COALICIÓN INTERAMERICANA PARA LA CONVERGENCIA REGULATORIA
SECTOR DE TECNOLOGÍA MÉDICA

COALIZÃO INTERAMERICANA PARA CONVERGÊNCIA REGULATÓRIA
SETOR DE TECNOLOGIA MÉDICA

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Inter-American Coalition for Regulatory Convergence,
Medical Technology Sector
External Stakeholder Session

Date: **14 March 2024**
Time: **7:30 – 17:15 ET**
Platform: Hybrid (In-person & Zoom) Please click here to register to attend either virtually or in person.
Venue: **AdvaMed, 1301 Pennsylvania Ave NW, Suite 400, Washington, DC 20004**

Time	Topic
7:30-8:00	**AdvaMed-Sponsored Breakfast**
8:00 - 8:10	**Housekeeping Message and Welcome Remarks** Sandra Ligia González, IACRC
8:10 – 9:00	**The Role of Manufacturers in Ensuring Quality, Safety & Performance** (40 min) - **Regulatory Authority Views ○ Scott Colburn, Director - Division of All Hazards Response, Science and Strategic Partnerships (DARSS), Center for Devices and Radiological Health (CDRH), Office of Strategic Partnership and Technology Innovation (OST), FDA ○ Thiago Cunha, Coordinator, Coordination of Unique Audit for Health Products, ANVISA** - **Manufacturer's Views ○ Fatemeh Razjouyan, Medtronic ○ Tammy Steuerwald, Roche Diagnostics** **Q&A 10 min**
9:00 – 9:45	**Medical Device International Standardization – Initiatives to increase use of international standards for medical devices and engagement in Standards Development Organizations for medtech across the Americas.** (45 min) **Steven Bipes – AdvaMed** **Terry Woods - USFDA: CDRH/OST/DARSS – Acting Director, Standards and Conformity Assessment Program (SCAP)** **Q&A 15 min**

9:45 – 10:15	**Coffee Break**

10:15 – 11:30	**Key initiatives** **Moderator: Steven Bipes** - **Americas Business Dialogue (ABD) / Inter-American Development Bank (IDB)** ○ **Pablo Steneri, ABD Secretariat – IDB** - **GMTA / GDA / DITTA** ○ **Steven Bipes, AdvaMed** - **Americas RISE for Health** ○ **Patty Wu & Olivia Burzynska Hernández** **Q&A 15 min**
11:30 – 12:25	**Trade & Commerce – GRP & TBT as vehicles to facilitate medical devices and IVD trade and supply chain** (55 min) **Moderator: Steven Bipes, AdvaMed** **Christine Gomes & Beatrice Neal de Souza, US Department of Commerce – ITA – WestHem (20 min)** **Jonathan Goldberg - US Department of Commerce – ITA – Health Industries (20 min)** **Q&A 15 min**
12:25 – 12:45	**Dirección Nacional de Medicamentos, El Salvador** (20 min) **Moderator: Sandra Ligia González, IACRC** **Karina Flores - DNM** **Mario Vega - DNM**
12:45 – 14:00	**Luncheon with FDA Latam Office. How can we further collaborate to advance regulatory reliance and regulatory convergence?** **Vesa Vuniqi, FDA Latam Office** **Ana Patricia Pineda, FDA Latam Office**

14:00 – 14:30	**MDR / IVDR Implementation – Current situation and challenges ahead** **Diana Kanecka & Jesús Rueda – MedTech Europe** **Q&A 10 min**
14:30 – 15:00	**GMDN Overview** **Deniz Bruce, CEO GMDN Agency, TBC** **Q&A 10 min**
15:00 – 15:05	**Closing remarks for the External Stakeholders Session Sandra Ligia González**