Inter-American Coalition for Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF POLICY, LEGISLATION, AND INTERNATIONAL AFFAIRS
OFFICE OF GLOBAL POLICY AND STRATEGY

# Medical Devices Webinar Series
# Part I
# ISO 13485 and MDSAP Audit Model

**Date: 02 June 21**
**Time: 9:00 – 12:00 CT**
**Platform: Zoom**

**Objective:** Explain how medical devices inspections are conducted using the MDSAP model based on the ISO 13485, and how agencies may align to ISO 13485

| TIME | AGENDA – Part I |
|---|---|
| **9:00 – 9:05** | **Medical Devices Webinar Series Opening: Housekeeping message**<br>Sandra Ligia González, Technical Secretariat, IACRC |
| **9:05 – 9:10** | **Welcome Message**<br>*Melissa Torres*, **USFDA** |
| **9:10 – 11:55** | **Part I**<br>**Moderator:** *Vesa Vuniqi*, **USFDA**<br><br>**MDSAP audit model**<br>*Kimberly Lewandowski-Walker,* **USFDA** (60 min.)<br><br>**Auditing Organization Assessment Program**<br>*Marc- Henri Winters,* **USFDA** (30min.)<br><br>**Good Manufacturing Practices in Brazil: Resolution RDC 16/2013, similarities and differences compared to ISO 13485:2016**<br>*Thibério Mundim Ferreira Pires*, **ANVISA** (30 min.)<br><br>**USFDA's Transition from CFR820 to ISO 13485**<br>*Melissa Torres*, US**FDA** (15 min.)<br><br>Questions (30 min) |
| **11:55 – 12:00** | **Closing Remarks**<br>*Katherine Serrano*, **USFDA** / Sandra Ligia González - IACRC |