

The 11th Asian Harmonization Working
Party (AHWP) Meeting
AHWP Pre-Meeting Workshop

September 13•15, 2006
Seoul, Korea





Overview

- AHWP Pre-Meeting Workshop
 - ✓ September 13•14 2006, Seoul, Korea
- The 11th Asian Harmonization Working Party (AHWP) Meeting
 - ✓ September 15 2006, Seoul, Korea
- Participant :
 - ✓ Representatives from regulatory authorities from Member Economies
 - ✓ Regulatory affairs professionals from industry groups and other interested parties
- Language : English, Korean
- Event : Korean Domestic Medical Device Exhibition



Program (Tentative)

	12 September	13 September		14 September		15 September
08:00-08:30				Registration		Registration
08:30-09:00		Registration		Plenary Session III		Opening Ceremony(AHWP Meeting)
09:00-9:30		Opening Ceremony (AHWP Pre-Meeting Workshop)		Break		AHWP Meeting
09:30-10:00		Opening Ceremony (Exhibition)		Plenary Session III		
10:00-10:30		Lunch		Plenary Session IV		
10:30-11:00		Plenary Session I		Lunch		
11:00-11:30		Break		Plenary Session IV		
11:30-12:00		Plenary Session II		Break		
12:00-12:30		Photo-Taking		Workshop III		
12:30-13:00		Workshop I		Workshop II		
13:00-13:30		Break		Break		
13:00-14:00		Workshop I		Workshop II		
14:00-14:30		Break		AHWP Technical Committee Meeting		
14:30-15:00		Gala Dinner				
15:00-15:30	Arrival and Pre-registration					
15:30-16:00						
16:00-16:30						
16:00-17:00						
17:00-17:30						
17:30-18:00						
18:00-18:30						
18:30-19:00						
19:00-20:00	Cocktail Party					Close
20:00~						

EXHIBITION

EXHIBITION

EXHIBITION



Program Day 1

12 September		13 September	
08:00-08:30			
08:30-09:00		Registration	
09:00-9:30			
09:30-10:00		Opening Ceremony (AHWP Pre-Meeting Workshop)	
10:00-10:30		Opening Address, Welcome Address	
10:30-11:00		Opening Ceremony (Exhibition)	
11:00-11:30		Opening Address, Exhibition tour	
11:30-12:00			
12:00-12:30		Lunch	
12:30-13:00			
13:00-13:30		Plenary Session I	
13:00-14:00		What's Really Happening in Conformity Assessment Procedures for Regulators ?	
14:00-14:30		Break	
14:30-15:00		Plenary Session II	
15:00-15:30		Adoption of the STED (Summary Technical Document) : An Efficient Submission Format	
15:30-16:00		Photo-Taking	
16:00-16:30	Arrival and Pre-registration	Workshop I	Workshop II
16:00-17:00		Evidence Gathering in Clinical Trials	Experiences Implementing Global Medical Device Nomenclature as A Regulatory Requirement
17:00-17:30		Break	
17:30-18:00		Workshop I	Workshop II
18:00-18:30		Evidence Gathering in Clinical Trials	Experiences Implementing Global Medical Device Nomenclature as A Regulatory Requirement
18:30-19:00	Cocktail-Party		
19:00-20:00		Gala Dinner	
20:00-			

EXHIBITION



Program Day 2

14 September	
08:00~08:30	Registration
08:30~09:00	
09:00~9:30	Plenary Session III
09:30~10:00	Implementing Risk Management to your Advantage
10:00~10:30	Break
10:30~11:00	Plenary Session III
11:00~11:30	Implementing Risk Management to your Advantage
11:30~12:00	Plenary Session IV
12:00~12:30	Practical Issues in Drug-Device Combination Products
12:30~13:00	
13:00~13:30	Lunch
13:00~14:00	
14:00~14:30	Plenary Session IV
14:30~15:00	Practical Issues in Drug-Device Combination Products
15:00~15:30	Break
15:30~16:00	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Workshop III</p> <p>Surviving A Regulatory Inspection on your Quality System</p> </div> <div style="width: 45%;"> <p>Workshop IV</p> <p>Ensuring the Safety of Marketed Medical Devices - Vigilance reporting system.</p> </div> </div>
16:00~16:30	
16:00~17:00	
17:00~17:30	
17:30~18:00	Break
18:00~18:30	AHWP Technical Committee Meeting
18:30~19:00	
19:00~20:00	
20:00~	

EXHIBITION



Program Day 3

15 September	
08:00~08:30	Registration
08:30~09:00	
09:00~9:30	Opening Ceremony Welcome Address by Chair, AHWP
09:30~10:00	AHWP Meeting
10:00~10:30	Agenda 1 Adoption of Agenda
10:30~11:00	Agenda 2 Roll Call
11:00~11:30	Agenda 3 Confirmation of the Report of 10thAHWP Meeting
11:30~12:00	Agenda 4 AHWP as the Liaison Member of GHTF
12:00~12:30	Agenda 5 TOR for participation of Member Economies as focal point in GHTF SC and SGs
12:30~13:00	Agenda 6 Structure of AHWP, TOR
13:00~13:30	Agenda 7 Updates on AHWP TC Activities
13:00~14:00	Agenda 8 AHWP Work Program for 2005-2007
14:00~14:30	- Comparative study on the existing medical device regulations in AHWP Member Economies
14:30~15:00	- Formalization of a post marketing alert system
15:00~15:30	-Capability Submission Dossier Template
15:30~16:00	-Common Submission Dossier Template
16:00~16:30	-Funding
16:00~17:00	Agenda 9 Closing Session
17:00~17:30	Close
17:30~18:00	
18:00~18:30	
18:30~19:00	
19:00~20:00	
20:00~	
20:00~	

EXHIBITION



Registration

- On-line registration :
www.asiahwp.org

- Off-line registration
 - ✓ Download a registration form from
www.asiahwp.org
 - ✓ Send to the congress secretariat by e-mail
or by fax
 - e-mail : medicaldevice@kfda.go.kr
 - fax : +822-3402-0589



Registration (cont.)

● Fee

- ✓ For Industry, Non-government representative : 450 US\$
- ✓ For Government representative : 220 US\$
- ✓ For Accompanying person : 50 US\$

NOTE : Accompanying person is able to attend only the Gala Dinner

- Early Birds : By July 31, 2006
- ✓ For Industry, Non-government representative : 400 US\$
- ✓ For Government representative : 200 US\$
- ✓ For Accompanying person



Budget Estimation

Income •	Registration fees for Conference	\$62,800
Income •	KHIDI : Donation	\$41,897
Income •	AMCHAM : Supports all Reception	\$10,914
Income •	KMDIA : Supports a Portion of Experts Costs	\$18,883
Income Total (•+•+•+•)		\$134,494
Expense •	Amount for Rent	\$29,500
Expense •	Reception Cost	\$10,914
Expense •	Event Cost	\$65,569
Expense •	PCO etc.	\$28,512
Expenses total(•+•+•+•)		\$134,494
Balance(Income-Expenses)		\$0



Detailed Expense

Expense •

- Main Conference Room(1room, large)
- Second Conference Room(4rooms, small)
- Office(2offices)
- Lunch Offer(3times)
- Snack(5times)

Amount for Rent

\$29,500

Expense •

- Reception at Hotel

Reception Cost

\$10,914



Detailed Expense (cont.)

Expense •

- Advertisement and brochures
- Support the Least Developed countries
- Support VIPs
- Cost for Interpreting
- Office Supplies
- Labor Costs(15persons, field service)
- Expert from PCO(5person, 5month)
- Extra Costs

Event Cost

\$65,569

- ❖ VIP : Speakers for Sessions, 9persons
- ❖ PCO : Professional Congress Organizer



Detailed Expense (cont.)

Expense •

- Service Cost for PCO
- V.A.T
- Reserved Fund

PCO etc.

\$28,512

Venue

