The 21st AHWP Annual Meeting Program

Radisson Blu Cebu Hotel, Cebu, Philippines
November 21-25, 2016

Day-1: AHWP Playbook Training Workshop

21 Nov 2016		Speakers
08:30 – 09:00	Registration	
09:00 – 09:10	Welcome Address by AHWP Chair	**Dr Hee-kyo Jeong** Chair, AHWP Director General, Medical Device Evaluation Department, MFDS, Republic of Korea
09:10 – 09:20	Opening Remarks by TC Chair	**Mr Ali M. Al-Dalaan** TC Chair, AHWP Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
09:20 – 09:30	Opening Remarks on Capacity Training Project	**Ms Tran Quan** AHWP Vice Chair (Industry) Vice President Regulatory Affairs APACMed Singapore
09:30 – 09:45	Mileposts in our 'Playbook' Journey	**Ms Joanna Koh** Principal Consultant, MDnet.Regulatory Consultants Singapore
9.45 – 10.40	Cybersecurity "What's lurking in the Airwaves"	**Mr Eric Woo** Regional Director, ECRI Institute, Asia Pacific Office Singapore
10:40 – 11:10	PHOTO SESSION cum TEA BREAK	
11.10- 11.50	Highlights of Essential Principles for Safety, Quality and Performance for Registered Medical Devices – essential for Emerging Countries	**Mr Greg Leblanc** Director, Regulatory Affairs and Quality Systems Cook (Canada) Inc. Canada
11.50 – 12.40	Fact or Myth?	**Mr Vincent Lam**

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	"CSDT by any other name will be as complicating"	TÜ V SÜ D Malaysia
12:40 – 13:40	LUNCH	
13:40 – 14:45	"What should be in That Product Dossier"	**Mr Seet Wing Gang** Director Unser Solutions Pte Ltd Singapore
14:45 – 15:35	Small group discussions on 'Screening of dossier documents for Premarket Registration Submission' (Break up into small groups)	**Mr Seet Wing Gang** And Group Facilitators
15:35 – 16:00	TEA BREAK	
16:00 – 17:00	PANEL DISCUSSION 'How will the upcoming EU MDR & IMDRF recommendations affect AHWP efforts on Capacity Building Projects for Emerging Countries'	**Ms Joanna Koh** (Moderator) (MDNet.Regulatory) **Mr Greg Leblanc** (Cook Inc) **Ms Petra Kaars-Wiele** (Abbott Laboratories) **Mr Seet Wing Gang** (Unser Solutions) **Ms Miriam Schuh** (Reuschlaw Legal Consultants)
17:00 – 17:10	Closing Remarks	**Ms. Joanna Koh**

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Day-2: AHWP Playbook Training and TC Workshop

22 Nov 2016			Speakers	
08:30 – 08:40	Recap of Day-1 Sessions		**Ms Joanna Koh**	
08.40 – 9.10	GMDN : A Useful Aid for Postmarket Reviews		**Mr Mark Wasmuth** CEO, GMDN Agency (UK)	
09:10 – 10.10	Post Market – Report & review (JOINT PRESENTATION) 1) What to report (Industry Speaker) 2) What is reviewed (Regulator Speaker)		Industry: **Mr Terry Song** Head of Quality & Regulatory Affairs ASEAN, Boston Scientific Corporation Regulator: **Mr Sodikin Sadek** Director of Postmarket Control Medical Devices and Health Household Products, MOH, Republic of Indonesia	
10.10 – 11.00	Product Liability – An almost 360 Degree View		**Ms Miriam Schuh** Head of the Medical Device Department Reuschlaw Legal Consultants Germany	
11.00 – 11.20	TEA BREAK			
11.20 – 12.10	Man VS IT – Technology needs for Regulatory Controls for Emerging Economies		**Mr Alfred Kwek** Regional Director Government Affairs/HME Samsung Electronics Singapore	
12:00 – 13:00	LUNCH			
	AHWP TC Workshop		**Updates on Philippine Regulatory System**	
13:00 – 13:05	Opening Words	**Mr Ali M. Al-Dalaan** TC Chair, AHWP Executive Director, Medical Devices	Opening Words	**Ms Maria Cecilia MATIENZO** Division Chief,

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		Sector, Saudi FDA, Kingdom of Saudi Arabia		Licensing and Registration Division, Center for Device Regulation, Radiation Health, and Research, Food and Drug Administration, Philippines
13:05 – 15:05	**Standards Session**		Updates on Philippine Regulatory System	**Ms Maria Cecilia MATIENZO** Division Chief, Licensing and Registration Division, Center for Device Regulation, Radiation Health, and Research, Food and Drug Administration, Philippines
13:05 – 13:10	Opening Words	**Mr Tony Low** Co-Chair WG-8		
13:10 – 13:40	Highlighted Updates on ISO13485:2016	**Mr Tony Low** Co-Chair WG-8		
13:40 – 14:10	Updates on IEC60601 and implementation experiences	**Mr Dennis Chew** Regional Director, APRC, IEC, Singapore		
14:10 – 14:40	Updates on standards for SaMD	**Dr Ir Peter W.J. Linders** Director Global Regulations & Standards, Philips The Netherlands		
14:40 – 15:05	Panel Discussion - How new version of standards were launched, implemented, and worked out among themselves, etc.	**Moderator: Dr Ir Peter W. J. Linders** **Mr Ali M. Al-Dalaan** Executive Director, Medical Devices Sector, Saudi FDA,		

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		Kingdom of Saudi Arabia **Mr Seil Park** Assistant Director, Division of High-Tech Medical Devices, MFDS, Republic of Korea **Mr Dennis Chew** Regional Director, APRC, IEC, Singapore **Mr Tony Low** Co-Chair of WG8		
15:05 – 15: 20	TEA BREAK			
15:20 – 17:20	**Clinical Evaluation Session**			
15:20 – 15:45	Comparative Overview of Global Clinical Investigation Regulations		**Manish Narang** Abbott	
15:45 – 16:10	Clinical Evaluation for IVD Medical Devices		**Ms Shelley Tang** Principal Stellar consulting Australia	
16:10 – 16:35	Clinical Investigation and Evaluation for General Medical Devices		**Dr Justin Yoo** RA,QA/Reimbursement & HealthCare Economics/Government Affairs, Manager, Corporate Relations Ambassador, St. Jude Medical, Korea	
16:35 – 16:55	Overview of ISO14155 Clinical Investigation Requirements		**Ms Mie Ohama** Medtronic, Australia	

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16:50 – 17:20	Panel Discussion: Speakers	Moderators: **Ms Yuwadee Patanawong** Director of Medical Device Control, Thailand FDA **Ms Sumati Randeo** Director Global Strategy, Regulatory Affairs & Advocacy, Abbott Quality and Regulatory, Abbott Laboratories, India **Mr Aseem Sahu** (Deputy Drug Controller, India) **Ms Shelley Tang** (Stellar consulting, Australia) **Dr Wilma Hartung** (TÜ V Rheinland LGA Products GmbH, Germany) **Ms Mie Ohama** (Medtronic, Australia) **Manish Narang** (Abbott Vascular, India) **Dr Justin Yoo** (St. Jude Medical, Korea) **Mr Alfred Kwek** (Samsung Electronics, Singapore)
17:20 – 17:30	Closing Remarks	**Mr Alfred Kwek** TC Co-chair, AHWP (Industry) Regional Director, Government Affairs/HME, Samsung Electronics, Singapore

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Day-3: AHWP TC Workshop (Continue)

23 Nov 2016		Speakers
09:00 – 09:10	Opening & Recap	**Mr Ali M. Al-Dalaan** TC Chair, AHWP Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
09:10 – 10:30 (80min)	KEYNOTE SESSION: Panel discussion – Harmonizing…harmonized…are we there yet?	Moderator: **Mr Alfred Kwek** Co-chair, AHWP TC (Industry) Regional Director, Government Affairs/HME, Samsung Electronics, Singapore **Mr Ali AL Dalaan** (Chair, AHWP TC) **Ms Carol Yan** (Co-chair of Regulatory Affairs, APACMed) **Mr Fabio Pereira Quintino** (Chair, IMDRF) **Mr Michael Flood** (Locus Consulting Pty Ltd) **Ms Geraldine Lissalde-Bonnet** (Public Policy Director, GS1) **Dr Phillipe Auclair** (TC Advisor, AHWP) **Ms Robyn Meurant** (Technical Officer, WHO)
10:30 – 12:45	**AHWP-DITTA Joint Session on Software as a Medical Device (SaMD)**	
10:30 – 10:35	Welcome and Introduction	**Dr Sethuraman Rama** Deputy Director, Medical Device Branch, HSA, Singapore

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10:35 – 10:55	Quality System for SaMD	**Mr Tony Yip** Co-chair, AHWP WG3
10:55 – 11:10	TEA BREAK	
11:10 – 11:40	Clinical Evaluation of SaMD	**Mr Keiichiro Ozawa** Chair, DITTA Medical Software WG
11:40 – 12:10	Regulations on mobile applications with emphasis on EU and US	**Dr Ir Peter W.J. Linders** DITTA
12:10 – 12:35	Panel – SaMD: speakers	Moderator: **Dr. Sethuraman Rama** Chair , AHWP WG3 **Mr Tony Yip (**Co-chair, AHWP WG3) **Mr Keiichiro Ozawa (**Chair, DITTA Medical Software WG) **Dr Ir Peter W.J. Linders** (DITTA)
12:35 – 12:40	Closing Words	**Mr Keiichiro Ozawa** Chair of DITTA Medical Software WG
12:40 – 13:40	LUNCH	
13:40 – 16:50	**Korea Regulatory Session**	
13:40 – 13:45	Opening Words	**Dr Jeong-rim Lee** Director, Cardiovascular Devices Division, Ministry of Food & Drug Safety (MFDS), Republic of Korea
13:45 – 14:20	Korea Medical Device Regulatory System and Industry Status	**Ms Hye-kyung Son** Scientific Officer, Division of Medical Device Policy, Ministry of Food & Drug Safety (MFDS), Republic of Korea **Ms Ja-ryeong Shin** Head of Regulatory, Quality, Health

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		Economics & Government Affairs Boston Scientific Korea Co., Ltd., Republic of Korea
14:20 – 14:40	Approval Process of Medical Devices	**Mr Se-il Park** Assistant Director, Division of High-tech Medical Devices, Ministry of Food & Drug Safety (MFDS), Republic of Korea
14:40 – 15:00	Clinical Investigation for Medical Device Approval	**Mr Sang-hag Lee** Managing Director, R & D Center Mekics Co., Ltd., Republic of Korea
15:00 – 15:15	Q&A	
15:15 – 15:35	TEA BREAK	
15:35 – 16:15	Quality Management System for Medical Device	**Dr Jang-yong Choi** Deputy Director, Safety Evaluation Division, Ministry of Food & Drug Safety (MFDS), Republic of Korea **Mr Young-soo Seol** Production Director, Ilooda Co., Ltd., Republic of Korea
16:15 – 16:35	Overview of Medical Device Adverse Event (AE) Vigilance System and Management	**Dr Min-a Oh** Team Manager, Safety Evaluation Team Korea Medical Device Information & Technology Assistance Center (MDITAC), Republic of Korea
16:35 – 16:45	Q&A	
16:45 – 16:50	Closing Words	**Mr Seung-hwan Jung** Deputy Director, Cardiovascular Devices Division, Ministry of Food & Drug Safety (MFDS), Republic of Korea

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16:50 – 17:00	Closing Remarks	**Mr Alfred Kwek** TC Co-chair, AHWP (Industry) Regional Director, Government Affairs/HME, Samsung Electronics, Singapore
19:00 – 21:00	Regulators Dinner (by Invitation)	

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Day-4: 20th AHWP Technical Committee (TC) Meeting

24 Nov 2016		Speakers
08:00 – 09:45	AHWP TC & WG Leaders Meeting with TC Advisors (Closed Meeting)	AHWP & TC & WG Leaders & TC Advisors
10:00 – 10:05	Welcome Speech	**Ms Maria Cecilia Matienzo** Division Chief, Licensing and Registration Division, Center for Device Regulation, Radiation Health, and Research, Food and Drug Administration, Philippines
10:05 – 10:20	- Opening of TC Meeting - Adoption of Agenda - Roll Call	**Mr Ali M. Al-Dalaan** TC Chair, AHWP Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
10:20 – 11:30	Non-member Economy Updates: - The EU Medical Device Regulations (EU MDR) and impact on MD Industry (10:05 – 10:45) - Japan (10:45 – 11:15)	**Dr W. Hartung** Regional Business Field Manager Medical Germany, TUV Rheinland LGA Products GmbH **Mr Hiroshi Ishikawa** Expert, Office of Standards and Guidelines Development, Pharmaceuticals and Medical Devices Agency (PMDA)
11:30 – 12:00	GS1 Updates & UDI Development Around the World - Challenges Faced in Implementing Current Requirements	**Ms Geraldine Lissalde-Bonnet** Public Policy Director GS1 Global Office

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12:00 – 12:15	TEA BREAK	
12:15 – 12:25	Updates on Amendment to AHWPTC Term of Reference/ House Rules - Mechanism for WG Documents Endorsement	**Dr Jeong-Rim Lee** TC Co-chair (Regulatory Authority) Director, Cardiovascular Devices Division, Ministry of Food and Drug Safety (MFDS), Republic of Korea
12:25 – 12:45	Work Group Updates: • WG1 – Pre-market: General MD	**Mr Essam Mohammed Al Mohandis** Executive Director, Surveillance and Biometrics, Saudi FDA, Kingdom of Saudi Arabia **Ms Kate Kim** Director, Regulatory Affairs & Quality Assurance, Johnson & Johnson Medical North Asia (Korea, Taiwan, Hong Kong)
12:45 – 13:45	LUNCH	
13:45 – 15:45 (20min each)	Work Group Updates (Continued): • WG2 – Pre-market: IVDD	**Mr Wen-wei TSAI** Technical Specialist Division of Medical Devices and Cosmetics, TFDA, Department of Health, Chinese Taipei **Mr Albert Poon** Consultant, Freelance Hospital and Medical Device Consultancy, Hong Kong

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		SAR
	▪ WG3 – Pre-market: Software as a Medical Device	**Dr Sethuraman Rama** Deputy Director, Medical Device Branch, HSA, Singapore **Mr Tony Yip** Manager, Quality Assurance/ Regulatory Affiars, Far East Region, Elekta Limited, Hong Kong SAR
	▪ WG4 – Post-Market	**Ms Jennifer Mak** Senior Electronics Engineer, Medical Device Control Office Department of Health, Hong Kong SAR **Ms Kitty MAO** RA Manager, ASEAN & APEC RA Operation, GE Healthcare, Singapore
	▪ WG5 – Clinical Performance & Safety	**Ms Yuwadee Patanwong** Director of Medical Device Control, Thailand FDA **Ms Sumati Randeo** Director Global Strategy, Regulatory Affairs & Advocacy, Abbott Quality and Regulatory, Abbott Laboratories, India
	▪ WG6 – QMS: Audit & Assessment	**Mr Abdullah AL**

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		RASHEED Compliance & Enforcement Exec. Director, Saudi FDA, Kingdom of Saudi Arabia **Ms Shirley SUM** Senior Director, Johnsons & Johnsons regulatory Compliance (Asia Pacific), Johnson &Johnson, Singapore
	▪ WG7 – QMS: Operation & Implementation	**Ms Aidahwaty M.Olaybal** Principal Assistant Director, Medical Device Authority, Ministry of Health, Malaysia **Mr Ee Bin Liew** Owner and consultant, Access-2-Healthcare, Singapore
15:45 – 16:00	TEA BREAK	
16:00 – 16:40	Work Group Updates (Continued): ▪ WG8 – Standards	**Ms Maria Cecilia Matienzo** Division Chief, Licensing and Registration Division, Center for Device Regulation, Radiation Health, and Research, Food and Drug Administration, Philippines **Mr Tony Low** Medosociate/MMDPA Malaysia
	▪ STG (U&N) –UDI & Nomenclature	**Mr LI Jun**

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		Deputy Division Director, Department of Medical Device Registration, CFDA, China **Ms Carol Yan** Senior Director, Johnson & Johnson, China
16:40 – 17:10	Highlight of AHWP Playbook Training	**Mrs Joanna Koh** Principal Consultant, MDnet.regulatory Consultants, Singapore
17:10 – 17:30	Speech by TC Advisors Representative	TC Advisor Representative
17:30 – 17:35	Closing Remarks	**Dr Jeong-Rim Lee** TC Co-chair (Regulatory Authority) Director, Cardiovascular Devices Division, Ministry of Food and Drug Safety (MFDS), Republic of Korea
19:00	**Gala Dinner (Open to all participants)**	

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Day-5: 21st AHWP Annual Meeting

25 Nov 2016		Speakers
09:00 – 09:30	Opening Ceremony - Welcome Address	**Ms Nela Charade G. Puno** Director General, Food and Drug Administration, Philippines
	- Opening Speech	**Dr Hee-kyo Jeong** Chair, AHWP Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety (MFDS), Republic of Korea
	- Group Photo	
09:30 – 12:00	Updates By AHWP & International Organizations:	
	· AHWP	**Ms Tran Quan** Vice-Chair, AHWP (Industry) Vice President Regulatory Affairs APACMed
	· AHWP TC	**Mr Ali M. Al-Dalaan** TC Chair, AHWP Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
	· IMDRF	**Mr Fabio Pereira Quintino** Chair, IMDRF

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		Manager, Operation Permit Office Brazilian Health Regulatory Agency (ANVISA)
	▪ APEC	**Mr Lupi Trilaksono** APEC-AHC Representative, MOH, Indonesia
	▪ ASEAN	**Mr Zamane Abdul Rahman** ASEAN Representative, MDA, MOH, Malaysia
	▪ WHO	**Ms Robyn Meurant** Technical Officer, Essential Medicines and Health Products, WHO
12:00 – 13:00	LUNCH	
13:00 – 14:15	Updates By AHWP & International Organizations (Cont.): ▪ APACMed	**Mr Fredrik Nyberg** Chief Executive Officer, Asia Pacific Medical Technology Association (APACMed)
	▪ ISO	**Dr Ir Peter W. J. Linders** Chair, ISO TC210
	▪ IEC	**Mr Dennis Chew** Regional Director, APRC, IEC, Singapore
14:15 – 14:40	Updates by AHWP Liaison Members: ▪ GS1	*(Presentation time slot changed to Day-4 due to*

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		speaker travel schedule updates)
	▪ DITTA	**Mr Keiichiro Ozawa** Chair of Medical Software WG, DITTA
14:40 – 15:40	Regulatory Updates from Member Economy: ▪ Philippines	**Ms Maria Cecilia Matienzo** Division Chief, Licensing and Registration Division, Center for Device Regulation, Radiation Health, and Research, Food and Drug Administration, Philippines
	▪ Kazakhstan	**Ms Gulnar Berkimbayeva** Head, Department of Primary Expertise of Medical Devices, National Center of Expertise of Medicines and Medical Device, Kazakhstan
	▪ Vietnam	**Mr Nguyen Minh Tuan** Director, Department of Medical Equipment & Construction Ministry of Health, Vietnam
15:40 – 16:00	TEA BREAK	
16:00 - 16:40	Regulatory Updates from Member Economy (Cont.): ▪ China	**Mr Gao Guobiao** Deputy Director General, Medical Device Registration Department, CFDA, People's Republic of China

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	▪ Laos PDR	**Mr Bounxou Keohavong** Medical Product Supply Center, Ministry of Health, Laos PDR
	▪ Chile	**Ms Maria Cecilia Lopez** Professional Medical Devices Office, Public Health Institute of Chile
	▪ India	**Mr Aseem Sahu** Deputy Drugs Controller, Ministry of Health & Family Welfare, DGHS, India
16:40 – 17:10	Resolutions: i. Application for Joining AHWP Member Economy from UAE, Sultanate of Oman, Kingdom of Bahrain, Zimbabwe (short speech by applicant representatives) ii. Application for Joining AHWP Liaison Member from APACMed (short speech from Mr Fredrik Nyberg, CEO) iii. Amendment to AHWP TOR – AHWP Vision & Mission iv. Amendment to AHWP TOR & House Rules – TC WG Document Endorsement Mechanism v. Amendment to AHWP TOR – Official Observer vi. WG1 Document on "Guidance on Regulatory Practices for Combination Products" vii. WG1 Document on "Guidance for Minor	**Dr Hee-kyo Jeong** Chair, AHWP Director General, Medical Device Evaluation Department, MFDS, Republic of Korea **Mr Bryan So** (Moderator) Executive Deputy Secretary General, AHWP Principal Consultant, Hong Kong Productivity Council, Hong Kong SAR

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		Change Reporting"	
	viii.	WG2 Document on “Principles of In Vitro Diagnostic (IVD) Medical Devices Classification”	
	ix.	WG2 Document on “Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices”	
	x.	WG2 Document on “Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices”	
	xi.	WG3 Document on “Guidance document on Risk Categorisation of Software as a Medical Device”	
	xii.	WG4 Document on "Guidelines for adverse event reporting of Percutaneous Coronary Intervention (PCI) devices[1] for the Medical Device Manufacturer or its Authorized Representative"	
	xiii.	WG4 Document on “Post Market Resource Center”	
	xiv.	WG6: “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”	
	xv.	WG6: “Competence and Training Requirements for Auditing Organizations”	
	xvi.	WG6: “MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization”	
	xvii.	WG6: “MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes”	

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17:10 – 17:20	Announcement of 22nd AHWP Annual Meeting Host	**Dr Hee-kyo Jeong** Chair, AHWP Director General, Medical Device Evaluation Department, MFDS, Republic of Korea
17:20 – 17:30	Closing Remarks	**Dr Hee-kyo Jeong** Chair, AHWP Director General, Medical Device Evaluation Department, MFDS, Republic of Korea
17:45 – 18:15	**The 5th AHWP ASL Annual General Meeting (AGM)**	AHWP ASL Members (Open to AHWP Member Economy Only)

**Programme may be subject to changes.*