**COVID-19 Medical Device Regulatory Convergence Project (Indonesia)**

***Webinar on Good Regulatory Practices and Medical Device Regulation***

Good regulatory practices (GRPs) include formalized, mandatory principles and practices by which regulatory authorities develop technical regulations for all regulated sectors, aligned with international standards. They are, in essence, a quality control mechanism that provide a benchmark for developing and implementing highest quality, cost-effective and efficient regulatory oversight. Unsurprisingly, the medical device sector is one of the most regulated sectors globally, given the **diverse range of products**; **challenges in accurately determining safety, efficacy, and quality**; **complexities in production, distribution, and surveillance**; and **impact on health of citizens**. It is therefore critical that government agencies and authorities responsible for the oversight of the medical device industry adhere to GRPs that are grounded on sound legal frameworks and international norms and standards.

This two-part webinar, held in partnership with the **Ministry of Health, Indonesia,** and **Gadjah Mada University**, will focus on the World Trade Organization’s (WTO) Technical Barriers to Trade (TBT) agreement and legal obligations as it relates to GRPs and Indonesia’s national commitments, global frameworks for medical device regulations, and best practices on management of safety and efficacy of medical devices.

The webinar is part of the ***COVID-19 Medical Device Regulatory Convergence Project (MDRC)***, a U.S. government-funded public-private partnership, between the **U.S. Agency for International Development (USAID)** and the **American National Standards Institute (ANSI),** in collaboration with **the Advanced Medical Technology Association (AdvaMed)**. **The MDRC’s mission is** to advance regulatory convergence with key global partners, in partnership with standards developing organizations, as well as national and regional health and regulatory authorities.

**Agenda**

**Webinar 1:** **Global Trends in Good Regulatory Practice**

**Wednesday, 15 June 2022 – 0900 to 1100 Indonesia time (GMT +7)**

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| **Time (Indonesia)** | **Session** |
| 0900 - 0910 | **Opening Remarks by Dr. Lucia Rizka Andalusia,** Director General of Pharmaceutical Services & Medical Devices, Ministry of Health, Indonesia **Introduction by Prof. Laksono Trisnantoro**,Special Advisor to Indonesia’s Minister of Health for Resilience of Pharmaceutical and Medical Device Industries |
| 0910-0915 | **Introductory Remarks by Steven Bipes**, Vice President AdvaMed and MDRC Project Lead, on the MDRC, and the utility of international standards / guidance in the medical device sector, including its immediate benefits in the midst of COVID-19, and to building long-term resilience in the national health systems for future pandemics and health crises. |
| 0915 - 1005 | **Panel: Overview of Good Regulatory Practices and Standards**This panel will discuss broad elements of the WTO TBT agreement and legal obligations as it relates to GRPs. It will examine Indonesia’s commitments to the WTO TBT, and the adoption and implementation of GRPs at the national level, including by the health regulators, and the role of the National Standardization Agency (BSN) on GRP Implementation, standardization, conformity assessment, and accreditation, and membership at international standards developing organizations (SDOs), as well as conformance to quality and standards for medical-device sector.Moderator: **Mugant Mehanathan**, MDRC Lead, Southeast Asia, Crowell & Moring InternationalSpeakers* **Renata Amaral**, GRP Lead, MDRC
* **Konny Sagala**, Director of System for Standards and Conformity Assessment Implementation, BSN Indonesia

**Q&A (15 mins)** |
| 1005 - 1055 | **Panel: Global Frameworks for Regulation of Medical Devices**This panel will consider the international frameworks and fora 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 (AMDD). Local experts will also discuss the extent to which Indonesia’s medical device regulations are aligned with international guidance. Moderator: **Jesús Rueda Rodríguez**, Director General Strategies, Special Projects and International Affairs, MedTech EuropeSpeakers* **Agnes Sitta Kijo**, Technical Officer, World Health Organization
* **Wong Woei Jiuang**, Assistant Group Director, Medical Devices Cluster, Health Products Regulation Group, Health Sciences Authority, Singapore
* **Lupi Trilaksono**, Head of Working Group, Directorate of Pharmaceuticals and Medical Devices Resiliency, Ministry of Health, Indonesia

**Q&A (15 mins)** |
| 1055 – 1100 | **Closing Remarks by** **Mugant Mehanathan**, MDRC Lead, Southeast Asia, Crowell & Moring International |