ASIAN HARMONIZATION WORKING PARTY WORKSHOP (4TH DEC-8TH DEC 2017)

Venue: The grand hotel, Nelson Mandela Road, Vasant Kunj - Phase II, New Delhi-110070

Day 1 (4th December, 2017)

Time (hrs)	TOPIC	NAME & DESIGNATION
08:00-09:00	Registration	AHWP India Secretariat
09:00-09:10	Welcome address	**Dr. G.N. Singh** DCG(I), Ministry of Health and Family Welfare, GOI
09:10-09:20	Welcome address	**Dr. Jagdish Prasad** DG, DGHS, Ministry of Health and Family Welfare
09:20-09:30	Welcome address	AHWP Chair – **Dr. Hee-Kyo Jeong** Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea
09:20-09:35	Lamp lighting	Chief Guest and other officials
09:35 -09:50	Inaugural address	Hon'ble Guest from Ministry of Health and Family Welfare Hon'ble Guest from Ministry of Commerce and Industry
09:50-10:00	Opening Remarks	**Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia

10.00-10.40	India Regulatory Update • Brief overview India– opportunities for medical devices sector, Presence of Medical Devices and IVD industry, Availability and affordability of medical devices. • An overview of regulations of medical devices and IVDs in India. • Recent updates/major policy changes in medical devices regulations. • Policy for Import / Export. Major Policies for providing ease of doing business towards growth of the country.	Session Chairs AHWP Chair – • **Dr. Hee-Kyo Jeong** Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea • **Sh. Sudhir Kumar**, Joint Secretary(Regulation), MoHFW Session Co-Chairs • **Dr. G.N. Singh** Drugs Controller General (I), CDSCO • **Dr. S.E Reddy** Joint Drugs Controller (I), CDSCO Presenter • **Dr. V.G Somani** Joint Drugs Controller (I), CDSCO
10:40-11:00	**Tea Break**	
11.00-11:30	Singapore Regulatory Update An overview of regulations of medical devices and IVDs in Singapore	**Dr. Rama Sethuraman** Deputy Director, Health Science Authority, Singapore
11:30-12:00	Japan Regulatory Update An overview of regulations of medical devices and IVDs in Japan	**Mr. Hiroshi YAGINUMA** Director, Office of Regenerative Medicine Product Evaluation Medical Device Evaluation and Licensing Division Pharmaceutical Safety and Environmental Health Bureau, MHLW

12:00-12:30	South Korea Regulatory Update An overview of regulations of medical devices and IVDs in South Korea	**Mr. Seil Park** Assistant Director Division of High-tech devices Department of MD evaluation Korea MFDS **Mr. Young Wook Ahn** Assistant Director Division of In-vitro Diagnostic Devices Department of MD evaluation Korea MFDS
12:30-13:00	Australia Regulatory Update An overview of regulations of medical devices and IVDs in Australia	**Mr. Michael Flood** Ex-TGA, Locus Consulting Pty Ltd Australia
13:00-14:00	**Lunch**	
14:00-14:30	South Africa Regulatory Update An overview of regulations of medical devices and IVDs in South Africa ·	**Ms. Andrea Julsing Keyter** Deputy Director : Medical Devices, National Department of Health Inspectorate & Law Enforcement Unit, South Africa
	DITTA SESSION	
14:30-15:00	Medical Device Single Audit Program (MDSAP)	Speaker needs to be confirmed
15:00-15:20	**Tea Break**	
15:20-15:50	Design controls, Risk Management, Verification and Validation and product release	**Mr. Fred Viaud** VP Quality & Regulatory - Philips Philips Healthcare
15:50-16:20	Adapting your ISO 13485 to the new Requirements	**Mr. Grant Ramaley** Convener, Medical Device Working Group for ISO 13485 International Accreditation Forum, Aseptico, Director of Regulatory Affairs
16:20-16:50	Role of Technical Standards and updates on international technical standards	**Dr. Peter Linders** Director, Standards & Regulations, Regulatory Standards, Philips Healthcare

16:50-17:20	Clinical Trial Environment - Australia	**Dr. Catherine Bourgeois** Vice President, Field Clinical Affairs, Emerging Markets & ANZ, Abbott
17:20-17:30	Closing Remarks	**Dr. Jeong-Rim Lee** TC Co-Chair Director, Cardiovascular Devices Division Department of MD evaluation Ministry of Food and Drug Safety (MFDS)

Day 2 (5th December, 2017): AHWP Playbook Training Workshop

09:00-09:10	Welcome speech – TC Capacity Building Program	**Ms. Tran Quan** Capacity Building Team Leader, Vice President, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed), Singapore
9.10-9.20	Opening Speech Play Book Training Session	**Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director Medical Devices Sector Saudi Food & Drug Authority Kingdom of Saudi Arabia
	Introduction of the 2 Day Training Program	**Ms. Joanna Koh** AHWP PB Program Co-ordinator & Lead Trainer, Principal Consultant MDnet Regulatory Consultants Singapore
09:20-10.00	Preparatory steps to MD Controls –ASEAN experience / Centering on the AMDD elements	**Mr. Zamane Abdul Rahman** Chief Executive, Medical Device Authority, Ministry of Health Malaysia
10.00-10:40	“Takes 2 to Tango” – CSDT/EP and standards	**Mr. Seet Wing Gang** Head Regulatory Intelligence,

		Greater Asia, Becton Dickinson
10:40-11:00	**Tea Break**	
11:00-11:40	Classification Rules GMD/IVD D –Why The Rules? Is there an alternative?	**Mr. Greg LeBlanc** M.Sc., RAC, Director, Regulatory Affairs and Quality Systems, Cook (Canada) Inc.
11:40-12:20	CAB Role and Grouping – A balance between Regulatory Controls and Processes with the Economics of MD Industry	**Dr. Vincent Lam** MHS Manager and Senior Product Specialist, TUV SUD Product Service
12:20-13:00	Objectives and limitations: In-country Lab Testing	**Ms. Junya Onae** Manager, Asia-pacific manager, Global Technology Assessment Center, TUV Rheinland
		Mr. Petra Kaars-Wiele Senior Director Regulatory, Quality & Labeling, Abbott Diagnostics
13:00-14:00	**Lunch**	
14:00-14:30	Clinical Investigation and evaluation for Medical Devices: Regulator perspective	**Dr. Mijung Son** Regulator (MFDS) Korea
14:30-15:00	Clinical Investigation and evaluation for Medical Devices: Industry perspective	**Mr. Arthur Brandwood** Brandwood Biomedical, Founder and Principal Consultant
15:00-15:20	**Tea Break**	
	Panel Discussion: Clinical Investigations and Real World Evidence	**MODERATOR:** **Ms. Sumati Randeo** Director Global Strategy Regulatory Affairs & Advocacy Abbott Laboratories
		Ms. Katy Peterson Director, Global RA Boston Scientific
		Ms. Kate Hyeong Joo Kim Director, Regulatory Strategy & Innovation, ASPAC Director Regulatory Affairs, North Asia, Johnson & Johnson Medical, Republic of Korea

15.20 – 16.00		**Mr. Kwan Han Ong** Regional Associate Director, Clinical Affairs Asia Pacific Regional Associate Director, Regulatory Affairs, APAC
		Dr. V.G Somani Joint Drugs Controller (I), CDSCO
16:00-16:30	Performance evaluation of IVD regulation	**Dr. Benny Ons** Director of Regulatory Affairs at BD Diagnostics and BD Biosciences Europe, Becton Dickinson International Becton Dickinson B.V.
16:40-17:10	Affiliate Member (i) GS1 Updates (ii) UDI Databases: Useful Tools for Regulatory Controls. How to utilize them in the MD Life Cycle especially in referencing for Pre Market Assessments	**Ms. Ulrike Kreysa** Vice-President Healthcare, GS1 Global Office
17:10-17:20	Closing Remarks	**Ms. Joanna Koh** AHWP PB Program Co-ordinator & Lead Trainer, Principal Consultant MDnet Regulatory Consultants Singapore
19:00 hrs Onwards	**Gala Dinner (On invitation basis only)**	

Day 3 (6th December, 2017): AHWP Playbook Training Workshop and TC WORKSHOP

09:00-09:10	Recap of PB session 1 and intro of session 2	**Ms. Joanna Koh** Principal Consultant MDnet Regulatory Consultants Singapore
09:10-09:55	Post Market - Medical Device Post market for Digital Healthcare: Cybersecurity prevention for MDs	**Mr. John Ramesh** Managing Director TUV Rheinland LLC, Oman & Regional Feild Manager, Bussiness Solutions, IMEA & APAC

09:55-10:40	Post Market - A Growing Global Concern: Counterfeit Medical Devices	**Dr. Nazeeh S. Alothmany** Vice Executive President, Medical Device Sector, Saudi FDA, KSA
10:40-11:00	**Tea Break**	
11:00-11:40	Advertisement and Labeling	**Mr. Er Alfred Kwek** Director, Public Affairs, Edwards Life Sciences S PL
11:40-12:10	Panel Discussion on the PB Initiatives and Road ahead	**Moderator:** **Mr. Scott Sanderson** 3M Health Care, International Regulatory Affairs and Quality Compliance Leader, Medical Division, Minnesota
		Dr. Adrianti Anaya Director of Medical Devices and Household Health Pdts Evaluation
		Ms. Agnes Sitta Kijo Manager, Medical Devices; Diagnostics Registration, Tanzania Food & Drugs Authority
		Mr. Grant Ramaley Aseptico, Director of Regulatory Affairs
12.10-12.20	Closing of AHWP PlayBook Training Program for the Current Cycle.	**Ms. Joanna Koh** AHWP PB Program Co-ordinator & Lead Trainer Principal Consultant MDnet Regulatory Consultants Singapore
AHWP Technical Committee (TC) Workshop		
12:20-12:25	Opening words by TC Chair	**Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director Medical Devices Sector Saudi Food & Drug Authority Kingdom of Saudi Arabia
APACMed SESSION		

12:25-13:00	Device & Operation Risks of Tele-medicine and e-Health: Regulatory Consideration across Jurisdictions	**Ms. Ann Graves** Vice President, International Regulatory Affairs, Abbott
13:00-14:00	**Lunch**	
1400:-14:30	Regulatory on Medical Devices using 3D Printing – From Manufacturing to AE Reporting (e.g. QMS, QMS audit, pre-market submissions, clinical trial, AE reporting and recall)	**Dr. Jang Yong Choi** Deputy Director, Division of Medical Device Safety Evaluation Medical Device Safety Bureau Ministry of Food and Drug Safety (MFDS)
14:30-15:00	Diagnostic Devices based on AI and Big Data Analytics – Thoughts on Validation and Risk Management	**Ms. Nicole Taylor Smith** Senior Director, Global Regulatory Affairs Policy & Intelligence, Johnson & Johnson
15:00-15:20	**Tea Break**	
15:20- 15:50	Panel discussion: Challenges and issues to regulate an innovative medical devices: Barriers and Enablers to development	**Moderator:** **Ms. Miang Tanakasemsub** Head, Regulatory Affairs (Asia & Russia), Alcon
		Mr. Biten Kathrani Director R&D for Boston Scientific India as the speaker) Senior International Trade Specialist, Industry & Analysis, U.S. **Mr. Matthew Hein** Senior International Trade Specialist Industry & Analysis U.S. Department of Commerce| International Trade Administration Office of Health and Information Technologies
		Sh. Somnath Basu Asst. Drugs Controller (I), CDSCO **Sh. Sunil Kulshrestha** Asst. Drugs Controller (I), CDSCO

Parallel Session		
AHWP TC Workshop (Parallel 1)		
15:50 -16:10	Changing global regulatory environment – opportunity and threat in industry - focused on premarket	**Mr. Jeongpyo Hong** Manager, Regulatory Affairs Health & Medical Equipment Business, Samsung Electronics
16:10-16:40	Pre- market approval – Essential Principles for safety, quality and performance	**Mr. Michael Flood** Principal, Locus Consulting Pty Ltd
16:40-17:00	Use of Real World Evidence in clinical and regulatory decision from Industry experience	**Dr. Justin Yoo** Government Affairs Health Economics & Reimbursement, Manager Corporate Relations Ambassador St. Jude Medical Korea YH, Abbott
17:00-17:20	Post-market control of medical devices-How far we have gone towards harmonization	**Ms. Jennifer MAK Kit-shu** Senior Electronics Engineer (Medical Device Control Office), Department of Health Medical Device Control Office, Department of Health, Hong Kong China
17:20 -17:40	TGA Reforms for Medical Devices & IVDs and Clinical trial landscape in major countries in APAC	**Ms. Mie Ohama** Principal clinical quality specialist at Medtronic Clinical Research Institute, Interntional quality, Sydney Australia
17:40 – 18:00	Q&A	**Sh. Aseem Sahu** Dy. Drugs Controller (I), CDSCO
18:00 – 18:10	Closing Remarks	**Dr. Jeong-Rim Lee** TC Co-Chair Director, Cardiovascular Devices Division Department of MD evaluation Ministry of Food and Drug Safety (MFDS)
India Industry Workshop (Parallel 2)		

15:50 -16:10	Medical Devices Rules, 2017- Technical Requirements of manufacture and import of medi cal devices	**Sh. Aseem Sahu** Dy. Drugs Controller (I), CDSCO **Sh. Ravikant Sharma** Asst. Drugs Controller(I), CDSCO
16:10-16:30	Medical Devices Rules, 2017- Investigational Medical Devices/new IVD approval	**Sh. Ravikant Sharma** Asst. Drugs Controller(I), CDSCO **Sh. Somnath Basu** Asst. Drugs Controller(I), CDSCO
16:30-17:00	Panel Discussion: Opportunities and Way Forward in Manufacturing of Medical Devices (MD) and IVD sector –"Make in India Program" by Invest India (DIPP)	**Mr. Sanjay Arudi** Senior Director Regulatory Affairs Sustainable Healthcare Solutions, GE Healthcare
		Mr. R. Asok Kumar Vice President (QA&RA), Johnson & Johnson Medical, India
		Mr. Himanshu Baid Managing Director of Poly Medicure Limited, India
		Mr. Sudhakar Mairpadi Director - Quality & Regulatory Philips Electronics India Limited (Health Care sector)
		Mr. Rajiv Nath Forum Coordinator Association of Indian Medical Device Industry (AiMeD)
		Dr. V. G. Somani Joint Drugs Controller (I), CDSCO
17:00-17:30	Q & A	Q & A
17:30-17:40	Closing Remarks	**Dr. V. G. Somani** Joint Drugs Controller (I), CDSCO

Day 4 (7th December, 2017): AHWP TC Meeting

Day4: AHWP TC Meeting		
09:00-10:40	AHWP TC & WG Leaders Meeting with TC Advisors (Closed Meeting)	AHWP & TC & WG Leaders & TC Advisors

10:40-11:00	**Tea Break**	
11:00-11:05	Welcome Speech	
11:05-11:25	Opening of TC Meeting -Roll call -Adoption of Agenda -Announcement of the Election Arrangement for Office Bearers of AHWPTC and AHWPTC WGs	**Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia **Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
11:25-13:05 (20min each)	WG updates: WG1 WG2 WG3 WG4 WG5	WG Chair & Co-chairs
13:05-14:05	**Lunch**	
14:05- 15:25 (20min each)	WG updates (Continued) -WG6 -WG7 -WG8 -STG	WG Chair & Co-chairs
15:25-15:45	**Tea Break**	
15:45-16:15	Highlight of AHWP PB Training	**Ms. Joanna Koh** Principal Consultant MDnet Regulatory Consultants Singapore
16:15-16:45	Speech by TC Advisors Representative	TC Advisor Representative

16:45-16:55	Closing Remarks	**Mr. Alfred Kwek** Regional Director, Government Affairs/HME Samsung Electronics, Singapore **Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
19:30:00 onwards	**Gala Dinner**	

Day 5 (8th December, 2017): AHWP annual meeting

09:00-09:30	Opening Ceremony -Congratulation Address -Opening Speech by AHWP Chair -Group Photo	**Official,** Ministry of Health and Family Welfare, India **Dr. Hee-Kyo Jeong** AHWP Chair Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea All Participants
09:30-09:45	Roll Call Adoption of Agenda Adoption of 21st AHWP Annual Meeting Minutes	**Dr. Hee-Kyo Jeong** AHWP Chair Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea Supported by **Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China

09:45-10:15	Updates by AHWP and AHWP TC AHWP AHWP TC	**Ms. Tran Quan** AHWP Vice Chair Vice President, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed), Singapore **Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
10:15-10:30	Announcement of Election Arrangement for Office Bearers of AHWP	**Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
10:30-11:00	**Tea Break**	
11:00-12:00 (15min each)	AHWP Member Economy updates -China -India -Tanzania -APEC - ASEAN	 **Mr. GAO Guo Bia** Deputy Director General of Medical Device Registration Department, China Food and Drug Administration People's Republic of China **Dr. V. G. Somani** Joint Drugs Controller, CDSCO, India **Mr. Mitangu Adam Fimbo** Director of Medicines and Complementary Products., Tanzania FDA **Dr. Arianti Anaya** Director of Medical Devices and Household Health Pdts Evaluation, MOH, Indonesia **Mr. Zamane Abdul Rahman**

		Chief Executive, Medical Device Authority, Ministry of Health Malaysia
12:00-12:30 (10 min each)	AHWP Liaison Member Updates -APACMed - DITTA	**Mr. Fredrik Nyberg** CEO APACMed
12:30-13:15 (10 min each)	Endorsement of New Member Economies - Mexico (TBC) To be finalized by AHWP - Kenya (TBC) To be confirmed by AHWP Speech by New Liaison - GMDN (TBC) To be confirmed by AHWP	**Ms. Carol Liu** AHWP Secretariat, Vice President, Regulatory Affairs, ASPAC Johnson & Johnson People's Republic of China
13:15-14:15	**Lunch**	
14:15-14:35	Secretariat Updates - Secretariat Report - Financial Report	**Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
14:35-14:45	Resolutions - Amendment to AHWP TOR/HR – Participation of WG activities - STG change to WG - To be confirmed by AHWP	**Dr. Hee-Kyo Jeong** AHWP Chair Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea Supported by **Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
14:45-16:00	Election of AHWP Leadership of 2018-2020 - Briefing on Election Rules and List of Candidates - Election - Endorsement of Newly Elected Office Bearers of AHWP	**Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit

	- Endorsement of Newly Elected Office Bearers of AHWPTC - Endorsement of Newly Elected Office Bearers of AHWPTC Working Group	Hong Kong Productivity Council Hong Kong SAR, China
16:00-16:30	**Tea Break**	
16:30-16:40	Announcement of 23rd AHWP Annual Meeting Host	**Dr. Hee-Kyo Jeong** Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea
16:40-16:50	Speech by Newly Elected Chair of AHWP	
16:50-17:00	Closing Remarks by Outgoing Chair of AHWP	**Dr. Hee-Kyo Jeong** AHWP Chair Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea
17:00-17:30	The 6th AHWP ASL Annual General Meeting (AGM)	**ASL Members only** **(Transfer to another room)**