

## **Programme of the AHWP Hong Kong Meeting (4-7 November 2009)**

***Venue: Hong Kong Convention & Exhibition Centre, Wan Chai***

Date	4 <sup>th</sup> Nov 2009 (Wednesday)	5 <sup>th</sup> Nov 2009 (Thursday)	6 <sup>th</sup> Nov 2009 (Friday)	7 <sup>th</sup> Nov 2009 (Saturday)
Time	9 <sup>th</sup> AHWP TC Meeting (Room S224-225)	Workshop (Room S221)	14 <sup>th</sup> AHWP Meeting (Room N101)	14 <sup>th</sup> AHWP Meeting (Room N101)
08:00	Registration (Room S228)		Registration (Room N101 Concourse)	
08:30	AHWP TC Meeting (Session 1)	Workshop (Session 1)	Registration	AHWP Meeting (Session 4)
09:00			Opening Ceremony	
09:30			<i>Photo Taking (Golden Bauhinia Square)</i>	
10:00	Tea Break			
10:15	AHWP TC Meeting (Session 2)	Workshop (Session 2)	Photo Taking	AHWP Meeting (Session 5)
11:00			AHWP Meeting (Session 1)	
12:30	Lunch Break (1/F, The Harbourview Hotel)		Lunch Break (Room N201)	End of 14 <sup>th</sup> AHWP Meeting
14:00	AHWP TC Meeting (Session 3)	<i>Visit to the Hong Kong International Medical Devices and Supplies Fair (Hall 3F)</i>	AHWP Meeting (Session 2)	
15:30	Tea Break			
15:45	AHWP TC Meeting (Session 4)	Workshop (Session 3)	AHWP Meeting (Session 3)	
18:00		<i>AHWP Cocktail Reception (Hall 3F Concourse)</i>	Meeting Break	
19:00			<i>AHWP Gala Dinner (King Palace Restaurant, 5/F, China Resources Building)</i>	

## **Agenda of the 9<sup>th</sup> AHWP TC Meeting on 4<sup>th</sup> November 2009**

Time	Agenda Items
8:30	- Welcome Address by AHWP TC Chair
8:35	- Adoption of Agenda
8:40	- Roll-call
9:00	- Progress Report by WG and STG :
9:00	➤ <u>WG1</u> : Pre-Market Evaluation
9:15	➤ <u>WG1a</u> : In-vitro Diagnostic Device
9:30	➤ <u>WG2</u> : Post-Market Surveillance and Vigilance
9:45	➤ <u>WG3</u> : Quality Management System
10:00	Tea Break
10:15	➤ <u>WG4</u> : Quality System Audit
10:30	➤ <u>WG5</u> : Clinical Evidence Requirements
10:45	➤ <u>WG6</u> : Capacity Building and Regulatory Training
11:00	➤ STG(LE): AHWP Legal Entity
11:15	➤ STG(N): Medical Device Nomenclature
11:30	- Revised Terms of Reference
11:30	➤ Proposed New Terms of Reference
11:55	➤ Resolution: Adopting the Proposed AHWP and AHWPTC Terms of Reference
12:00	- Establishment of Legal Entity for AHWP Secretariat
12:00	➤ Draft Memorandum and Articles of Association
12:25	➤ Resolution: Setting up a Legal Entity in Hong Kong for Administering AHWP Activities
12:30	Lunch Break
14:00	- Medical Device Nomenclature
14:00	➤ Updates on GMDN (Inaugural Policy Advisory Group Meeting)
14:15	➤ Hong Kong Experience
14:30	➤ Requirements of Medical Device Nomenclature System for AHWP
15:00	➤ Presentation by GMDN Agency - Compliance to AHWP Requirements
15:30	Tea Break
15:45	➤ Presentation by ECRI Institute - Compliance to AHWP Requirements
16:15	➤ Resolution: Adopting the Proposed Requirements of Medical Device Nomenclature System for the AHWP in the Selection of Service Provider
16:30	- Regulatory Training
16:30	➤ Update on Proposal from North Eastern University
16:45	➤ Options and Way Forward
17:15	- Comparative Study on Regulatory Frameworks
17:45	- Any Other Business
18:00	End of 9 <sup>th</sup> AHWP TC Meeting

## Programme of Workshop on 5<sup>th</sup> November 2009

**(Theme: Medical Device Regulatory Requirements, Compliance and Harmonization)**

Time	Speakers	Tentative Presentation Topics
<i>Session 1 (Moderator: Dr. Jorge Garcia)</i>		
8:30	Dr. Rohan Hammett	<i>The Future of Medical Device Regulation in a Globalised Marketplace</i>
9:00	Mr. Bill Sutton	<i>USFDA's Centre for Devices and Radiological Health</i>
9:30	Mr. Kentarou Azuma	<i>Medical Device Regulation in Japan</i>
10:00	<i>Tea Break</i>	
<i>Session 2 (Moderator: Mr. Michael Gropp)</i>		
10:20	Dr. Joel Nobel	<i>Essential Elements of an Effective and Efficient Medical Device Regulatory Framework</i>
10:50	Dr. Jorge Garcia	<i>Managing a Post-Market Surveillance System</i>
11:20	Prof. Tony Chan	<i>Total Life Cycle Risk Management of Medical Devices</i>
11:50	Mr. Alfred Kwek	<i>Paving Way for Harmonization</i>
12:20	Arrangements of the lunch and the visit to the Hong Kong International Medical Devices and Supplies Fair	
12:30	<i>Lunch Break</i>	
14:00	<b>Visit to the Hong Kong International Medical Devices and Supplies Fair</b>	
15:30	<i>Tea Break</i>	
<i>Session 3 (Moderator: Prof. Tony Chan)</i>		
15:50	Ms. Carolyn Albertson	<i>Medical Device Regulatory Requirements: Classification</i>
16:10	Mr. Leighton Hansel	<i>Unique Device Identification Systems (UDI) and their Implications to the Industry</i>
16:30	Ms. Sumati Randeo	<i>Update on ASEAN Regulatory Frameworks and Way Forward for AHWP (a View from Industry)</i>
16:50	Mr. Michael Gropp	<i>Regulatory Harmonization and Medical Technology Innovation</i>
17:20	Dr. Phillip Auclair	<i>Realizing Medical Device Technologies into Marketable Products</i>
17:50	<i>End of Workshop</i>	
18:00	<b>AHWP Cocktail Reception</b>	

## Agenda of the 14<sup>th</sup> AHWP Meeting on 6-7 November 2009

14 <sup>th</sup> AHWP Meeting 6 <sup>th</sup> Nov 2009 (Friday)		14 <sup>th</sup> AHWP Meeting 7 <sup>th</sup> Nov 2009 (Saturday)	
09:00	<b>Opening Ceremony</b>	08:30	<b>AHWP Collaborations with Other International Organization</b>
	> Welcome Speech by Host: Dr PY Lam, Director of Health, Hong Kong, China	08:30	AHWP-LSIF Collaboration
	> Speech by Guest of Honour: Mr. Zhang Jingli, Vice Commissioner of State Food and Drug Administration, China	09:00	AHWP-APEC Collaboration
	> Opening Remarks by Co-Host: Mr Raymond Yip, Assistant Executive Director, Hong Kong Trade Development Council	09:30	AHWP-GHTF Collaboration & GHTF Update
	> Opening Remarks by Mr Joseph Poon, Acting Director (Technology Development), Hong Kong Productivity Council	10:00	Tea Break
	> Opening Speech by Chair: Mr. Wang Baoting	10:15	GHTF Study Groups Update (15 minutes for each SG)
	> Souvenirs to Host, Guest of Honour, Co-Host, Event Manager and Diamond Sponsor	11:30	<b>AHWP Way Forward</b>
09:30	Photo Taking	11:30	Panel Discussion: Prospects and Challenges of Harmonization Organizations
	Tea Break	12:10	Confirmation of 15 <sup>th</sup> AHWP Meeting Venue
11:00	<b>14<sup>th</sup> AHWP Meeting</b>	12:20	Meeting Closing Remarks
	> Adoption of Agenda	12:30	<b>End of 14<sup>th</sup> AHWP Meeting</b>
	> Admission of New AHWP Members		
	> Roll Call <only the official representatives>		
	> Confirmation of the 13 <sup>th</sup> AHWP Meeting Minutes		
11:20	2008/09 – 2011/12 AHWP Future Plan		
	> 2008/09 Work Report		
	> Work Plan		
	> Work Target		
11:40	<b>AHWP Technical Committee (TC) &amp; Working Groups Reports</b>		
11:40	TC Report and Work Plan		
11:50	WG1 Report and Work Plan		
12:00	WG1a Report and Work Plan		
12:10	WG2 Report and Work Plan		
12:20	WG3 Report and Work Plan		
12:30	Lunch Break		
14:00	WG4 Report and Work Plan		
14:10	WG5 Report and Work Plan		
14:20	WG6 Report and Work Plan		
14:30	STG(N) Report and Work Plan		
14:40	STG(LE) Report and Work Plan		
14:50	Medical Device Nomenclature Issues		
14:50	> Update on AHWP Requirements		
15:00	> Medical Device Nomenclature System Service Providers Q&A		
15:30	Tea Break		
15:45	> Resolution 1: Adopting the Proposed Requirements of Medical Device Nomenclature System for the AHWP in the Selection of Service Provider		
16:00	Unique Device Identification Update		
	> Update & AHWP Position		
16:10	AHWP Organizational Construction		
16:10	> AHWP website & sponsorship		
16:20	> Resolution 2: Adopting the Proposed AHWP and AHWP/TC Terms of Reference		
16:30	> Resolution 3: Setting Up a Legal Entity in Hong Kong for Administering AHWP Activities		
16:40	<b>AHWP Member Economies Regulatory Updates</b>		
16:40	2009 Summary and Comparison of AHWP Regulatory Frameworks		
17:00	<b>Major Regulatory Changes in AHWP Member Economies</b>		
17:00	Regulatory Update by Philippines		
17:20	Regulatory Update by Saudi Arabia		
17:40	Regulatory Update by India		
18:00	Meeting Break		
19:00	<b>Gala Dinner</b>		