



Medical Devices Webinar Series - Session IV
Utilization of Voluntary Consensus Standards and Conformity Assessment
Overview and Perspectives of National Regulatory Authorities, Conformity Assessment Sector and Industry for
Medical Technologies

Date: 17 March 2022

Time: 11:00am-14:10pm ET

Objective: Provide the perspectives of government authorities, industry and the conformity assessment sector and industry on how conformity assessment is a global tool used by regulators and industry to demonstrate compliance with requirements – facilitating the manufacture and approval of quality, safe, secure, interoperable, effective and accessible medical devices for health systems and patients in the Americas.

TIME	AGENDA
11:00 – 11:05 (5 min)	Medical Devices Webinar Series Opening: Housekeeping message Sandra Ligia González, Executive Secretary – Inter-American Coalition for Regulatory Convergence – Medical Technology Sector (IACRC)
11:05 – 11:10 (5 min)	Welcome Message USFDA – Vesa Vuniqui, Latin America Office
11:10 – 12:30 (80 min)	Conformity Assessment as Essential Resource for Medical Device Regulatory Authorities, Industry and Regulatory Convergence Moderator: Steven Bipes - AdvaMed (5 minutes) Overview of Conformity Assessment and Government utilization of CA: Gordon Gillerman, Director, Standards Coordination Office, U.S. National Institute of Standards and Technology (NIST) (15 minutes) MedTech Industry Experience with CA: Elisabeth George, Head of Global Regulations and Standards, Philips (15 min) Conformity Assessment Sector Perspective: Martin Michelot, TIC Council (15 min) IECEE CB Scheme: Steven Margis, IECEE Chair & Director Conformity Assessment – UL (15 minutes) Question and Answer Session (15 min)
12:30-12:35 (5 min)	Break



TIME	AGENDA
<p>12:35 – 14:00 (85 min)</p>	<p>Panel discussion: Utilization of International Standards and Conformity Assessment by Medical Device National Regulatory Authorities</p> <p>Moderator: Stacey Sullivan, USFDA (5 min)</p> <p>Colombia</p> <ul style="list-style-type: none"> • Ministry of Health, Soleiny Marín Cortés (15 minutes) • INVIMA – Eleonora Celis Cañas (15 min) <p>Mexico</p> <ul style="list-style-type: none"> • COFEPRIS – Llaneth Bolaños Valerio (15 min) • FEUM – Rafael Hernández (15 min) <p>Question and Answer Session (20 min)</p>
<p>14:00 – 14:10 (10 min)</p>	<p>Closing Remarks</p> <p>USAID, Daniel Vázquez / IACRC, Sandra Ligia González</p>