

The Agenda and Status of Invitation for Speakers, VIP and Moderators for the 17th AHWP TC Meeting, TC Training, and Annual Meeting (ver. 2012.09.13)

Session	Speaker		Contact by	Status		Note
	Name	Position		Invitation letter	Confirmation	
2nd Nov AHWP TC Meeting						
Welcome address	Dr. Shiow-Ing Wu	Deputy Director-General, TFDA, DOH	Steve Chen, TFDA		Awaiting confirmation	
3rd Nov AHWP Training						
Opening Speech	Mrs. Joanna Koh	Director Medical Device, HSA, Singapore; AHWP TC Chair	Secretariat	N/A	Confirmed	
Welcome Address	Dr. Shiow-Ing Wu	Deputy Director-General, TFDA, DOH, Chinese Taipei	Steve Chen, TFDA		Awaiting confirmation	
Parallel session 1						
QMS/GDP	Mr. Grant Ramaley	Convener for IAF Working Group, ISO 13485 Medical Device Conformity, Assessment System	Secretariat	Sent	Confirmed	Carol's email (9/7)
	Mr. Egan Cobbold	Quality Systems Officer, Medical Devices Bureau, Health Canada	Steve Chen, TFDA		Awaiting decision	Carol's email (9/7)
	Ms. Jan Welch	Deputy Director of Regulatory Affairs, CDRH, FDA	Steve Chen, TFDA		Awaiting decision	Carol's email (9/7)
	Mr. Jeffrey Gren	Director, Office of Health and Consumer Goods, U.S. Department of Commerce	Jack Wong/TFDA	OC suggest not to invite this time		Carol's email (9/10)
Enhancement of PMS in EU	Mr. Laurent Sellés	Deputy Head of Unit Cosmetics and Medical Devices, EC	Steve Chen, TFDA		Confirmed	Selles' email (7/30)
Use of NCAR and SADS in Reporting	Ms. Isabelle Demade	Principal Administrator, Directorate General for Health and Consumers, EC	Steve Chen, TFDA		Awaiting decision	Carol's email (9/7)

Elements of a successful registry in the PMS system	Ms. Tina Wu	TFDA, Chinese Taipei	Steve Chen, TFDA		Confirmed	
		Zimmer representative, US	Miang, Zimmer		Awaiting decision	OC telecon
Moderator/Facilitator	Mr. Y. S. Kuo Dr. Jau-Min Wong	Chairman, TMBIA, Chinese Taipei National Taiwan University	Steve Chen, TFDA	NA	Awaiting confirmation	
Parallel session 2						
Medical Software	Mr. Bakul Patel Mr. Laurent Sellés, Ms. Gao Li Mr. Peter Linders	Policy Advisor, Office of Center Director, CDRH, FDA Deputy Head of Unit Cosmetics and Medical Devices, EC SFDA, PRC CENELEC TC 62 Chair and IEC 82304-1 Co-leader	DITTA, Secretariat & Mrs. Joanna Koh		Awaiting confirmation	Carol's email (9/10)
Affordable and accessible IVD	Prof. Rosanna Peeling	Professor & Chair of Diagnostics Research, LSHTM, UK	Steve Chen, TFDA		Awaiting confirmation	Will come to Taiwan for 11/6 conference
Clinical rationale of medical devices and medical technology advances in medical device	Dr. Mitchell Krucoff Dr. Krishnan Ranga	Duke university, US Duke University, US	Tran Quan, GE		Declined Awaiting decision	Carol's email (9/7)
	Dr. Herb Lerner	Deputy Division Director, CDRH, FDA			Declined	
Moderator/Facilitator	Dr. Yio-Wha Shau Dr. Chin-Yuan Tzen, Dr. Rong-Sen Yang,	General Director, BDL, ITRI, Taiwan Chairman, TSMM, Chinese Taipei Dept. Orthopedics Surgery, NTUH	Steve Chen, TFDA		Awaiting confirmation	

5th Nov AHWP Annual Meeting

Welcome Address	Dr. Jaw Jou Kang	Director-General, TFDA, DOH, Chinese Taipei	Steve Chen, TFDA		Awaiting confirmation	
Opening Speech	Dr. Saleh Al-Tayyar,	Chairman, AHWP; Director General, Medical Devices Sector, SFDA, KSA	Secretariat		Confirmed	Carol's email (9/10)
Keynote: Regulations update and	Mr. Hui-Hua Jiang,	Executive Secretary, Board of Science and Technology, Executive	Steve Chen,		Confirmed	

medical devices and biotech development in Chinese Taipei		Yuan, Chinese Taipei	TFDA			
GHTF status report	Mr. Kazunari Asanuma,	Deputy Director, Office of Medical Devices Evaluation, Pharmaceutical and Food Safety Bureau, MHLW	Secretariat		Confirmed	Johanna's email (9/12)
IMDRF status report	Mr. Kazunari Asanuma,	Deputy Director, Office of Medical Devices Evaluation, Pharmaceutical and Food Safety Bureau, MHLW	Secretariat/TFDA		Informally declined	Johanna's email (9/12)
AHWP status report and strategic framework	Dr. Saleh Al-Tayyar,	Chairman, AHWP; Director General, Medical Devices Sector, SFDA, KSA	Secretariat	NA	Confirmed	Carol's email (9/10)
Country update:			AHWP secretariat	sent		Carol's email (9/10)
1. China						
2. Thailand						
3. Indonesia						
4. Brazil						
5. Chile	Ms. Maria Lopez	Instituto de Salud Publica			Confirmed	
6. Cambodia						
Report by AHWP TC	Mrs. Joanna Koh,	Director Medical Device, HSA, Singapore; AHWP TC Chair	Secretariat	NA	Confirmed	
Report by Secretariat	Mr. Ali M. Al-Dalaan, Mr. Bryan So, Dr. Saleh Al-Tayyar,	Secretary General, AHWP; Executive Director, Medical Devices Sector, SFDA, KSA Secretariat AHWP; Sr. Consultant, HKPC Chairman, AHWP; Director General, Medical Devices Sector, SFDA, KSA	Secretariat	NA	Confirmed	Carol's email (9/10)
Closing remark	Ms. Li-Ling Liu,	AHWP Vice-Chair; Director of Division of Medical Device and Cosmetic, TFDA	TFDA	NA	Confirmed	
1 st AGM of AHWP ASL	Mr. Ali M. Al-Dalaan, Mr. Bryan So,	Secretary General, AHWP; Executive Director, Medical Devices Sector, SFDA, KSA Secretariat AHWP; Sr. Consultant, HKPC	Secretariat	NA	Confirmed	Carol's email (9/10)
Potential GHTF Speakers to Invite						
	Ms. Nancy Shadeed	Health Canada (SG1 Pre-market)	TFDA		Awaiting decision	

					decision	
	Dr. Susanne Ludgate	Deputy Director of the Devices division, MHRA UK (SG5, Clinical Safety and Performances)	TFDA		Awaiting decision	
	Ms. Andrea Kunca	Head of Office of Devices Authorisation (ODA), TGA	TFDA		Awaiting decision	
	Ms. Kimberly A. Trautman,	Associate Director, International Affairs, CDRH, FDA	TFDA		Awaiting decision	
	Mr. Matthias Neumann	Federal Ministry of Health Germany	TFDA		Awaiting decision	
	Ms. Adriana Velazques Berumen	WHO	TFDA		Awaiting decision	