IMDRF International Medical Device Regulators Forum

IMDRF Training:

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47)

Webinar – Wednesday, September 11, 2024

8:00 AM – 12:00 PM ET

Opening Remarks	
Title	**Welcome**
Speakers	Melissa Torres (U.S. FDA)
Time	5 minutes (8-8:05 AM)
Contents	*Welcome and overview of agenda, highlighting importance of engagement and background regarding selection of training format and topic*
Session 1: Introduction to the Essential Principles	
Title	**Scene Setting, Scope of, Rationale for, and Orientation to IMDRF/GRRP WG/N47**
Speaker	Ken Cavanaugh (U.S. FDA) and Industry Representative: Tammy Steuerwald – Roche Diagnostics
Time	30 minutes (8:05-8:35 AM)
Contents	*Role and importance of EPs from an industry and regulator perspective (e.g., consistency, clarity, demonstrate safety and performance* *Scope of the N47, including rationale for initiation of this specific work item. Foreshadow conformity assessment for discussion later and underscore importance of how all regulatory requirements work together to ensure safe, effective, high quality medical products (e.g., need adverse event reporting and post-market surveillance to identify issues after marketing authorization; all ties back to QMS); Note roles of different stakeholders in supporting EP implementation throughout device lifecycle.* *Provide overview of contents and walk through General Essential Principles (IMDRF/GRRP WG/N47 Section 4.0)* Source: IMDRF/GRRP WG/N47: Introduction, 1.0 Scope
Title	**Good Regulatory Practices**
Speaker	Kristan Callahan (U.S. FDA)
Time	30 minutes (8:35-9:05 AM)
Contents	
Session 2: Essential Principles	
Title	**Part 1: Essential Principles Applicable to all Medical Devices and IVD Medical Devices**
Speaker	Augusto Geyer (ANVISA)
Time	45 minutes (9:05-9:50 AM)
Contents	*Walk through language, providing applicable standards and examples* - *General* - *Clinical Evaluation* - *Chemical, Physical, and Biological Properties* - *Sterilization and Microbial Contamination* - *Considerations of Environment and Conditions of Use* - *Protection against Electrical, Mechanical, and Thermal Risks*

	- *Active Medical Devices and IVD Medical Devices and Medical Devices connected to them* - *Medical Devices and IVD Medical Devices that Incorporate Software or are Software as a Medical Device* - *Medical Devices and IVD Medical Devices with a Diagnostic or Measuring Function* - *Labelling* - *Protection against Radiation* - *Protection against the Risks posed by Medical Devices intended by the Manufacturer for use by Lay Users* - *Medical Devices and IVD Medical Devices Incorporating Materials of Biological Origin* Source*:* IMDRF/GRRP WG/N47 Section 5.0
Break 15 minutes (9:50-10:05 AM)	
Title	**Essential Principles Applicable to Medical Devices other than IVD Medical Devices**
Speaker	Augusto Geyer (ANVISA)
Time	15 minutes (10:05-10:20 AM)
Contents	- *Chemical, Physical, and Biological Properties* - *Protection against Radiation* - *Particular Requirements for Implantable Medical Devices* - *Protection against the Risks Posed to the Patient or User by Medical Devices* - *Supplying Energy or Substances* - *Medical Devices Incorporating a Substance Considered to be a Medicinal Product/Drug* Source*:* IMDRF/GRRP WG/N47 Section 6.0
Title	**Essential Principles Applicable to IVD Medical Devices**
Speaker	Augusto Geyer (ANVISA)
Time	15 minutes (10:20-10:35 AM)
Contents	- *Chemical, Physical, and Biological Properties* - *Performance Characteristics* Source*:* IMDRF/GRRP WG/N47 Section 7.0
Session 3: The Role of Conformity Assessment	
Title	**Overview of Conformity Assessment for Medical Devices and IVDs**
Speaker	Dr. Christopher Lam (HSA)
Time	15 minutes (10:35 AM-10:50 AM)
Contents	*Walk through GHTF/SG1/N78 and GHTF N046:2008, noting the different elements of conformity assessment and how each is used for EPs*
Title	**Utilization of Conformity Assessment by Regulatory Authorities**
Speaker	Dr. Christopher Lam (HSA)
Time	30 minutes (10:50 AM-11:20 AM)
Contents	*RAs must define how manufacturers use conformity assessment (CA) to demonstrate that compliance with requirements is fulfilled. International standards, CA and regulatory reliance are key tools toward global medical device convergence.*

	Discuss benefits and risks, which may be different for different device types, different device users, etc. RAs should also consider resources required for different types of CA and whether reliance may address needs. *RAs are generally given a high-level statute and tasked with developing more detailed regulations and then guidance documents with more descriptive recommendations on how a manufacturer may demonstrate conformance to the regulation.* *Provide examples of how CA implemented in different 2-3 jurisdictions.*
Closing	
Title	**Summary and Workshop Q&A**
Speaker	All presenters
Time	30 minutes (11:20-11:50 AM)
Contents	*Speakers review topics covered throughout the training and key themes, underscoring (again) the importance of EPs for all stakeholders*
Title	**Thank you!**
Speaker	
Time	10 minutes (11:50 AM-12:00 PM)
Contents	*Speakers adjourn the meeting, thanking the audience for their time and attention, identify any homework prior to the in-person session; (Point audience to feedback/survey on their experience?)*
Close	