Medical Devices Webinar Series - Session II
Utilization of Voluntary Consensus Standards and Conformity Assessment
Overview and Perspectives of WHO/PAHO, WTO and Standard Development Organizations

Date: 3 March 2022
Time: 10am-13:00pm ET

Objective: Provide the perspectives of PAHO/WHO, WTO and Standards Developing Organization (SDOs) on how international voluntary consensus standards for medical technologies are developed, maintained, and used by regulators and industry to operationalize regulatory reliance, regulatory convergence and to facilitate the manufacturing and approval of quality, safe, secure, interoperable, effective, and accessible medical devices for health systems and patients in the Americas.

TIME	AGENDA
10:00 – 10:05 (5 min)	**Medical Devices Webinar Series Opening: Housekeeping message** Sandra Ligia González, Executive Secretary – Inter-American Coalition for Regulatory Convergence – Medical Technology Sector (**IACRC**)
10:05 – 10:10 (5 min)	**Welcome Message** **Melissa Torres, Associate Director for International Affairs USFDA**
10:10 – 11:10 (60 min)	**Overview of International Reference Documents on National Regulatory Authority (NRA) Use of International Standards for Medical Technologies as Key Operationalization of Regulatory Reliance, Regulatory Convergence and Legal Compliance** **Moderator:** Vesa Vuniqi**, FDA** • **Health References for Medical Device NRAs:** Alexandre Lemgruber, Regional Advisor Health Technologies, **Pan American Health Organization (PAHO) / World Health Organization (WHO) Regional Office of the Americas** – (15 minutes) ○ WHO Global Model Regulatory Framework ○ WHO Good Regulatory Practices ○ WHO Good Reliance Practices • **Legal Obligations applicable to medical device NRAs:** Devin McDaniels, **WTO** and Renata Amaral, **IACRC** Technical Secretariat – GRP & Trade Lead (15 minutes) ○ **Technical Barriers to Trade (TBT): Trade agreements (WTO, regional, bilateral)** ○ **Good Regulatory Practices (GRP): Trade agreements and obligations (OECD, regional, bilateral)** • **International Standards - Development, Adoption and Use by Stakeholders including Regulatory Authorities:** Kory Eguino, **COPANT** (15 minutes) **Question and Answer Session** (15 min)

TIME	AGENDA
11:10 – 12:55 (105 min)	**Panel discussion: Overview of MedTech SDO Work:** • **In their roles as Secretariats of ISO and/or IEC Technical Committees** • **On their specific scopes of work** **Moderator** – Steven Bipes, **AdvaMed** • **ISO – Overview of all committees -** Steven Bipes (10 min) o Peter Linders, Chair **TC210 (Philips)** (10 min) o Verónica Viscovich, TC 210 Liaison, (**IRAM)** (10 min) • **IEC/TC 62 –** Brodie Pedersen (10 min) • **IMDRF and standards –** Kenneth Cavanaugh, USFDA (15 min) • **AAMI** – Hae Choe (10 min) • **CLSI & ISO TC212** – Patrick McGinn (10 min) • **MITA** – Carolyn Hull (10 min) • **ASTM International** – Craig Updyke (10 min) **Question and Answer Session** (10 min)
12:55– 13:00 (5 min)	**Closing Remarks** **PAHO,** Alexandre Lemgruber / **IACRC**, Sandra Ligia González