COVID-19 Medical Device Regulatory Convergence Project (Indonesia)

Regulatory Training on Medical Device-related Standards and Guidance
1900 – 2200 hrs (JKT), 8 September 2022
0730 – 1100 hrs (JKT), 9 September 2022

Day 1: Thursday, 8 September 2022 – 1900 to 2200 hrs Indonesia time (GMT +7)

Time (Indonesia)	Session
1900-1910	Welcome Remarks by **Ir. Sodikin Sadek**, Director of Medical Devices Production and Distribution
1910-1920	Opening Remarks by **Dr. Lucia Rizka Andalucia**, Director General of Pharmaceutical and Medical Devices
1920-1930	Introductory Remarks by **David Stanton**, Acting Director, Health Office, USAID Indonesia
1930-2000	Presentation of Landscape Analysis of Med-Device Industry in Indonesia by **Dr. Hargo Utomo**, Department of Management, University of Gadjah Mada
2000-2100	**Topic: Quality Management System and Good Distribution Practices (Medical Devices and In Vitro Diagnostics)** Speakers: • **Billie Jo Johnson**, Specialist, DEKRA MDSAP Audits ***50 mins presentation / 10 mins Q&A*** Scope: • ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes • Medical Device Single Audit Program (MDSAP)
2100-2200	**Topic: Artificial Intelligence and Software as a Medical Device** Speakers: • **Reza Pramono**, Chief Technology Officer, Digital Transformation Office, Ministry of Health, Indonesia • **Cassie Scherer**, Director, Regulatory Policy, Medtronic • **Diane Johnson**, Senior Director, Strategic Regulatory Affairs, Johnson & Johnson MedTech

	15 min presentation each / 15 mins Q&A Scope: Artificial Intelligence: • IMDRF/AIMD WG/N67 Machine Learning-enabled Medical Devices: Key Terms and Definitions Software as a Medical Device: • IMDRF/SaMD WG/N10 - Software as a Medical Device (SaMD): Key Definitions • IMDRF/SaMD WG/N12 - Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations • IMDRF/SaMD WG/N23 - Software as a Medical Device (SaMD): Application of Quality Management System • IMDRF/SaMD WG/N41 - Software as a Medical Device (SaMD): Clinical Evaluation
END	

Day 2: Friday, 9 September 2022 – 0730 to 1100 hrs Indonesia time (GMT +7)

0730-0830	**Topic: Pre-Clinical and Clinical Test/Evaluation of Medical Devices** Speakers: • **Alessandro Ferreira**, Brazil Health Regulatory Agency (Anvisa) • **Felicia Haynes**, Senior Principal Regulatory Affairs Specialist, Medtronic ***25 mins presentation each / 10 mins Q&A*** Scope: • IMDRF MDCE WG/N55 - Clinical Evidence - Key Definitions and Concepts • IMDRF MDCE WG/N56 - Clinical Evaluation
0830-0930	**Topic: Electrical Safety and Performance for Medical Devices and IVDs** Speakers:

	• **Indra Hardian Mulyadi**, Head, Biomedical Technology Expertise Group, Batam State Polytechnic ***50 mins presentation / 10 mins Q&A*** Scope: • IEC 60601 Medical Electrical Equipment
0930-0945	**COFFEE BREAK**
0945-1045	**Topic: Post Market Surveillance of Medical Devices and IVDs** Speakers: • **Adrien Inoubli**, Regional Adviser, Medical Products Regulation, WHO South-East Asia Regional Office • **Tanuj Shukla**, Affiliate Liaison (Asia Pacific), Post Market Quality, on behalf of **Tammy Steuerwald,** Global Head of Regulatory Policy, Foundational Principles & Supranational Organizations, Roche Diagnostics ***25 mins presentation each / 10 mins Q&A*** Scope: • WHO - Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics • ISO 20416:2020 - Post-Market Surveillance for Medical Device
1045-1100	Closing Remarks by **Prof. Laksono Trilaksono**, Advisor to Indonesia's Health Minister
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