Webinar on Conformity Assessment for Medical Devices
SaMD

Date: 29 August 2022
Time: 9:00 – 6:00 CT (10:00-7:00 EDT)
Hybrid event – Zoom + in person

Objectives. Provide an overview and practical implementation of IMDRF's principles of conformity assessment for medical devices as well as a case study for software as a medical device.

TIME	AGENDA
9:00 – 9:05	**Opening: Housekeeping Message** Sandra Ligia González, Technical Secretariat, IACRC
9:05 – 9:10	**Welcome Message** Vesa Vuniqi, International Relations Specialist, FDA Latin America Office
CONFORMITY ASSESSMENT FOR MEDICAL DEVICES OVERVIEW AND PRACTICAL IMPLEMENTATION ROUNDTABLE	
9:10 – 10:35	**Conformity Assessment for Medical Devices** **Moderator:** Sandra Ligia González, IACRC **Principles of Conformity Assessment for Medical Devices (GHTF/SG1/N78:2012)** - **Erin Cutts, US FDA (10 min)** **Practical Implementation of Conformity Assessment of Medical Devices - Panel** - **Erin Cutts, US FDA (30 min)** - **Francisco Iran Cartaxo, ANVISA (30 min)** Q&A - 15min
10:35-10:50	**BREAK**
10:50-12:05	**Practical Implementation of Conformity Assessment of Medical Devices – Panel (*continued)*** **Moderator:** Patricia Pineda, USFDA - **Mukoil Romanos, INVIMA (20 min)** - **Atilio Méndez, ANMAT (20 min)** - **Brenda Guadalupe Olvera, COFEPRIS (20 min)** Q&A – 15 min

12:05-12:50	**Approach to Conformity Assessment for Medical Devices – The Industry Perspective** **Moderator:** Sandra Ligia González, IACRC - **Fatemeh Razjouyan**, Director of Regulatory Policy, International and Harmonization | Global Regulatory Policy, Medtronic (15 min) - **Duglas Rodríguez-Calderón**, Head of LATAM Regulatory Policy, Global Regulatory Policy & Intelligence, Roche Diagnostics (15 min) Q&A - 15min
12:50-2:00	**LUNCH BREAK**
CONFORMITY ASSESSMENT FOR MEDICAL DEVICES CASE STUDY	
2:00-3:05	**Moderator:** Patricia Pineda, USFDA **Software as a Medical Device (SaMD) Key Definitions (IMDRF/SaMD WG/N12)** - **Cathy Bar, FDA (15 min)** **Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations** (IMDRF/SaMD WG/N12) - **Brendan O'Leary, FDA (15 min)** **Software as a Medical Device (SaMD): Application of Quality Management System (IMDRF/SaMD WG/N23)** - **Francisco Iran Cartaxo, ANVISA (15 min)** Q&A – 20 min
3:05-4:25	**Moderator:** Sandra Ligia González, IACRC **Practical Implementation of Conformity Assessment for SaMD** - **MiRa Jacobs, US FDA (30 min)** - **Francisco Iran Cartaxo, ANVISA (30 min)** Q&A – 20 min

4:25-4:40	**BREAK**
4:40-5:20	**Approach to Conformity Assessment for SaMD – The Industry Perspective** **Moderator:** Patricia Pineda, USFDA - **Diane Johnson**, Sr. Director North American Policy, Global Digital Health Policy Lead, Johnson & Johnson MedTech (15min) - **Duglas Rodríguez-Calderón**, Head of LATAM Regulatory Policy, Global Regulatory Policy & Intelligence, Roche Diagnostics (15 min) Q&A – 10 min
5:20 – 5:30	**Closing Remarks** FDA/IACRC