



**Joint Session of the
Inter-American Coalitions for Business Ethics and Regulatory Convergence
in the Medical Technology Sector**

Los Angeles | 7 June 2022

[*Welcome Members*](#)



General Information

- **Virtual guests:**
 - Please keep yourself muted throughout the duration of the session.
 - Use the chat box for any questions or comments.
 - *If you have any technical difficulties accessing the meetings during the day of the event, please contact:*
hugo@perlitteras.com; ablasi@crowell.com
- **In-person guests:**
 - Masks are available upon request, please let a team member know.
 - Simultaneous translation is offered for all hybrid Coalition activities. Please connect your device to the meeting Zoom (such as a cell phone or laptop) along with headphones. Please keep your mic muted once connected.
 - Restrooms
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Formal Launch and Signing Ceremony of the Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector



Ambassador Robert Holleyman
President & CEO, Crowell & Moring International
Former Deputy U.S. Trade Representative



Nacho Abia
Chief Executive Officer, Olympus Corporation of the Americas
Chief Operating Officer, Olympus Corporation
Board of Directors, AdvaMed

Strengthening Democratic Governance in the Americas through Ethical Business Conduct and Launch of the AdvaMed Code of Conduct



Ian Saunders
Deputy Assistant Secretary for the
Western Hemisphere,
Department of Commerce
United States



Lorena Brito da Justa Croitor
Federal Auditor of Finance and
Control, Coordinator of Audit in
the Health Area,
Comptroller General of the Union
Brazil



Christopher White
General Counsel &
Chief Policy Officer
AdvaMed

High-Level Remarks on the COVID-19 Medical Device Regulatory Convergence Project: MDRC Successes and Goals Through 2024



Mileydi Guilarte
*Deputy Assistant Administrator,
Bureau for Latin America and the
Caribbean, USAID
United States*



Joseph Tretler
*Vice President, International
Policy, American National
Standards Institute (ANSI)
Virtual*



Hector Orellana
*Vice President for Mexico and
North Latin America, Medtronic*

Driving Regional Trade and Investment

The Role of Good Regulatory Practices and Anti-Corruption



Daniela Ferreira de Matos
Deputy Secretary of Foreign Trade,
Ministry of Economy
Brazil



Hector Orellana
Vice President for Mexico and
North Latin America, Medtronic

The role of Good Regulatory Practices and Anti-Corruption on Driving Trade and Investment



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Good Regulatory Practices and Anti-Corruption are crucial for the business environment

Transparency



Rational Decision Making

Predictability



Foreign Direct Investment



Trade



The cost of regulatory inefficiency

State administrative inefficiency estimated to represent **13%** of the "**Brazil-cost**"

Around **US\$ 30 - 40 billion** dollars / year



Equivalent to the estimated cost of **tariff protection** in Brazil !

"At the border" $\neq$ "Within the border"



Domestic Initiatives



Economic Freedom Law

(Law n 13.874/2019)

Brazil Public Procurement Law

(Law n 14.133/2021)

4 Regulatory Decrees

Regulatory Agencies Law

(Law n 13.848/2019)

Business Environment Law

(Law n 14.195/2021)



International level Initiatives



OECD Recommendations

- Improving the Quality of Government Regulation
- Regulatory Policy Governance

Trade Agreements

- Brasil - Chile FTA
- Brasil - US Protocol on Trade Rules and Transparency
- Government Procurement Agreement
- WTO
- Services Domestic Regulation WTO

Cooperation

Commercial Dialogue



Brasil Foreign Trade Secretariat

US Department of Commerce

Good Regulatory Practices Annex



Central Coordinating Mechanism

coordination and review of good regulatory practices within the federal government

Public Consultations

private sector and civil society participation in regulatory process

Regulatory Impact Assessment

mandatory impact assessments for regulations of significant impact

Regulatory Agenda

publication of a biennial regulatory agenda and annual report on regulations

Review of regulations in effect

verify if the regulation achieved its desired objective, is still relevant, or if the current circumstances present alternatives to the current regulation

Anti- Corruption Annex



One of the first trade agreements to contain provisions on Anti-Corruption

Reinforces legislative obligations already assumed by Brazil and the United States in multilateral instruments

Mutual commitment to the fundamental elements necessary for a **fair shake** on trade



Government Procurement Agreement (GPA/WTO):

"Anti - corruption Agreement "

Transparency and non-discrimination in bidding processes

More **efficiency** and less costs in public purchases



US\$ 1,7 trillion market access for brazilian companies



Positive consequences in combating corruption



SECEX initiatives on Good Regulatory Practices

- ✓ Publication of the Foreign Trade Yearbook
- ✓ Impact Assessments for all trade agreements
- ✓ Public consultations for all regulations and impact assessment for high impact regulations
- ✓ Promotion of Good Regulatory Practices with governmental bodies involved in trade

Concluding Remarks

Good Regulatory Practices and Anti-Corruption are essential for a sound business environment

Complexity = Regulations affecting trade involve many different actors

Usually not simple/straightforward solutions



Disciplines in trade agreements and other international commitments **feed back** into domestic process



Thank you!



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Joint Coalition Closing Lunch

***Reminder: Reception Tonight with
U.S. Deputy Secretary of Commerce Don Graves***

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