsoring Workshop

AHC/DIA/IFPMA Asia Regulatory Conference

• Date : **April 26-28, 2011**



• Title : **Asia's Role in Global Drug Development**

• 730 participants from 24 economies including

- 55 experts invited as speakers and chairs,
- 64 AHC supported trainees, etc.



2011 AHC 1st Co-sponsoring Workshop

AHC/DIA/IFPMA Asia Regulatory Conference

● Update on ICH activities, focus on New Activities

- 20 Years of ICH: Learning and Accomplishments (*Justina A. Molzon*)
- Expanding Participation in ICH Technical Working Groups (*Mike Ward*)
- Japan's Experience with ICH and the Implementation of Guidelines (*Shinobu Uzu*)
- KFDA's Perspectives on the Implementation of ICH Guidelines (*Sun Hee Lee*)



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Regional Harmonization Initiatives

<Parallel tracks on Day 1>

- **Fighting counterfeit medicines in emerging countries**
: Addressing infrastructure and capacity gaps
- Ensuring quality - Enhance the approach of quality driven by **ICH Q8, Q9, Q10, and Q11: What about practical implementation?**



2011 AHC 1st Co-sponsoring Workshop

AHC/DIA/IFPMA Asia Regulatory Conference

● Asia's Regulatory Harmonization Initiatives

<Parallel tracks on Day 1>

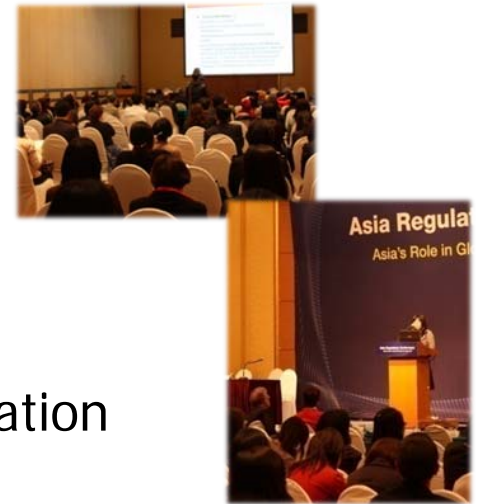
- **Practical uses of CTDs in Asia**

<Plenary sessions on Day 2>

- **Similar biotherapeutic products(SBPs) in Asia**
: Opportunities and challenges in regulatory evaluation

<Parallel tracks on Day 2>

- Ensuring quality – Harmonizing and optimizing **inspection approach** in the global environment



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AHC/DIA/IFPMA Asia Regulatory Conference

● Regulatory Trends on Clinical trials in Asia

<Plenary sessions on Day 2>

- Early and late clinical development in Asia

<Parallel tracks on Day 2>

- Establishing the Asia Pacific Region as an important partner in global pediatric development
- Ethical business practices : Towards better marketing compliance



*GCP tour after closing a workshop
: Seoul National University Hospital*

2011 AHC 1st Co-sponsoring Workshop

Asia Regulatory Conference

● Cooperation between Regulatory Authorities & Industries

<Plenary sessions on Day 3>

- **Electronic submissions and eCTD** as vehicle to reconcile differences in technical regulatory requirements
- **Pharmacovigilance**: How do regulatory agencies and industry work together to protect patients?
- **Good regulatory practices**, including assessment report, efficient use of certificate of pharmaceutical product(CPPs) and transparency

Future Plans



AHC is planning to ...

- Make long-term plans for AHC Workshops
 - to provide good training programs in the APEC region
- Expand the list of AHC Advisory Board members
- Add new features to AHC website
 - to better promote AHC activities and disseminate harmonization models



Thank You for Your Attention!

Send your additional comments or questions
to AHC secretariat
at ahckorea@khidi.or.kr

Please visit our website at www.apec-ahc.org