COVID-19 Medical Device Regulatory Convergence Project

Virtual Regional Workshop on Good Regulatory Practices and Medical Device Regulation
0900 – 1200 hrs (JKT), 28 February and 1 March 2023

Agenda

Day 1

Time (Indonesia)	Session
0900 - 0910	**Opening Remarks by Karl Fickenscher**, Senior Deputy Assistant Administrator, Bureau for Development, Democracy, and Innovation, USAID
0910 - 0920	**Welcome Remarks by Mohd Asni Abd Ghani,** Vice-Chair of the ASEAN Medical Device Committee
0920 - 0930	**Introductory Remarks by Steven Bipes**, Vice President for Global Strategy and Analysis, AdvaMed
0930-1020	**Presentation: Overview of International Good Regulatory Practices and Standards** The presentation will discuss elements of the WTO TBT agreement and legal obligations as it relates to GRPs. It will examine how countries can translate and implement these commitments at the national level and adopt GRPs, including by health regulators. The panel will also raise the key role of national standards organizations in promoting GRP implementation, standardization, conformity assessment, and accreditation, as well as reporting on conformance to quality and standards related to the medical-device sector. Moderator: **Marina Carvalho**, Good Regulatory Practices Lead, MDRC (5 min) • **Devin McDaniels**, Deputy Secretary, WTO Technical Barriers to Trade Committee *(Pre-recorded message)* • **Renee Hancher**, Director, Regulatory Policies, Office of WTO and Multilateral Affairs, U.S. Trade Representative's Office **Q&A** - 15 min
1020 - 1030	**BREAK**

1030 – 1140	**<u>Panel</u>: Global Frameworks for Regulation of Medical Devices** Speakers will highlight consensus approaches from international frameworks and for a dealing with medical device convergence efforts, including the WHO Guidelines: Model Regulatory Framework for Medical Devices and in vitro diagnostic medical devices (IVDs), Good Regulatory Practices and Good Reliance Practices, the International Medical Device Regulators Forum (IMDRF), the Global Harmonization Working Party (GHWP), and the ASEAN Medical Device Directive. Experts from AMS and the U.S. will also share how their respective countries have managed to interpret and align national regulations with international guidance. <u>Moderator</u>: **Sandra Liga Gonzalez**, Tier 2 Lead, MDRC(5 min) • **Agnes Sitta Kijo**, Technical Officer, World Health Organization (10 min) • **Tracey Duffy**, First Assistant Secretary, Medical Devices and Product Quality, Therapeutic Goods Administration (TGA), Australia (10 min) • **Eka Purnamasari**, Director, Medical Device Supervision, Ministry of Health, Indonesia (10 min) • **Tammy Steuerwald**, Global Head of Regulatory Policy, Foundational Principles & Supranational Organizations, Global Regulatory Policy and Intelligence, Roche Diagnostics (10 min) **Q&A** (25 min)
1140 - 1200	**Standards and Conformity Assessment – Overview** <u>Presenter</u>: **Scott Colburn**, Director, Standards and Conformity Assessment Program, Center for Devices and Radiological Health. U.S. Food and Drug Administration (15 min) **Q&A** (5 min)
<u>END OF DAY 1</u>	

<u>Day 2</u>

0900 - 0910	**<u>Welcome and Recap of DAY 1 by MDRC Southeast Asia Project Lead</u>**
0910 - 1030	**<u>Panel</u>: Use and Contextualization of Reliance Models to Streamline Medical Device Assessment** Globalized medical device manufacturing and distribution, complex manufacturing processes and supply chains, and innovative products mean that authorities may

	not always have the resources, expertise, or time to conduct pre-market assessments from scratch. This results in uncertainty, unnecessary delays, and additional costs before vital medical products can reach patients and healthcare providers. This panel will discuss regulatory reliance models in the Asia Pacific and elsewhere, sharing learning points for regulators on designing and adapting such models, as well as capacity-building and training for implementation at the national level through relevant case studies and sharing of country experience. Panelists will also examine how the CSDT contributes to advancing the reliance agenda in the region by harmonizing information submitted to authorities for medical device registration (both General Medical Devices and In Vitro Diagnostic Devices), and in the process, reducing costs for manufacturers and national regulatory authorities, removing barriers to trade, and facilitating timely access to medical devices. Moderator: **Seet Wing Gang**, Director, Regulatory Affairs, Cook Medical (5 min) • **Neil Mafnas**, Center for Devices and Radiological Health, US Food and Drug Administration *(On MDSAP – Reliance applied to Quality Management Systems;* 10 min) *(To be recorded post-workshop)* • **Wong Woei Jiuang**, Assistant Group Director, Medical Devices Cluster, Health Products Regulation Group, Health Sciences Authority, Singapore (*On CSDT – the Why and the How*; 10 min) • **Cecilia C. Matienzo**, Director, Center for Device Regulation, Radiation Health and Research (CDRRHR), Philippines (*On Utilization of CSDT as a Reliance Mechanism;* 10 min) • **Veravoot Sermsinsiri**, Director, Medical Devices, Food and Drug Administration, Thailand **Q&A** (20 min)
1030 - 1040	**BREAK**
1040 - 1155	**Panel: Post-Market Surveillance – Regulators' Role and Private Sector Stakeholder Perspectives** Post-market surveillance is essential to ensure that medical devices continue to be safe, perform as intended, and remedial actions and improvements are undertaken, as necessary. The IMDRF has elaborated on requirements for post-market surveillance, harmonization of these requirements across regulatory environments, and reporting guidelines for adverse events. Similarly, the WHO has released guidance on post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. This panel will discuss the implications of

	these guidance, and the responsibility of manufacturers, and how regulators can collaborate with industry to uphold medical device safety and standards. Moderator: **Adrien Inoubli**, Regional Adviser, Medical Products Regulation, WHO South-East Asia Regional Office (5 min) • **Anita Sands**, Technical Officer, Incidents and Substandard / Falsified Medical Products Team, World Health Organization (*On Post-Market Surveillance and Market Vigilance;* 10 min) • **Lailing Liew**, Regulatory Consultant, Health Sciences Authority (HSA), Singapore (*On Medical Devices: Post-Market Surveillance National Competent Authority Report Exchange Criteria and Report Form* and *IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes*; 10 min) • **Dini Kusumawati**, Team Leader, Medical Device Product Supervision, Ministry of Health, Indonesia (*On Regulators' Perspectives*; 10 min) • **Nicole Taylor Smith**, Global Head, Regulatory Science and Policy, Philips (*On Industry Overall MDPerspective*; 10 min) **Q&A** (10 min)
1155 - 1200	**Closing Remarks by Steven Bipes**, Vice President for Global Strategy and Analysis, AdvaMed

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