Advanced Training for Medical Device Regulators Around Critical and Emerging Technologies 2026
(ATCET-2026)

Mexico City, Mexico
15–19 June 2026

Location: Frida Kahlo Auditorium, Marriott Reforma Hotel, Paseo de la Reforma 276, Col. Juárez, Cuauhtémoc, 06600 Ciudad de México.
Languages: Simultaneous interpretation (English - Spanish) available via Zoom.

AGENDA

Monday, June 15, 2026 – Day 1

8:00 – 9:00	**Registration**
9:00 – 9:05	**Welcome Remarks** • Sandra Ligia González, ATCET-2026 Project Director, Inter-American Coalition for Regulatory Convergence – Medical Technology Sector (IACRC) Executive Secretary
9:05 – 9:30	**Opening Remarks** • Rosa Aurora Azamar Arizmendi, General Coordinator of the Federal Sanitary System, COFEPRIS • Jorge Iliou Silvero, National Director, Paraguayan National Health Surveillance Directorate (DINAVISA) (Virtual) • Michelle Rodriguez, Director U.S. Food and Drug Administration (USFDA) LATAM Office (Virtual) • João Carapeto, President, Mexican Association of the Innovative Medical Device Industry (AMID)
9:30 – 9:45	**ATCET-2026 Project and Goals for the Week** • Sandra Ligia González, ATCET-2026 Project Director
9:45 – 10:30	**Panel**. **Regulators' Vision for the Future of Medical Device Oversight** Moderator: Sandra Ligia González, ATCET-2026 Project Director • Alison Iglesias, Director. Directorate of Registration of Medical and Dental Devices, DINAVISA • Kenneth J. Cavanaugh Jr., Associate Director for International Policy and Strategy, U.S. Food and Drug Administration (USFDA) (Virtual) Q&A 10 min
10:30 – 11:00	**Coffee Break**
11:00 – 11:30	**WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. How is it relevant to the rapidly evolving medical device technologies?**

	• Tammy Steuerwald, Head of Regulatory Policy for Foundational Principles and Supranational Organizations, Roche Diagnostics, IMDRF Industry Group, AdvaMed Q&A 5 min
11:30 – 12:00	**Implementation of a Quality Management System for the regulatory processes of a National Regulatory Authority. Challenges & Benefits** • Nancy C. Braier, Deputy Office Director, CDRH Office of the Center Director & Associate Center Director for Quality Management and Organizational Excellence Program, USFDA/CDRH (Virtual) Q&A 5 min
12:00 – 13:30	**Lunch Break**
13:30 – 14:30	**Panel**. **Medical Device Regulatory Framework in Mexico. What to expect from the latest regulation updates?** Moderator: Juan Antonio Dorantes, Dorantes Advisors • Rafael Hernández, Deputy Director of Pharmacopeia Development and Scientific Coordination, Pharmacopoeia of the United Mexican States (FEUM) • Ana Riquelme, Executive Director, AMID Q&A 20 min
14:30 – 15:15	**DINAVISA Regulatory Framework Overview** Moderator: Roberta Mele Mazza, Roche Diagnostics, IACRC EC, AdvaMed • Alison Iglesias, Director. Directorate of Registration of Medical and Dental Devices, DINAVISA • Carmen Portillo, Director. Directorate of Registration of *In Vitro* Diagnostic Products, DINAVISA Q&A 5 min
15:15 – 15:45	**Coffee Break**
15:45 – 16:15	**Regulatory Convergence. Does a risk-based approach in developing regulations have a role?** • Diane Wurzburger, VP Regulatory, Quality and Global Policy, GE Healthcare, IMDRF Industry Group, AdvaMed Q&A 5 min
16:15 – 16:50	**Impact of variation in risk classification criteria on the implementation of Reliance.** • Fatemeh Razjouyan, Senior Director, Regulatory Policy, International, and Harmonization, Medtronic, IMDRF Industry Group, AdvaMed Q&A 5 min
16:50 – 17:00	**Adjourn**

Tuesday, June 16, 2026 – Day 2

8:30 – 9:00	**Registration**
9:00 – 10:30	**Panel. Good Reliance Practices at work** Moderator: Diane Wurzburger, VP Regulatory, Quality and Global Policy, GE Healthcare, IMDRF Industry Group **High level principles, IMDRF Playbook and TGA Experience** • Tracey Duffy, First Assistant Secretary, Medical Devices and Product Quality Division, Australian Therapeutic Goods Administration (TGA) (Virtual) **Implementation of Reliance. A success story for Singapore Health Sciences Authority (HSA)** • Wong Woei Jiuang, Assistant Group Director of the Medical Devices Cluster, Health Science Authority Singapore (HSA) (Virtual) **Reliance Implementation Map** • Tammy Steuerwald, Head of Regulatory Policy for Foundational Principles and Supranational Organizations, Roche Diagnostics, IMDRF Industry Group, AdvaMed **Dialogue: Lessons learned, the good and the bad** Q&A 10 min
10:30 – 11:00	**Coffee Break**
11:00– 12:30	**A Reliance Journey by COFEPRIS** Moderator: Ana Riquelme, Executive Director, AMID **Reliance Journey by COFEPRIS** • Edgardo Arenas, Liaison of International Affairs, COFEPRIS **Impact of the Equivalence Agreements with USFDA, HC and PMD on access to medical devices.** • Adriana Flores Zambrano, Head Regulatory Affairs Committee, AMID **Dialogue: Leveraging lessons learned for the future** Q&A 10 min
12:30 – 14:00	**Lunch Break**
14:00– 15:30	**A Reliance Journey by COFEPRIS** • Moderator: Ana Riquelme, Executive Director, AMID **Industry experiences to date – Case Studies Part I** Nallely Contreras, Werfen, Deputy Head Regulatory Affairs Committee, AMID
15:30 – 16:00	**Coffee Break**
16:00 – 16:30	**Industry experiences to date – Case Studies Part II** Moderator: Ana Riquelme, Executive Director, AMID • Mónica García Rincón, Becton Dickinson, Deputy Head Regulatory Affairs Committee, AMID • Sandra Ligia González, Executive Secretary, IACRC

	Dialogue: Opportunities to foster utilization and benefits Q&A 10 min
16:30 – 16:50	**Reliance for Software as Medical Device. Challenges and Opportunities** • Renata Brandão, Senior Director Medical Devices Regulatory Affairs, LAD, Vicechair LATAM WG AdvaMed Q&A 5 min
16:50 – 17:00	**Adjourn**

Wednesday, June 17, 2026 – Day 3

8:30 – 9:00	**Registration**
9:00 – 10:15	**DINAVISA. Experiencing Reliance for MDs and IVDs** Moderator: María Fernanda Carvajal, GE Healthcare, IACRC WG Lead • Alison Iglesias, Director. Directorate of Registration of Medical and Dental Devices, DINAVISA • Carmen Portillo, Director. Directorate of Registration of *In Vitro* Diagnostic Products, DINAVISA **Industry experiences to date.** • Roberta Mele Mazza, Technical Director South America Network Argentina, Uruguay, Bolivia & Paraguay, Roche Diagnostics, IACRC EC, AdvaMed **Dialogue: Opportunities to foster utilization and benefits** Q&A 10 m
10:15 – 10:45	**Enabling Reliance Through Data – Hands-on Experience - Part I** **Health Canada Database** • Seema Vyas, Head QA/RA Medtronic, Canada Q&A 5 min
10:45 – 11:15 am	**Coffee Break**
11:15 – 13:00	**Enabling Reliance Through Data – Hands-on Experience - Part II** Moderator: María Fernanda Carvajal, GE Healthcare, IACRC EC, AdvaMed, TBC **FDA Database** • Scott Colburn, BSN, MS, Director, Office of Readiness and Response (ORR), Office of Strategic Partnership and Technology Innovation (OST), USFDA/CDRH Chair, ISO TC210 – Quality Management and corresponding general aspects for products with a health purpose including medical devices (Virtual) **ANVISA Database** • Leticia Fonseca, Deputy Executive Secretary & Diagnostics Lead, IACRC Q&A 5 min.
13:00 – 14:15	**Lunch Break**
14:15 – 15:15	**Enabling Reliance Through Data – Hands-on Experience - Part III** Moderator: Tammy Steuerwald, Roche Diagnostics **Australia: Therapeutic Goods Administration (TGA) Database** • Jane Shum, Acting Director Medical Device Authorization, TGA **Singapore: Health Sciences Authority (HSA) Database** • Wong Woei Jiuang, Assistant Group Director of the Medical Devices Cluster, HSA Q&A 5 min **Dialogue on how to leverage data availability to facilitate operationalizing reliance.** Q&A 5 min

15:15 – 15:45	**Panel: Reliance through medical device lifecycle & Change management.** Moderator: Duglas Rodríguez, Roche Diagnostics, IACRC WG Lead, AdvaMed • Angélica Celaya, Verificadora o Dictaminadora Especializada de la Comisión de Autorización Sanitaria, COFEPRIS • Alison Iglesias, Director. Directorate of Registration of Medical and Dental Devices, DINAVISA Q&A 5 min
15:45 – 16:00	**Coffee Break**
16:00 – 16:55	**Reliance through medical device lifecycle. Post-market surveillance** • Tammy Steuerwald, Head of Regulatory Policy for Foundational Principles and Supranational Organizations, Roche Diagnostics, IMDRF Industry Group, AdvaMed Q&A 10 min
16:55 – 17:00	**Adjourn**
17:00 – 18:30	**Reception**

Thursday, June 18, 2026 – Day 4

8:30 – 9:00	**Registration**
9:00 – 9:05	**Day 4 Opening – Framing of GRP and Standards for Critical and Emerging Technologies** • Nora Moudiyne-Schweninger, Senior Manager, International Development, American National Standards Institute (ANSI)
9:05 – 9:25	**International Obligations and its relationship with Domestic Regulations** • Kristan Callahan, Director, WTO and Multilateral Affairs, Office of the U.S. Trade Representative (USTR) Q&A 5 min
9:25 – 9:40	**Good Regulatory Practices (GRP)** • Kristan Callahan, Director, WTO and Multilateral Affairs, USTR Q&A 5 min
9:40 – 10:00	**Technical Barriers to Trade (TBT) & GRP - Checklist Update Launch** • Marina Carvalho, Trade & GRP Lead, IACRC Q&A 5 min
10:00 – 10:20	**Regulatory Impact Assessment. A practical approach** • Marina Carvalho, Trade & GRP Lead, IACRC Q&A 5 min
10:20 – 10:45	**Coffee Break**
10:45 – 11:15	**Good Regulatory Practices in Mexico. How current frameworks impact medical devices** • Juan Antonio Dorantes, Managing Partner, Dorantes Advisors Q&A 5 min
11:15 - 11:45	**International Standards – What for?** • Scott Colburn, BSN, MS, Director, Office of Readiness and Response (ORR), Office of Strategic Partnership and Technology Innovation (OST), USFDA/CDRH Chair, ISO TC210 – Quality Management and corresponding general aspects for products with a health purpose including medical devices (Virtual) Q&A 5 min
11:45 – 12:30	**Trade and Regulations - Opportunities and Challenges in Mexico for the Medical Technology Sector** Moderator: Sandra Ligia González, ACTEC-2026 Project Director • Javier Dávila, General Director Evaluation and Planning, Ministry of Economy, Mexico Q&A 5 min
12:30 – 13:30	**Lunch Break**
13:30 – 14:30	**International Standards – Role of the Mexican General Directorate of Standards (DGN) and the Paraguayan National Institute of Technology, Standardization and Metrology (INTN) to facilitate access to medical devices**

	Moderator: Juan Antonio Dorantes, Managing Partner, Dorantes Advisors • Luis Iván Hernández, Director Standardization, Mexican Association for Standardization and Certification (ANCE) • Carolina Barrios, National Standards Department, INTN **Dialogue: Recommendations for effective involvement** Q&A 5 min
14:30 – 15:15	**The Role of Voluntary Consensus Standards in Regulatory Frameworks** • Terry O. Woods, PH.D., FASTM, FAIMBE, Director, Division of Standards & Conformity Assessment (DSCA), USFDA/CDRH/OST/ORR Chair, ASTM F04 Medical and Surgical Materials and Devices (Virtual) Q&A 5 min
15:15 – 16:15	**Standards and Conformity Assessment - building regulators' confidence in device safety and performance** • Eric Franca, Director, Conformity Assessment Program (CAP) Assistant Director, Division of Standards and Conformity Assessment (DSCA), USFDA/CDRH/OST/ORR IEC US National Committee Council Member (Virtual) Q&A 10 min
16:15-16:35	**Conformity Assessment Checklist – Compliance with International Obligations** • Marina Carvalho, GRP & Trade Lead, IACRC Q&A 5 min
16:35 – 16:40	**Adjourn**

Friday, June 19, 2026 – Day 5

8:30 – 9:00	**Registration**
9:00 – 9:40	**Trade and Regulations - Opportunities and Challenges in Paraguay for the Medical Technology Sector** • Andrea Fernández, Director of Information and Notification of Ministry of Industry and Commerce (MIC) Paraguay (Virtual) Q&A 5 min
9:40 – 10:00	**Medical Technology Sector Map – Brazil and the Americas** • Marina Carvalho, Trade & GRP Lead, IACRC • Leticia Fonseca, Deputy Executive Secretary, IACRC Q&A 5 min
10:00 - 10:45	**The Role of Manufacturers in Ensuring Quality, Safety & Performance** Moderator: Sandra Ligia González "ACTEC-2026" Project Director • Angélica Celaya, Verificadora o Dictaminadora Especializada de la Comisión de Autorización Sanitaria, COFEPRIS • Melissa Torres, Executive Vice President Technology and Regulatory Affairs, AdvaMed • Fatemeh Razjouyan, Senior Director, Regulatory Policy, International, and Harmonization, Medtronic, IMDRF Industry Group, AdvaMed Q&A 5 min
10:45 – 11:15	**Coffee Break**
11:15 – 12:15	**MDSAP. A success story: Auditing Organizations and Industry Perspective** Moderator: Melissa Torres, Executive Vice President Technology and Regulatory Affairs, AdvaMed • John Castro, Auditor, SGS North America Inc. (Virtual) • Rosa Castañeda, Medtronic, Baja's Medical Device Cluster (Virtual) Q&A 10 min
12:15 – 13:15	**Panel**. **Artificial Intelligence, Machine Learning, Real World Evidence for medical devices: Building an Agile Framework for Quality, Safety and Performance** Moderator: Fatemeh Razjouyan, Senior Director, Regulatory Policy, International, and Harmonization, Medtronic, IMDRF Industry Group, AdvaMed • Melissa Torres, Executive Vice President Technology and Regulatory Affairs, AdvaMed • Diane Wurzburger, VP Regulatory, Quality and Global Policy, GE Healthcare, IMDRF Industry Group Q&A 10 min
13:15 – 13:30	**Closing Remarks** • Nora Moudiyne-Schweninger, Senior Manager, International Development, American National Standards Institute (ANSI) • Sandra Ligia González, ATCET-2026 Project Director