APEC Roundtable Dialogue on Global Regulatory Convergence for Medical Devices & Accelerating Digital Health Regulatory Convergence in the Asia-Pacific

November 08 - 10 2022 | Seoul, Korea (Hybrid format)

APEC Roundtable Dialogue
Workshop on Global Regulatory Convergence for Medical Devices

Day One: November 8, 2022 (COEX 402 / Webex)

Advancing Global Regulatory Convergence for Medical Devices and IVDs	
10:30 – 10:45 AM	**Coffee/Tea Break Following Conclusion of Soonchunhyang University APEC Center of Excellence Workshop** **In person participants:** Registration and coffee/tea **Virtual participants:** Join virtual meeting using *[Link will be provided to all registered participants]*
10:45 – 10:55 AM *(10 minutes)*	**Host: AHC Representative** **Welcome Remarks: Roundtable objectives and event structure** (5 minutes each) • **Representative,** Title, AHC
Session I: ***Review of Outcomes and Recommendations from November 2021 Dialogue on Regulatory Flexibilities During COVID-19***	
10:55 – 11:30 AM *(35 minutes)*	**Presentation:** (25 minutes / 10 minutes Q&A) • **Janet Trunzo,** Senior Executive Vice President, Technology and Regulatory Affairs, AdvaMed Identified key regulatory flexibilities during COVID-19 included: • Expedited and prioritized review of qualifying products, such as through emergency use pathways; • Adding reliance pathways; • Having flexible clinical trial requirements; and • Adopting digital tools, including permitting electronic submissions and remote inspections. Opportunities included: • advancing regulatory reliance and convergence; • adopting agile premarket pathways; • adopting policies that enable alternative sources of evidence; • developing a common emergency use pathway; • adopting state-of-the-art digital technologies; and • facilitating public-private partnerships.

Session II: *Review of International Foundational Best Practices and Guidance Documents that Enable the Recommendations of the November 2021 Dialogue*	
WHO Guidance Documents and Global Model Regulatory Framework	
11:30 AM – 12:00 PM *(30 minutes)*	**Presentations:** (20 minutes / 10 minutes Q&A) • **Agnes Kijo,** Technical officer, Regulation and Safety Unit, World Health Organization This presentation will overview: • Global Model Regulatory Framework • Good reliance practices in the regulation of medical products – Annex 10, WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-Fifth Report • Good regulatory practices in the regulation of medicalproducts – Annex 11, WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-Fifth Report
IMDRF Guidance Documents	
12:00 – 12:30 PM *(30 minutes)*	**Presentations:** (20 minutes / 10 minutes Q&A) • **Melissa Torres,** Associate Director for International Affairs, Center for Devices and Radiological Health, U.S. FDA Topics the presentation will cover include: • Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices • Principles of Labelling for Medical Devices and IVD Medical Devices • Principles Conformity Assessment for IVD Medical Devices • Medical Device Single Audit Program (MDSAP)
12:30 – 1:15 PM *(45 minutes)*	**Lunch**

Session III: ***Panel Discussion on the Implementation of Identified Foundational Best Practices and Guidance Documents to Advance Regulatory Convergence***	
1:15 – 2:20 PM *(55 minutes)*	The panel will review the key takeaways and recommendations from Session II. **<u>Panelists:</u>** **Regulatory Perspective:** • **Agnes Kijo,** Technical officer, Regulation and Safety Unit, World Health Organization **Industry Perspectives:** • **Tammy Steuerwald,** Global Head of Regulatory Policy, Foundational Principles & Supranational Organizations 15 min Opening Statements (5 min each) 25 min Facilitated discussion around prepared questions 15 min Q&A • <u>Moderator:</u> **Sandra Ligia González,** Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector
2:20 – 2:35 PM *(15 minutes)*	**Coffee / tea break**
In-Person Regulatory & Industry Dialogue Sessions	
2:35 – 3:20 PM *(45 minutes)*	**Case Study 1:** ***Singapore/Thailand Reliance Pilot*** • *During COVID-19, Singapore and Thailand undertook an abridged review of their reliance pilot and how it resulted in new regulation* • *Review of how the pilot and subsequent regulations impacted patient access* Q&A **Presenter 1: Miang Tanakasemsub,** Head of Regulatory Affairs, J&J **Presenter 2: Patcharaporn Nontasawadsri,** Pharmacist, practitioner level, Pre-Marketing Sub-Division, Medical Devices Control Division, FDA, Thailand **Presenter 3: Dr. Lakshmidevi Balakrishnan,** Regulatory Consultant, Medical Devices Branch, Singapore Health Sciences Authority

3:20 – 3:50 PM *(30 minutes)*	**Case Study 2:** ***Canada & U.S. and the Use of Digital Tools for Premarket Electronic Submissions and Remote Inspections*** • *The use of remote inspections proved invaluable in the fight and recovery from COVID-19. Looking forward, the U.S. FDA speaks to the use of remote inspections beyond the pandemic.* • *Health Canada speaks to the use of electronic submissions in facilitating premarket review and its role in universal dossiers.* Q&A **Presenter : Jesus Rueda**, Strategies, Special Projects & International Affairs, MedTech Europe
3:50 – 4:20 PM *(30 minutes)*	**Case Study 3:** ***Republic of Korea and the Benefits of Emergency Use Authorizations (EUA)*** • *The Republic of Korea overviews its use of EUAs during the pandemic and the benefits of regulatory flexibilities* Q&A **Presenter: Dr. Ho-Sang Jeong,** Director, In Vitro Diagnostic Devices Division, NIFDS MFDS
4:20 – 4:30 PM *(10 minutes)*	**Day One In-Person Program Closing**

Day Two: November 9, 2022 (COEX 402 / Webex)

Review of Best Practices and Opportunities for Regulatory Innovation	
8:45 – 9:00 AM	**In person participants:** Registration and coffee/tea **Virtual participants:** Join virtual meeting using *[Link will be provided to all registered participants]*
Session I: ***Deep Dive into the Medical Device Single Audit Program***	
9:00 – 9:40 AM *(40 min)*	**Presentation:** (30minutes / 10minutes Q&A) **on the Medical Device Single Audit Program (MDSAP)** **Regulatory Perspective:** • **Kenneth Chen**, Senior Regulatory Officer, U.S. FDA
Session II: ***Opportunities for Innovation***	
9:40 – 10:30 AM *(50 minutes)*	***Expanding Patient Access Based on Lessons Learned*** *During the November 2021 roundtable, participants identified key regulatory flexibilities and opportunities to implement lessons learned form COVID-19. This session will feature a presentation on the importance of global regulatory convergence and reliance in expand patient access to vital medical technologies. Thereafter, a panel discussion will seek to synthesize the workshop's recommendations and identify additional opportunities for global regulatory convergence and reliance.* Moderator: **Sandra Ligia González,** Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector Panelists: • **Agnes Kijo,** Technical officer, Regulation and Safety Unit, World Health Organization • **Eric Woo**, Regional Director, Asia Pacfic, ECRI Institute • **Jesus Rueda**, Strategies, Special Projects & International Affairs, MedTech Europe • **Janet Trunzo**, Senior Executive Vice President, Technology and Regulatory Affairs, AdvaMed • **You Kyoung Lee**, Professor, Soonchunhyang University & Director, SCH APEC CoE Team Q&A (10 minutes)
10:30 – 10:40 AM *(10 minutes)*	• **Day Two In-Person Program Closing**

APEC Roundtable Dialogue on Accelerating Digital Health Regulatory Convergence in the Asia-Pacific: Overview of Key IMDRF Documents & Opportunities for Post-Pandemic Regulatory Innovation & Convergence

Day Two: November 9, 2022 (COEX 402 / Webex)

Opening & Introduction	
1:30 – 1:45 PM *(15 minutes)*	**Host: AHC Representative** **Welcome Remarks: Roundtable objectives and event structure** (7.5 minutes each) • **Representative,** Title, AHC • **Maggie Henkin,** CMI
SaMD Qualification	
1:45 – 2:15 PM *(30 minutes)*	**Presentations: Landscape** (20 minutes / 10 minutes Q&A) • **Sharad Shukla**, Director, Regulatory Affairs, MedTech, Johnson & Johnson • Moderator: **Maggie Henkin,** CMI
2:15 – 2:45 PM *(30 minutes)*	**Presentations: SaMD Risk Classification** (20 minutes / 10 minutes Q&A) • **Dr. Sethuraman Rama**, Director, Medical Devices Branch, Health Sciences Authority (HSA) ○ HSA's Guidance "Guidelines on Risk Classification of Standalone Medical Mobile Applications and Qualification of Clinical Decision Support Software (CDSS)", published in April 2022 • Moderator: **Maggie Henkin,** CMI
Regulatory & Industry Dialogue Sessions	
2:45 – 3:45 PM *(60 minutes)*	**Dialogue Session 1: Regulation of Software as Medical Devices – Software Qualification** (40 minutes / 20 minutes Q&A) **Topic : Considerations for Determining if a product is regulated as a device** **Panel** • **Dr. Sethuraman Rama**, Director, Medical Devices Branch, HSA, Singapore • **Dr. David Hau**, Senior Medical Adviser, Medical Devices Authorisation Branch at Therapeutic Goods Administration, Australia (IMDRF SaMD Working Group)

	• **Kitty Mao**, Director of Regulatory Affairs, Asia Pacific, GE Healthcare • Moderator : **MinYong Choi**, Consultant
3:45 – 4:00 PM *(15 minutes)*	**Coffee / Tea Break**
4:00 – 5:00 PM *(60 minutes)*	**Dialogue Session 2: SaMD Risk Classification** (40 minutes / 20 minutes Q&A) **Topic: The benefits of the IMDRF risk classification document. Addressing the challenges of applying the IMDRF concepts** **Panel** • **Dr. Sethuraman Rama**, Director, Medical Devices Branch, HSA, Singapore • **Dr. David Hau**, Senior Medical Adviser, Medical Devices Authorisation Branch at Therapeutic Goods Administration, Australia (IMDRF SaMD Working Group) • **Sharad Shukla**, Director, Regulatory Affairs, MedTech, Johnson & Johnson • Moderator : **Dr. MinYoung Kim**, Professor, Department of Rehabilitation Medicine, CHA Medical Center

Day Three: November 10, 2022 (COEX 301 / Webex)

Opening & Introduction	
8:45 – 9:00 AM *(15 minutes)*	**In person participants:** Registration and coffee/tea **Virtual participants:** Join virtual meeting using *[Link will be provided to all registered participants]*
Software Products with Multiple Functions	

9:00 – 9:30 AM
(30 minutes)
	Presentations: Software Products with Multiple Functions (20 minutes / 10 minutes Q&A)
	• **Brendan O'Leary**, Acting Director, Digital Health Center of Excellence, FDA, USA
	  ○ U.S. Food and Drug Administration (FDA) – Multiple Function Device Products: Policy and Considerations Guidance for Industry and Food and Drug Administration Staff
	• **Thierry Sirdey,** Head, Department for Medical Devices and Cosmetics and In Vitro Diagnostic Devices, National Agency for the Safety of Medicines and Health Products, France **(remote)**
	  ○ Moderator: **Maggie Henkin,** CMI **(in-person)**

Total Product Life Cycle Management	
9:30 – 10:00 AM *(30 minutes)*	**<u>Presentations: Considerations for SaMD and SiMD – Alignment of approaches</u>** (20 minutes / 10 minutes Q&A) • **Allan Chuan Qin**, Senior Regulatory Affairs Manager for Software Products, China, GE Healthcare: Alignment of SaMD and SiMD
10:00 – 10:15 AM *(15 minutes)*	**Coffee / Tea Break**

10:15 – 11:15 AM
(60 minutes)
	<u>Presentations: Change Management</u> (20 minutes / 40 minutes Q&A)
	• **Brendan O'Leary**, Acting Director, Digital Health Center of Excellence, FDA, USA
	  ○ US FDA – AI/ML-Based SaMD Action Plan
	  ○ US FDA's Discussion Paper – Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)
	• **Cassie Scherer**, Senior Director of Digital Health Policy and Regulatory Strategy, Global Regulatory Policy, Medtronic
	• <u>Moderator</u>: **Dr. Jaesoon Choi**, Associate professor, Biomedical Engineering, University of Ulsan College of Medicine

Unique Considerations for AI	
11:15 – 12:00 PM *(45 minutes)*	**<u>Presentation: Overview of IMDRF AI Technical Documents and Unique Considerations for AI</u>** (20 minutes) • **Youngwoo Bae,** Assistant Director, Digital Health Devices Division, Department of Medical Device Evaluation, MFDS • **Dr. Camille Vidal**, Senior Director of Regulatory Affairs for Software, Digital and Advanced Visualization Products, GE Healthcare • **Moderator: Maggie Henkin,** CMI
12:00 – 12:15 PM *(15 minutes)*	**Day Two Hybrid Program Wrap up & Closing Remarks** • **AHC** • **Maggie Henkin,** CMI