

June 6 & 7: Inter-American Coalitions for Business Ethics and Regulatory Convergence in the Medtech Sector

Participants (In-Person: 55)

C-Suite, Regional Presidents, and ABD Chairs:

1. Nacho Abia, CEO, Olympus Corporation of Americas
2. Christopher White, General Counsel & Chief Policy Officer, AdvaMed
3. Sujata Dayal, Global Chief Compliance Officer, Medline Industries
4. Héctor Orellana Brun, VP North Latin America, Medtronic
5. Ambassador Robert Holleyman President and CEO of Crowell & Moring International
6. Steven Bipes, Vice President-Global Strategy and Analysis, AdvaMed (ABD Transparency & Regulatory WG Co-Chair)
7. Patricia Wu, Vice President & Managing Director, C&M International (ABD Health WG Chair)

Medtech Company Leaders:

1. Duglas Rodríguez Calderón, Head of Latin America Regulatory Policy, Roche Diagnostics
2. Mark Lloyd Davies, Global Head of Strategic Initiatives: Lung Cancer Initiative & International Forums, Johnson & Johnson
3. Luz Sosa, Government Affairs & Policy Senior Manager, Johnson & Johnson Chile S.A.
4. John Baloy, Director Global Strategic Regulatory, Abbott Laboratories
5. Verónica García García, Regulatory Affairs Manager, BBraun
6. Malena Tapia, Doctor, Roche Ecuador

Medtech Industry Associations Leaders:

1. Marisol Sánchez, Executive President, Medical Devices Chamber, ANDI-CDMIS (Colombia)
2. Cristina Murgueito, Executive Director, ASEDIM (Ecuador)
3. Bruno Boldrin Bezerra, Executive Director - ABRAIDI & Chair – ABIIS (Brazil)
4. José Márcio Cerqueira Gomes, Executive Director -ABIIS (Brazil)
5. Carlos Gouvêa, Executive President – CBDL & IES/ABIIS (Brazil) /ALADDIV (LatAm)
6. Ana Laura Riquelme Francistain, Executive Director, AMID (Mexico)
7. Sandro Stapleton, President, CCL-COMSALUD (Peru)
8. Angélica Garuti Marques, RA Manager, ABIMED (Brazil)
9. Khauaja Jorge, Compliance & Legal Manager, ABIMED (Brazil)
10. Amanda Martinez, Technical Affairs Manager, CCL-COMSALUD (Peru)

Regional Government & National Standards Body Leaders:

1. GeanLuca Lorenzon, Secretary for Competition Advocacy and Competitiveness, Secretariat for Competition Advocacy and Competitiveness - SEAE/MOE (Brazil)
2. Marcos Heleno Guerson de Oliveira Junior, President, Brazilian National Institute for Metrology, Standardization and Industrial Quality – INMETRO (Brazil)
3. Diego Eugenio Pizzeta, General Coordinator International Coordination, INMETRO (Brazil)
4. Marcos Aurélio Lima de Oliveira, Coordinator of the National Quality Infrastructure Policy WG, Brazilian National Institute for Metrology, Standardization and Industrial Quality (INMETRO)
5. Daniela Ferreira de Matos, Advisor, Brazilian Foreign Trade Secretariat, Ministry of Economy – (SECEX/MOE)
6. Paula Costim, Ministry of Economy (SECEX/MOE)

7. Lina Valencia, Director of Governance, Human Rights and Peace, Colombia National Planning Department (DNP)
8. Lorena Brito da Justa Croitor, Federal Auditor of Finance and Control, Coordinator of Audit in the Health Area, Brazilian Comptroller General of the Union (CGU)
9. Mónica Vivas, Standardization Director, Colombian Institute of Technical Standards and Certification (ICONTEC)
10. Daniel Trillos, Subdirector de Normalization, Colombian Institute of Technical Standards and Certification (ICONTEC)
11. Jorge Emanuel Reis Cajazeira, Head of International Affairs, Brazilian Association of Technical Standards (ABNT)
12. Karina Ninzoli Luro Nazello, Brazilian Association of Technical Standards (ABNT)
13. Daniela Matos, Advisor, Brazilian Ministry of Economy (SECEX/ME)
14. Raúl Romero Anaya, Mexican General Directorate of Standards (DGN)

U.S. Government Officials:

1. Renee Hancher, GRP Lead, Office of the United States Trade Representative (USTR)
2. Deputy Assistant Administrator Mileydi Guilarte, Bureau for Latin America and the Caribbean, U.S. Agency for International Development (USAID)
3. Ian Saunders, Deputy Assistant Secretary for the Western Hemisphere, U.S. Department of Commerce (DOC/ITA)
4. Lynn Costa, Senior Advisor (Western Hemisphere), U.S. Department of Commerce (DOC/ITA)
5. Jason Rodriguez, U.S. Department of Commerce (DOC/ITA)

MDRC Team:

1. Renata Amaral, Lead, Good Regulatory Practices, Inter American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)
2. Andrew Blasi, Technical Secretary, Inter American Coalition for Business Ethics in the Medical Technology Sector (IACBE)
3. Sandra Ligia González, Executive Secretary, Inter American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)
4. Leticia Fonseca, Executive Secretary, Brazil, Inter American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)
5. Susan Suárez Gutiérrez, MDRC Liaison to the Government of Colombia, Inter American Coalition for Regulatory Convergence in the Medical Technology Sector (MDRC)
6. Jessica Roop, Senior Manager, International Development, American National Standards Institute (ANSI)
7. Christian Roatta, MDRC Project Manager, Consultant, Crowell & Moring International (CMI)
8. Christopher Gundermann, Crowell & Moring International (CMI)
9. Olivia Burzynska-Hernandez, Senior Consultant, Crowell & Moring International (CMI)

Participants (Virtual: 69)

Medtech Industry Leaders:

1. Claudia Brabata, Director, Market Access & Public Affairs Latin America, Medtronic
2. Sergio Pinto, Senior Director of Compliance, Johnson & Johnson/ AdvaMed
3. Laura Sugano, Compliance Counsel and DPO LatAm, Philips Medical Systems

4. Fernando García Castro, Regulatory Affairs Manager, 3M Argentina
5. Zaria Smith, Regulatory Affairs Specialist, Medtronic
6. Greg LeBlanc, Director of Regulatory Affairs, Cook Canada (Cook Medical)
7. Oryana Villarraga, Especialista de Calidad y Asuntos Regulatorios, Productos Roche SA
8. Diana Pinzón, Government and Regulatory Affairs Head, Alcon
9. Daisy Sonderegger, LatAm Legal Affairs Manager, Terumo Blood and Cell Technologies
10. Alicia De Hoyos, Regulatory Affairs Manager, Bioana S.A.P.I de C.V
11. Mariel Alcoba, Head Legal & Compliance, Boston Scientific
12. Patricia Lopes Pessoa Nogueira, RAQA Specialist, Stryker
13. Sandra Moreira Dalberto, Regulatory Affairs Director, Johnson & Johnson
14. Emma González Escandón, Government Affairs and Access, Boston Scientific
15. Daniella Ossada, RA Manager, Siemens Healthineers
16. Gabriel Foresto Carniel, Regulatory Affairs Specialist, GE Healthcare
17. Rodrigo Urra, Compliance Manager, Zimmer Biomet
18. Ericka Guirados, RA Senior Director, Medtronic
19. Elaine Sepulveda, RA/QA Analyst, Varian Medical Systems
20. Pedro Rivera, Smith & Nephew
21. Carr Slayton, Boston Scientific
22. Emmanuel Franco, Medtronic
23. Jaime Torres, Medtronic
24. Liliana Panchón, Regulatory Intelligence Director, Abbott Laboratories
25. Igor Zanetti, Medtronic
26. Anna Karina, Medtronic
27. Christie Márquez, Medtronic
28. Christian Cruz, Johnson & Johnson
29. María Gracia Fuentes, GE Healthcare, Mexico
30. Priscila Freitas, GE Healthcare, Mexico
31. Ellen Cobra, Latin America Regulatory Affairs, W.L Gore
32. Nataly Trejos, Associate Director for Latin America Regulatory Policy, Johnson & Johnson
33. Roxana Gabriela Luna, Medtronic
34. Verónica Escudero Barrientos, Compliance Officer, INTEMED S.A.

Medtech Industry Associations:

1. Ángela Flores, Executive Director, Asociación Nacional de Laboratorios Farmacéuticos - ALAFARPE & CDMMAA (Peru)
2. Arturo Tokumoto, Committees and Events Coordinator, AmCham & CDMMAA (Peru)
3. Victoria Del Castillo, Executive Director, CADIEM (Argentina)
4. Fernando Silveira Filho, Executive President, ABIMED (Brazil)
5. Gabriela Garnham, ADIMECH (Chile)
6. Tamara Olmos, Compliance Manager, Zimmer Bioment Mexico / AMID (Mexico)
7. Sergio Madeira, IES (Brazil)
8. Heitor Lopes, ABRAIDI (Brazil)
9. Davi Uemoto, ABRAIDI (Brazil)
10. Deborah Pinto, ABRAIDI (Brazil)
11. Pat Fogarty, AdvaMed (U.S.)

Regional Government & National Standards Body Leaders:

1. Carolina Palhares, Director of Integrity, Ministry of Health, Brazil
2. Rubisel Velázquez Lugo, General Director of International Trade, Secretariat of Economy of Mexico
3. Aurelio Mejía, Director of Regulation, Ministry of Commerce, Industry and Tourism of Colombia (MinCIT), Colombia
4. Hernán Zúñiga, Coordinator of the Technical Regulations Group and SICAL, Ministry of Commerce, Industry and Tourism (MinCIT), Colombia
5. Ángela Goyeneche, Consultant, Ministry of Commerce, Industry and Tourism (MinCIT), Colombia
6. Ornella Montero, Ministry of Commerce, Industry and Tourism (MinCIT), Colombia
7. César Augusto Montano, Advisor, Colombia National Planning Department (DNP), Colombia
8. Jorge Daniel Alarcón, Director de Dispositivos Médicos, Cámara Nacional de la Industria Farmacéutica
9. Craig Updyke, Director Global Policy, ASTM International
10. Thais Robert Salem, Foreign Trade Analyst, Ministry of Economy, Brazil
11. Josely Chiarella, MSc, CBDL
12. Joseph Tretler Jr., Vice President for International Policy, American National Standards Institute (ANSI)
13. Leslie McDermott, Senior Director - International Development, American National Standards Institute (ANSI)
14. Meredith Shaddix, Program Administrator, International Development, American National Standards Institute (ANSI)
15. Viviana Salgado, Ministry of Economy, Mexico
16. María Teresa De Llano, Ministry of Economy, Mexico

U.S. Government Officials:

1. Mark Abdo, Associate Commissioner for Global Policy, U.S. Food and Drug Administration (FDA)
2. Katherine Serrano, Director of the Latin America Office, U.S. Food and Drug Administration (FDA)
3. Vesa Vuniqi, International Relations Specialist, Latin America Office, U.S. Food and Drug Administration (FDA)
4. Sarah Short, Office of the United States Trade Representative (USTR)
5. Jeff Hamilton, Commercial Officer, U.S. Commercial Service Brazil (DOC/ITA/FCS)
6. Laura Krishnan, International Trade Specialist, Office of Latin America and the Caribbean, International Trade Administration, U.S. Department of Commerce (DOC/ITA)
7. Daniel Vázquez, Sr. Standards Specialist, U.S. Agency for International Development (USAID)

Other:

1. Alexandre Lemgruber, Regional Advisor, Health Technologies, Pan American Health Organization (PAHO)
2. Teresa Furlan, U.S.

June 8: MDRC Workshop on Good Regulatory Practices

Participants (In-person: 26)

Regional Government & National Standards Body Leaders:

1. Jorge Emanuel Reis Cajazeira, Head of International Affairs, Brazilian Association of Technical Standards (ABNT)
2. Karina Ninzoli Luro Nazello, Brazilian Association of Technical Standards (ABNT)
3. Lina Valencia, Director of Governance, Human Rights and Peace, Colombia National Planning Department (DNP)
4. Marcos Aurélio Lima de Oliveira, Coordinator of the National Quality Infrastructure Policy WG, Brazilian National Institute for Metrology, Standardization and Industrial Quality (INMETRO), Brazil
5. Mónica Vivas, Standardization Director, Colombian Institute of Technical Standards and Certification (ICONTEC)
6. Daniel Trillos, Subdirector of Standardization, Colombian Institute of Technical Standards and Certification (ICONTEC)
7. GeanLuca Lorenzon, Secretary for Competition Advocacy and Competitiveness, Secretariat for Competition Advocacy and Competitiveness (SEAE), Brazil
8. Raúl Romero Anaya, Coordinator of Quality Infrastructure, General Directorate of Standards (DGN), Mexico

U.S. Government Officials:

1. Renee Hancher, GRP Lead, Office of the United States Trade Representative (USTR)

Health sector:

1. Duglas Rodríguez Calderón, Head of Latin America Regulatory Policy, Roche Diagnostics
2. Malena Tapia, Doctor, Roche Ecuador
3. John L. Baloy, Director, Strategic Regulatory, Abbott Laboratories
4. Verónica García García, Regulatory Affairs Manager, Bbraun

MedTech Industry Associations:

1. Cristina Murgueito, Executive Director, ASEDIM (Ecuador)
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3. Ana Laura Riquelme Francistain, Executive Director, AMID (Mexico)
4. José Márcio Cerqueira Gomes, Executive Director, ABIIS (Brazil)
5. Carlos Gouvêa, Executive President, CBDL/IES/ABIIS/ALADDIV (Brazil)
6. Sandro Stapleton, President, CCL-COMSALUD (Peru)

MDRC Team & Other:

1. Steven Bipes, Vice President-Global Strategy and Analysis, Advanced Medical Technology Association (ABD Transparency & Regulatory Co-Chair)
2. Renata Amaral, Lead, Good Regulatory Practices, Inter American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)
3. Sandra Ligia González, Executive Secretary, Inter American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)
4. Leticia Fonseca, Executive Secretary, Brazil, Inter American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)
5. Susan Suárez Gutiérrez, MDRC Liaison to the Government of Colombia, Inter American Coalition for Regulatory Convergence in the Medical Technology Sector

6. Andrew Blasi, Technical Secretary, Inter American Coalition for Business Ethics in the Medical Technology Sector
7. Christian Roatta, MDRC Project Manager, Consultant, Crowell & Moring International
8. Jessica Roop, Senior Manager, International Development, American National Standards Institute (ANSI)

Participants (Virtual: 29)

U.S. Government Officials:

1. Paul Fekete, Team Leader, Acting Head for the Center for Economics and Market Development, Bureau for Development, Democracy, and Innovation, U.S. Agency for International Development (USAID)
2. Jeff Hamilton, Commercial Officer, U.S. Commercial Service Brazil (DOC/ITA/FCS)
3. Laura Krishnan, International Trade Specialist, Office of Latin America and the Caribbean, International Trade Administration, U.S. Department of Commerce (DOC/ITA)

Industry Leaders:

1. Ericka Guirados, RA Senior Director, Medtronic
2. Elaine Sepulveda, RA/QA Analyst, Varian Medical Systems
3. Sandra Moreira Dalberto, Regulatory Affairs Director, Johnson & Johnson
4. Priscila Freitas, GE Healthcare, Mexico
5. Emmanuel Franco, Medtronic
6. Nimbe Ewald, Apple, U.S.

MedTech Industry Associations:

1. Ángela Flores, Executive Director, Asociación Nacional de Laboratorios Farmacéuticos (ALAFARPE) & CDMMAA
2. Tamara Olmos, Compliance Manager, Zimmer Bioment Mexico (AMID)

Regional Government & National Standards Body Leaders:

1. César Augusto Montaña Patarroyo, Colombia National Planning Department (DNP)
2. María Jimena Padilla Berrío, Colombia National Planning Department (DNP)
3. Estefanía Duque, Colombia National Planning Department (DNP)
4. Natalia Rodríguez, Colombia National Planning Department (DNP)
5. Angelica Villalba, Colombia National Planning Department (DNP)
6. Juliana Macías, Colombia National Planning Department (DNP)
7. Johanna Jiménez, Colombia National Planning Department (DNP)
8. Rafael Espejo, Colombia National Planning Department (DNP)
9. María Alejandra Vargas, Colombia National Planning Department (DNP)
10. Andrés Saavedra, Colombia National Planning Department (DNP)
11. Ricaurte Gutierrez, Colombia National Planning Department (DNP)
12. Laura Villarraga Albino, Colombia National Planning Department (DNP)
13. Hernán Zuñiga, Coordinator of the Technical Regulations Group and SICAL, Ministry of Commerce, Industry and Tourism (MinCIT), Colombia
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16. Meredith Shaddix, Program Administrator, International Development, American National Standards Institute (ANSI)
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