**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 2:** **Good Regulatory Practices in Indonesia and Stakeholder Perspectives**

**Wednesday, 22 June 2022 – 0900 to 1130 Indonesia time (GMT +7)**

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| 0900 - 0905 | **Introduction by Prof. Laksono Trisnantoro**,Special Advisor to Indonesia’s Minister of Health for Resilience of Pharmaceutical and Medical Device Industries |
| 0905 - 0910 | **Mugant Mehanathan**, MDRC Lead, Southeast Asia, Crowell & Moring International will provide a recap of Webinar 1, and outline the objectives of the current Webinar. |
| 0910 - 1000 | **Panel: Convergence in Medical Device Quality Management System: National Regulatory Authority and Industry Perspectives**The panel will provide an opportunity for sharing of best practices on management of safety and efficacy of medical devices through discussion of topics such as Good Manufacturing Practices, and the most common means for quality control - the Medical Device Single Audit Program (MDSAP) and ISO 13485 on quality management requirements for medical devices. Industry representatives will also share their observations about current processes and standards for medical device management in Indonesia. Moderator: **Sandra Ligia González**, Medical Device Sector Lead, MDRCSpeakers:* **Frédéric Hamelin,** Manager, Quality Systems Section, Medical Devices Directorate, Health Canada
* **Fikriansyah bin Irman**, Health System and Strategy Officer, Ministry of Health, Indonesia
* **Randy Teguh**, Secretary General, GAKESLAB

**Q&A (15 mins)*** **Melissa Torres**, Associate Director for International Affairs, Office of the Center Director, Center for Devices and Radiological Health, US Food and Drug Administration *[Video Recording will be made available along the rest of the materials of the webinar]*
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| 1000 – 1125 | **Panel: Post-Market Surveillance in Indonesia**This panel will discuss current post-market surveillance requirements in Indonesia, including manufacturers’ responsibility and collaboration between regulators and industry in meeting medical device safety and standards. The panel will reference IMDRF requirements for post-market surveillance and WHO guidance on post-market surveillance and market surveillance of medical devices, including in vitro diagnostics.Moderator: **IGM Wirabrata, Apt.**, Head of Center for Health Security System Policy and Health Resources, Health Development Policy Agency, Ministry of Health, IndonesiaSpeakers:* **Mark Swanson, ISO/TR 20416:2020** Medical devices — Post-market surveillance for manufacturers
* **Anita Sands**, Technical Officer, Incidents and Substandard / Falsified Medical Products Team, World Health Organization
* **Heru Sunaryo**, Head of Medical Devices Product Supervision, Ministry of Health, Indonesia
* **Erwin Hermanto**, Vice Chairman, ASPAKI

**Q&A (15 mins)** |
| 1125 - 1130 | **Closing Remarks by** **Mugant Mehanathan**, MDRC Lead, Southeast Asia, Crowell & Moring International |