



IMDRF Training:

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

19 September 2024

In Person 12:30-4:30 PM PT (Seattle)

Opening Remarks

Title	Welcome
Speakers	Scott Colburn (U.S. FDA)
Time	5 minutes (12:30-12:35 PM)
Contents	<i>Welcome and overview of agenda, highlighting importance of engagement and background regarding selection of training format and topic</i>
Title	Recap of Webinar
Speakers	Ken Cavanaugh (U.S. FDA)
Time	15 minutes (12:35-12:50 PM)
Contents	<i>Brief overview of lessons learned during the webinar; scene setting for the upcoming presentations and activities</i>

Session 1: Introduction to the Essential Principles

Title	Role of Standards and Relation to Essential Principles
Speaker	Scott Colburn (U.S. FDA) and Industry Representative: Jeffrey Eggleston - Medtronic
Time	80 minutes (12:50-2:10 PM)
Contents	<i>Reference to other IMDRF and GHTF documents of importance to N47 Discussion of importance of standards as means to demonstrating Essential Principles and how, in general, IMDRF engages with standards development organizations. Emphasize need for regulator involvement in standards development process and need for internationally harmonized standards contents. List some standards as examples, noting that additional examples will be provided throughout the training.</i> <u>Source:</u> IMDRF/GRRP WG/N47: 2.0 References and IMDRF standards documents

Q&A 15 minutes (2:10-2:25 PM)

Break 20 minutes (2:25-2:45 PM)

Title	Group Activity- Device Examples
Speaker	All Presenters
Time	60 minutes (5 minutes set up, 20 minutes in group, 30 minutes group recap, 5 minutes wrap up) (2:40-3:40 PM)
Contents	<i>Divide into five groups to discuss what EPs apply to five different types of device; groups then share experience trying to apply EP and storytelling to the larger group</i>

Session 3 Q&A 15 min (3:45-4:00 PM)

Closing

Title	Summary and Workshop Q&A
Speaker	Scott Colburn (U.S. FDA) and Industry Representative: Fatemeh Razjouyan - Medtronic

Time	25 minutes (4:00-4:25 PM)
Contents	<i>Speakers review topics covered throughout the training and key themes, underscoring (again) the importance of EPs for all stakeholders</i> <i>Attendees are invited to ask questions related to any topics discussed throughout the workshop and how everything ties together</i>
Title	Thank you!
Speaker	TBD
Time	5 minutes (4:25-4:30 PM)
Contents	<i>Speakers adjourn the meeting, thanking the audience for their time and attention; (Point audience to feedback/survey on their experience?)</i>

Close