INTER-AMERICAN COALITION FOR BUSINESS ETHICS
MEDICAL TECHNOLOGY SECTOR

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector

Los Angeles | 6 June 2022

Welcome Members

COALICIÓN INTERAMERICANA PARA LA
CONVERGENCIA REGULATORIA
SECTOR DE TECNOLOGÍA MÉDICA

COALIZÃO INTERAMERICANA PARA
CONVERGÊNCIA REGULATÓRIA
SETOR DE TECNOLOGIA MÉDICA

INTER-AMERICAN COALITION FOR
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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
  - Guest Wifi Network: *Pipeline*
    - Username: *guest@crowell.com*
    - Password: *Pochard*

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Opening Welcome Remarks

Sandra Ligia Gonzalez
Executive Secretary, Inter-American Coalition for Regulatory Convergence

Leticia Fonseca
Deputy Executive Secretary & Executive Secretary for Brazil, Inter-American Coalition for Regulatory Convergence

Renata Amaral
Technical Secretariat, Inter-American Coalition for Regulatory Convergence (GRP Lead)

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Coalition Progress Report & What to Expect for the Summit of the Americas

Sandra Ligia Gonzalez
Executive Secretary, Inter-American Coalition for Regulatory Convergence

Technical Secretariat Update
January – May 2022

Sandra Ligia González
Executive Secretary - IACRC

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External Engagement

- **FDA Latam Office**
  - Recurrent meetings
  - Support the Coalition's capacity building initiatives

- **Health Canada**
  - Support to the Workshop on ISO 13485 Certification – COFEPRIS

- **PAHO**
  - Application to become and Observer Member in prgoress
  - Joint organization of the X Meeting of Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas

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External Engagement

- **AHWP / GHWP**
  - Exploring opportunity to produce official translations to Spanish of selected documents

- **ISO / IEC – TC 210**
  - Application for IACRC Liaison with TC210 – in porgress

- **AAMI**
  - Support for the Workshop on Iso 13485 Certification – COFEPRIS

- **DEKRA**
  - Support on the Workshop on ISO 13485 Certification - COFEPRIS

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External Engagement

- **ABD (Health WG / Transparency and Regulatory Cooperation WG)**
- **IDB (ABD Secretariat, Trade team, GRP team, Health team)**
  - GRPs Survey
- **National/Regional Standards Bodies:**
  - COPANT
  - DGN
  - ICONTEC
  - INACAL
  - ABNT

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Case Work & Positions

- **Mexico**

- **NOM241 – Good Manufacturing Practices of Medical Devices**
  - COFEPRIS
  - Secretariat of Economy
  - United States - US Trade Department - NIST
  - Canada’s Notification Authority and Enquiry Point

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Upcoming Case Work and Positions

- **Country Specific:**
  - Colombia: Semantic Standard – work in progress

- **Regional:**
  - EU MDR / IVDR – Working Group
  - Country of Origin
  - Paper based apostille process
  - Software as Medical Device

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Documents availability in Spanish language

- **FDA's Emergency Use Authorization of Medical Products and Related Authorities – Guidance for Industry and Other Stakeholders**
- **Proposed for review/approval by FDA for official publication**

- **IMDRF:**
  - SaMD related documents
  - Clinical Investigation

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Policy Sessions

- **USAID/TCA EMD Webinar 1: Standards, Trade, and Innovation**
  - USAID
  - ANSI
  - Greenovations
  - The IAPMO Group
  - IACRC

- **ALCON LATAM**
  - Regulatory Policy

-

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Regulator Sessions

Webinar Series on Utilization of International Standards

Session 2:

- PAHO
- ISO / TC210
- USFDA
- MITA

WTO
IRAM
AAMI
ASTM International

COPANT
IEC / TC62
CLSI – ISO / TC212

Session 3:

- ABNT
- DGN

CB036
ANCE

ICONTEC
INACAL

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Regulator Sessions

Webinar Series on Utilization of International Standards

Session 4 – Part I

- NIST
- IECEE

PHILIPS

UL

TIC Council

Session 4 – Part II

- MoH Colombia
- FEUM

INVIMA

COFEPRIS

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Regulator Sessions

- **Workshop on ISO 13485 Certification**
  - Health Canada
  - AMII
  - DEKRA

- **Colombia – MDRC: MoH, INVIMA, DNP, MinCIT (Weekly Meetings)**
  - Clinical Investigation
  - Decrees 4725 & 3770
  - Emergency Use Authorization
  - Good Manufacturing Practices od Medical Devices
  - Processes & Procedures

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Attendees

- Policy and Regulator Sessions: 1,410
- MDRC Colombia: 494

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Upcoming events

- **Webinar Series on Software as Medical Device**
  - June – July

- **Stability Studies for Medical Devices**
  - October

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Website - Newsletters

Audience – 1,184

Newsletters - 11

COVID-19 Medical Device Regulatory Convergence Project MDRC

Geographical Scope

- **Africa**
  - Ghana
  - Kenya
  - South Africa
- **Asia**
  - Indonesia
  - Vietnam
- **Americas**
  - Brazil
  - Colombia
  - Mexico
  - Peru

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Africa

- **AMDRF**

- **Capacity Building Plan**
  - Good Regulatory Practices and Good Reliance Practices
  - Utilization of International Standards
  - Good Manufacturing Practices
  - Post-market Surveillance
  - Emergency Use Authorization

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Asia

- **Capacity Building**

- **Good Regulatory Practices and Medical Device Regulation: July 2022**
  - MoH
  - Gadhah Mada University
  - National Standards Body Indonesia, BSN
  - US Trade Department
  - WHO
  - WTO
- **Regional Meetings:**
  - Specific Technical Topics: Relliance, GMPs, Post-market Surveillance, etc.

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Brazil

- **Current Interactions and Development of Projects**
  - INMETRO
  - SEAE - Ministry of Economy
  - ABNT

- **Collaboration**
  - ANVISA – Capacity Building

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Colombia

	Procedural		Technical	
COVID-19	2	Regulatory Agility and EUAs (Emergency Use Authorization)	3	Support for implementation of: - MDSAP model - Clinical Research
RECOVERY FROM COVID-19	1	GPRs: Implementation of SOP's or instruments for the implementation of GPRs applied to the regulatory processes in the institutions involved: MinSalud, INVIMA & DNP	4	Ex-post evaluation of Decrees 4725 and 3770 Good Manufacturing Practices of Medical Devices

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Mexico

	Procedural		Technical	
COVID-19	2	• Regulatory Agility and EUAs (Emergency Use Authorization) • State-of-the-art systems for adverse event reporting	3	• Continue ISO and MDSAP training • Development of the requirements for obtaining health records of medical devices, aligned with international standards and published in the relevant regulatory instrument. • Alignment of the Advertising Regulation with international best practices.
RECOVERY FROM COVID-19	1	• Implementation of the Good Regulatory Practices Policy in the Quality. Management System of COFEPRIS and FEUM, in accordance with the recommendations generated by the WHO and in compliance with the commitments established between the government of Mexico and the WTO, the OECD, and the USMCA • Learning and exchanging experiences regarding IMDRF	4	• Update of the OFFICIAL MEXICAN STANDARD NOM-137-SSA1-2008, Labeling of Medical Devices. - Alignment with international standards regarding scope and terms. • Utilization of Accelerated Stability Studies to assign shelf life to MDs - Alignment with international references • Information on new technologies • Software as a medical device • Personalized medical devices • Medical Device Reprocessing

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Peru

	Procedural		Technical	
COVID-19	2	Regulatory Agility and Regulation for Emergency Use Authorization (EUA)	3	Extend the validity of technical documents (current 2 years) Acceptance of technical documents in English Labeling: supplementary information on secondary label (post-import)Acceptance of electronic signatures
RECOVERY FROM COVID-19	1	Good Regulatory Practices: Implementation of SOP's or instruments for the implementation of GRPs applied to the regulatory processes in the institutions involved: MINSA, DIGEMID, MINCETUR, PCM, INACAL	4	Elimination of retention sample requirement for unformed DMs Approval of registrations by "legal" manufacturer Regulation for custom implants Regulation for registration of accessories/equipment Acceptance of eIFU (Electronic Instructions) Update of Supreme Decree 016-2011-SA EU MDR / IVDR – Application of Reliance and Recognition Mechanisms

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Peru

- **Quality Regulatory Analysis**
  - Procedures tri-annual review
  - 8 Procedures related to MD under review
    - Regular meetings with ACR
    - Completion – August, 2022

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Summit of the Americas

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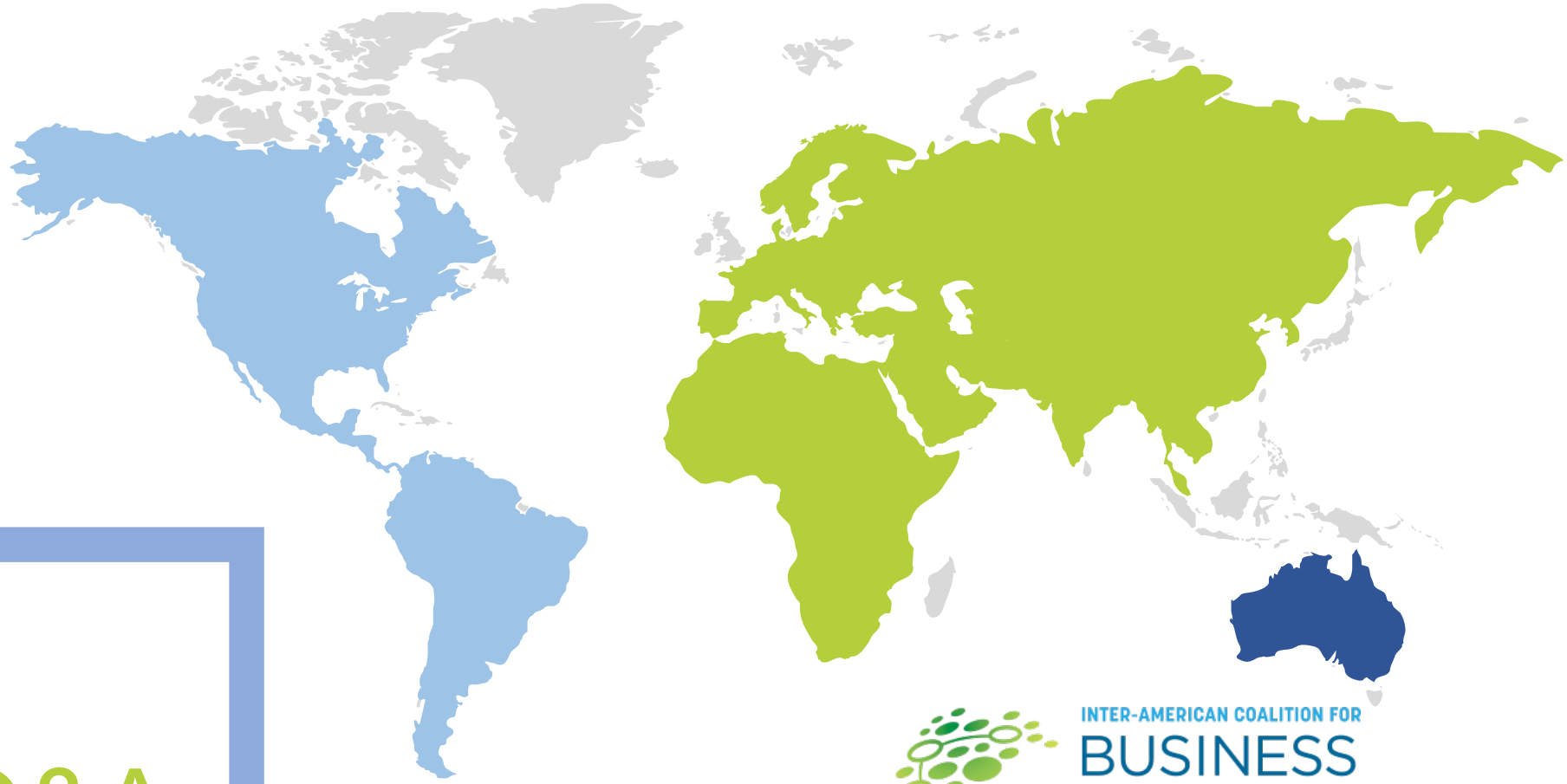
Expected Outcomes:

- ABD Recommendations
- Political Outcomes Statement
- Trade Ministers Commitments
- Individual government announcements



Q&A

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Remarks by the Office of the U.S. Trade Representative on U.S. bilateral, sub-regional, and regional efforts to advance Good Regulatory Practices (GRPs)

Renee Hancher

GRP Lead – Office of the U.S. Trade Representative (USTR)

U.S. Efforts to Advance Good Regulatory Practices

Renee Hancher

Director, Regulatory Policies

Office of the United States Trade Representative

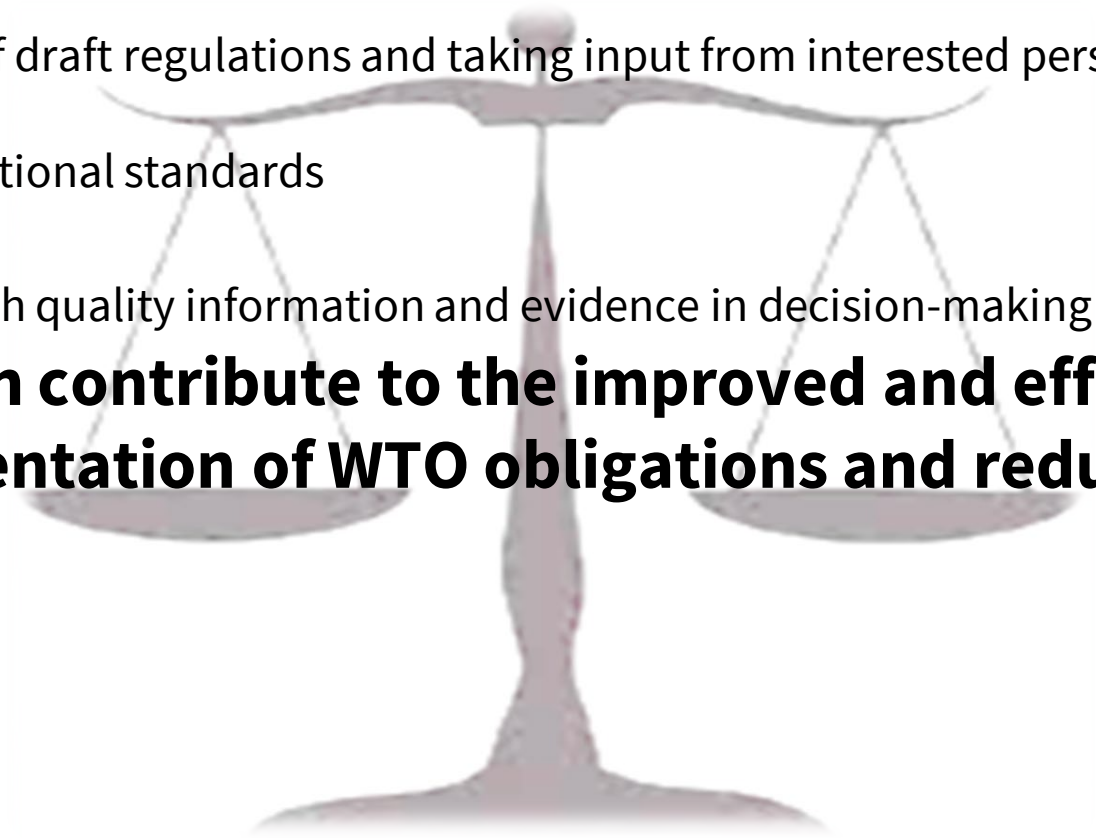
Renee.S.Hancher@ustr.eop.gov

Good Regulatory Practices and Trade

- Sound, transparent regulatory practices promote good governance
- GRPs are one of the building blocks for a stronger trading relationship
- Regulatory actions are a frequent trade irritant
- Transparency, inclusivity, predictability, and accountability support economic growth and trade

Good Regulatory Practices Strengthen Implementation of WTO Rules

- Transparency about existing rules and planned actions
- Notification of draft regulations and taking input from interested persons
- Use of international standards
- Relying on high quality information and evidence in decision-making



GRPs can contribute to the improved and effective implementation of WTO obligations and reduce trade frictions

USTR GRP Initiatives

- United States-Mexico-Canada Agreement
- Brazil Protocol on Trade Rules and Transparency
- Ecuador Protocol on Trade Rules and Transparency
- Indo-Pacific Economic Framework Trade Pillar
- U.S.-Taiwan Initiative on 21st Century Trade
- World Trade Organization
- Asia Pacific Economic Cooperation
- Summit of the Americas

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High-Level Report on GRP Trade Commitment Implementation: Brazil, Colombia, Mexico

GeanLuca Lorenzon
Secretary for Competition Advocacy and Competitiveness, Secretariat for Competition Advocacy and Competitiveness, Brazil

Aurelio Mejia
Director of Regulation, Ministry of Ministry of Commerce, Industry and Tourism of Colombia (Virtual)

Rubisel Velázquez Lugo
General Director of Intl Trade, Secretariat of Economy of Mexico (Virtual)

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Coffee Break

Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector
Los Angeles | 6 June 2022

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Presentation and Q&A on Brazil's National Quality Infrastructure

Marcos Heleno Guerson de Oliveira Junior

President, Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO)

National Institute of Metrology, Quality and Technology - INMETRO

Challenges of Quality Infrastructure in Brazil

Marcos Heleno Guerson de Oliveira Junior
President

INMETRO


CAUTION
WORK
IN PROGRESS

Economic Freedom Law

Art. 2 The principles that guide the provisions of this Law are:

I freedom as guarantee in exercise of economic activities;

II the **good faith** of the individual before the public power;

III the **subsidiary and exceptional** intervention of the State on the exercise of economic activities; and

IV the recognition of the vulnerability of the individual before the State.

Industry 4.0

Triple helix model of innovation

Government

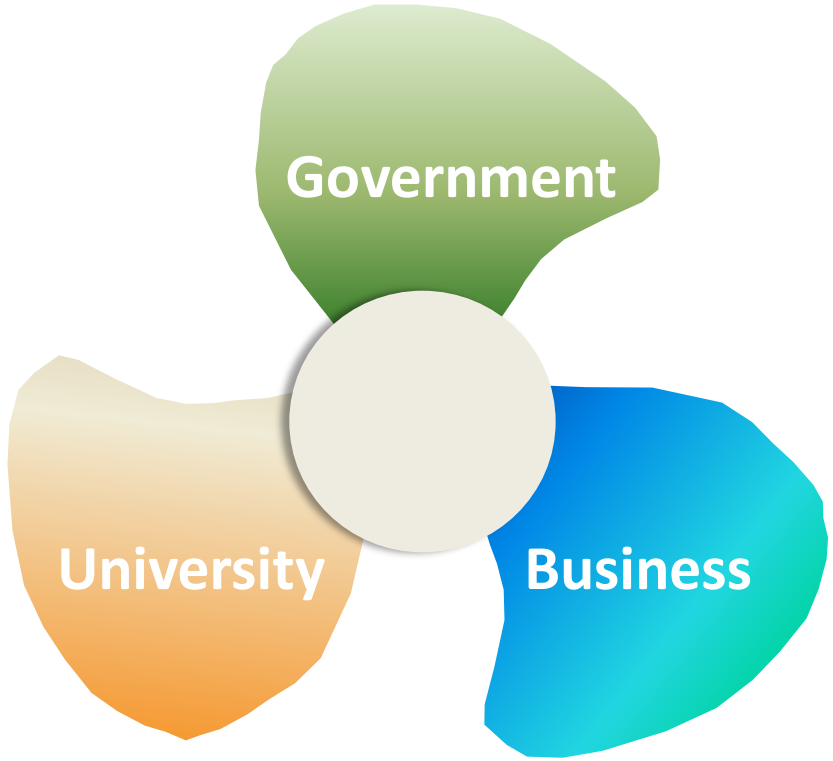
Organizes, regulates and promotes

University

Promotes basic and applied knowledge

Company

Place of application (economic and social gain)



Henry Etzkowitz

What is INMETRO?

The National Institute of Metrology, Quality and Technology – Inmetro – is a federal agency, linked to the Ministry of Economy, which works to strengthen national companies, through the adoption of mechanisms aimed at improving the quality and safety of products and services.

Founded in 1973, Inmetro occupies the Executive Secretariat of the National Council of Metrology, Standardization and Industrial Quality (Conmetro), an interministerial collegiate and normative body of the National System of Metrology, Standardization and Industrial Quality (Sinmetro).

Roles

Scientific Metrology

Legal Metrology

Conformity assessment

Regulation

Supervision

Accreditation

Overcoming technical barriers to trade

Technical cooperation

Education for quality

Laboratory Campus Of Inmetro

Dimensions of the scientific campus

2 million m^2

(52.7 thousands m^2 of built-up area)

Number of Laboratories

52

Buildings in the campus

55

Work force of the Inmetro System

6,500

professionals all over the country

INMETRO´s Mission

Enable quality infrastructure solutions that add confidence, quality and competitiveness to the products and services provided by Brazilian organizations, for the benefit of economic prosperity and the well-being of our society.

How to fulfil our mission?

TECHNOLOGICAL SUPPORT TO THE ORGANIZATIONS

- Scientific and industrial metrology
- Technical development and innovation support
- Foreign trade support
- Quality infrastructure qualification

MARKET FUNCTIONING SUPPORT

- Legal metrological control
- Accreditation
- Technical regulations and conformity assessment

Strategic objectives

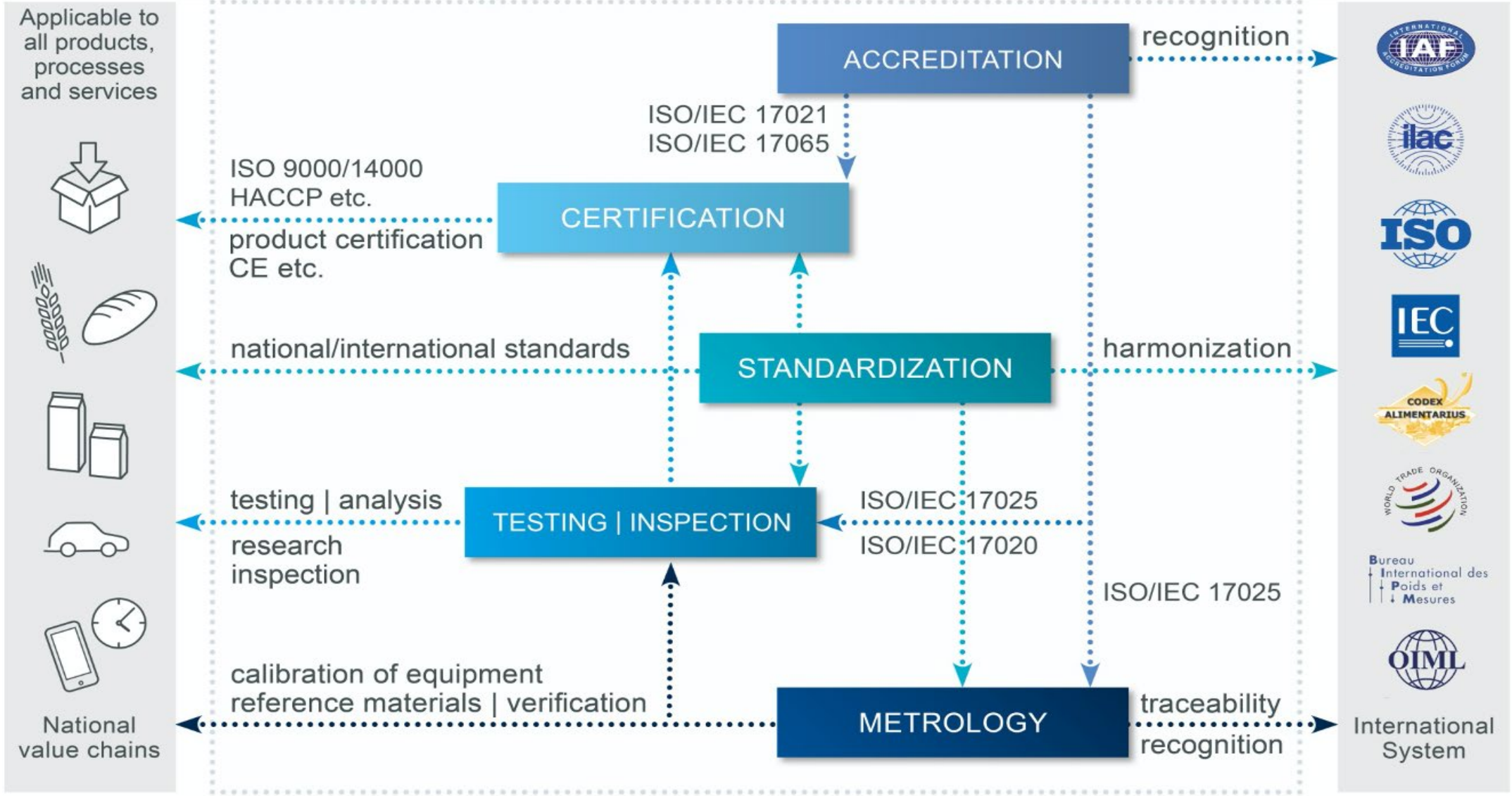
1. Provide quality infrastructure technological solutions to the productive sector, with emphasis on the demands of the economy 4.0
2. Improve regulatory efficiency in alignment with the principles of Economic Freedom
3. Increase the effectiveness of market supervision actions in their regulatory scope
4. Strengthen the activity of conformity assessment in the country
5. Making it more effective to overcome technical barriers to foreign trade
6. Redefine the understanding between society and Inmetro

How will we reach that?

- AXIS 1 — Strategic planning
- AXIS 2 — Modernization of the structure
- AXIS 3 — Modernization of the Processes
- AXIS 4 — Renegotiation with the Network
- AXIS 5 — Modernization of the Regulatory Framework
- AXIS 6 — Project Economical Recovery

Competitiveness and Quality

Quality Infrastructure



INMETRO

Regulatory Model

Vision

Regulatory model, as part of the **Quality Infrastructure**, in order to meet society's expectations, must guarantee a **safe** and **dynamic** market, to be **flexible**, more friendly to **innovation**, to promote **competitiveness** and to enhance **digitalization** (Industry 4.0)

How was the model presented?

A document that contains:

- **Vision**
- **Objectives**
- **Principles**
- **Guidelines**

Modernization of Regulatory Model OF INMETRO

Public Consultation

- **174 institutions** sent contributions;
- **10% of contributions** came from foreign institutions;
- **1146 suggestions** were presented;
- **Public Hearing** on the October 27th, 2021;
- **Publication of the Ordinance** in February 2022.

Modernization of Regulatory Model OF INMETRO

Next steps

- **Governance Committee:** government and industry
- **Choice of Pilot Cases**
- **Implementation deadline:** 5 years

Modernization of Regulatory Model OF INMETRO

INMETRO

National Policy of Quality Infrastructure

Quality Infrastructure

Adapted from: QUALIT Y INFRASTRUCTURE
UNIDO's UNIQUE APPROACH, 2018

Promoting Quality & Rule

Ensure quality and compliance with market standards and requirements for ***greater competitiveness and integration into global value chains***

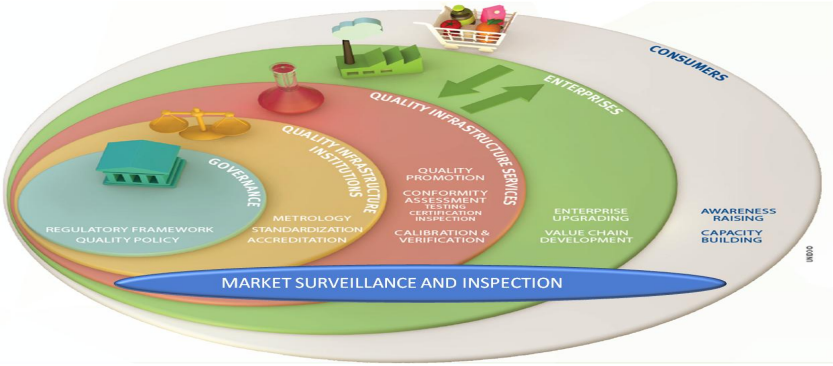
SYSTEMIC APPROACH

Demand driven IQ development

According to the needs of the private sector

IMPACT

Greater ability to meet quality standards and requirements to win market and consumer trust



Quality Infrastructure

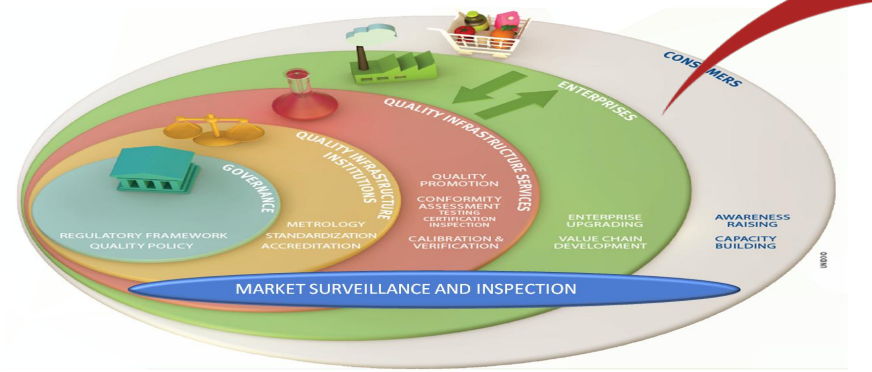
Actors and Interface

Complex System Involving Multiple Actors

- Regulatory Bodies and Authorities
- Technical Bodies – public and private
- Market Surveillance Bodies
- Companies and business sector
- NGOs and other private interested parts

Quality Infrastructure

Assure the sustainable development



NORMALIZATION

METROLOGY

ACCREDITATION

CONFORMITY ASSESSMENT

Transformation Road Map

National Policy of Quality Infrastructure

Jan 22 – May 22

Apr 20 – Mar 21

Phase 2
IMPLEMENTATION

Nov 21 – May 22

Modelo Regulatório DO INMETRO

Phase 1
APPROVAL

Jun 20 – Feb 22

Vision Statement

To be recognized by the productive sector and the market as a toolbox to overcome the challenges of society 4.0

Ouvidoria: 0800 285 1818

gov.br/inmetro

linkedin.com/company/inmetro

instagram.com/inmetro_oficial

facebook.com/Inmetro

youtube.com/tvinmetro

twitter.com/Inmetro

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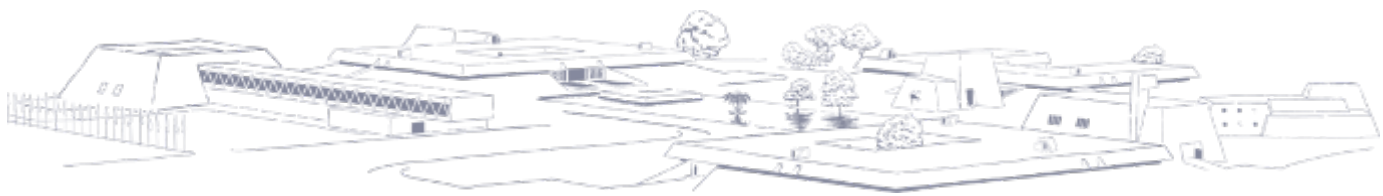
INMETRO

SECRETARIA ESPECIAL DE
PRODUTIVIDADE E COMPETITIVIDADE

MINISTÉRIO DA
ECONOMIA

PÁTRIA AMADA BRASIL
GOVERNO FEDERAL

Thank You!



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Remarks from Mark Abdoo, Associate Commission for Global Policy, U.S. Food and Drug Administration (FDA)

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Remarks from Alexandre Lemgruber, Regional Advisor, Health Technologies, PAHO

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Americas Business Dialogue – GRP Survey Findings and Next Steps

Sandra Ligia Gonzalez
Executive Secretary, Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector

Survey of Good Regulatory Practice Implementation in the Americas by Medical Device Regulatory Authorities

American Business Dialogue - IACRC

- 2021 – 2022
- Intened to be completed by government authorities within each country that is responsible for the implementation of foundational GRP applicabñe to MDs
- 15 Questions

Respondents:

- Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, Uruguay

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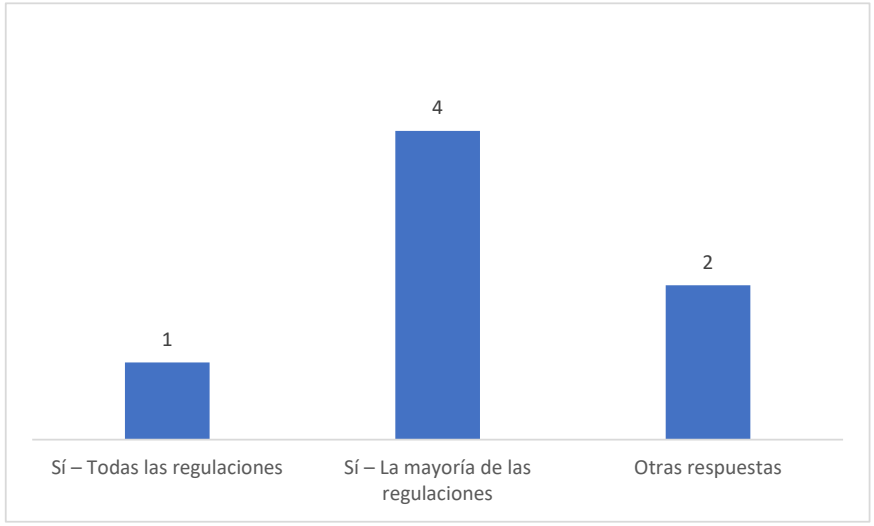
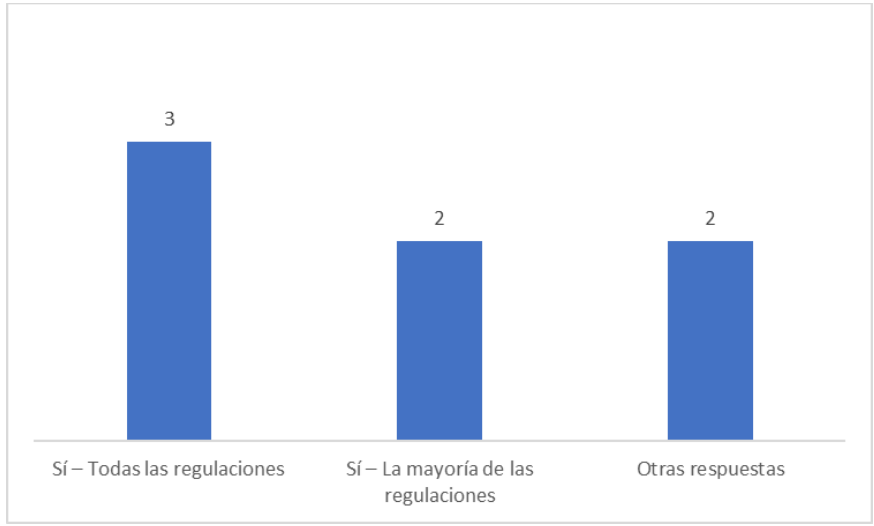
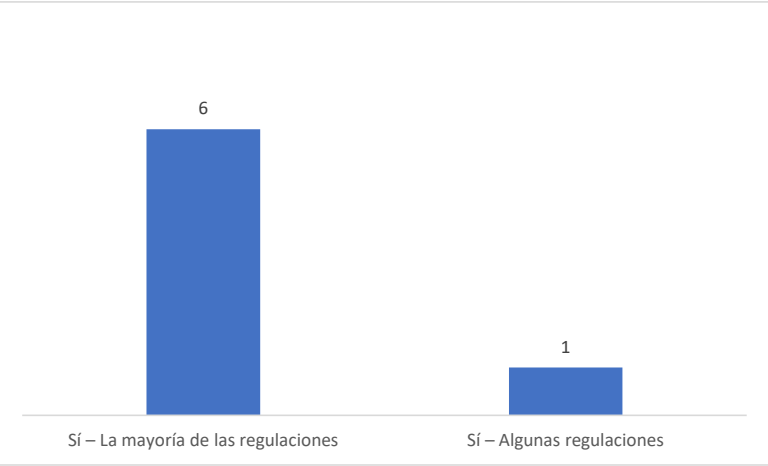
¿La autoridad reguladora emite previsiones regulatorias periódicas (ej. una publicación electrónica central, una publicación actualizada regularmente para notificar sobre todas las actividades regulatorias planeadas o en curso)?



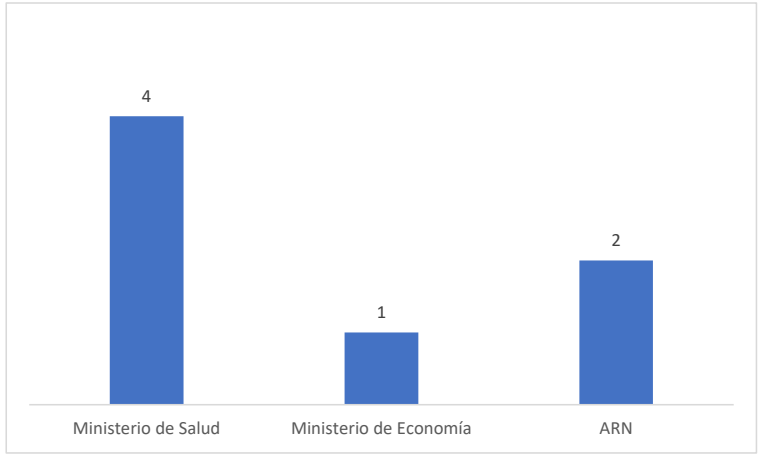
¿Se le da mantenimiento al Registro Regulatorio Nacional (ej. una ubicación central en línea donde se publiquen todas las regulaciones para acceso del público)?



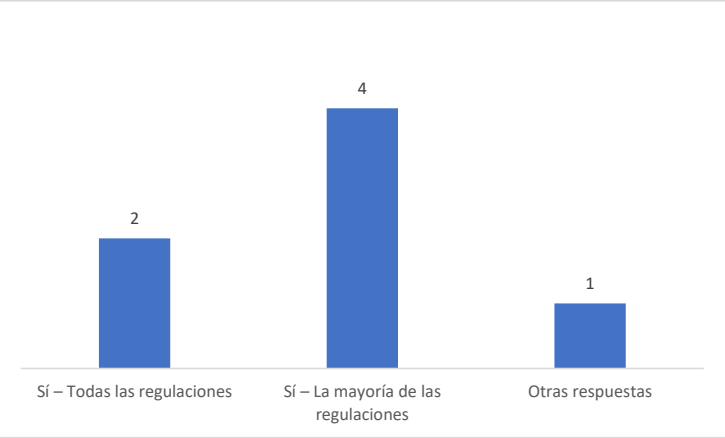
¿La autoridad reguladora proporciona avisos por adelantado sobre regulación propuesta?



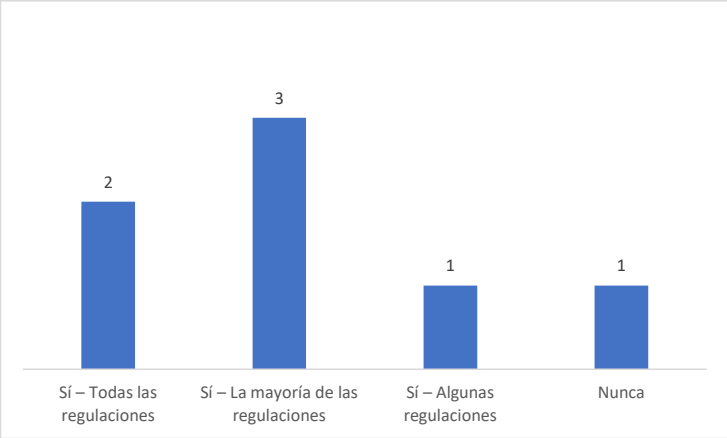
Por favor identifique el organismo coordinador y la secretaría/ministerio u oficina donde se encuentra:



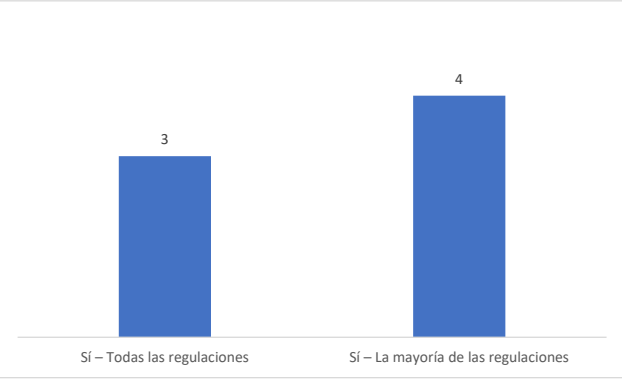
¿La autoridad reguladora de dispositivos médicos aborda y responde a los comentarios de las partes interesadas y publica las respuestas?



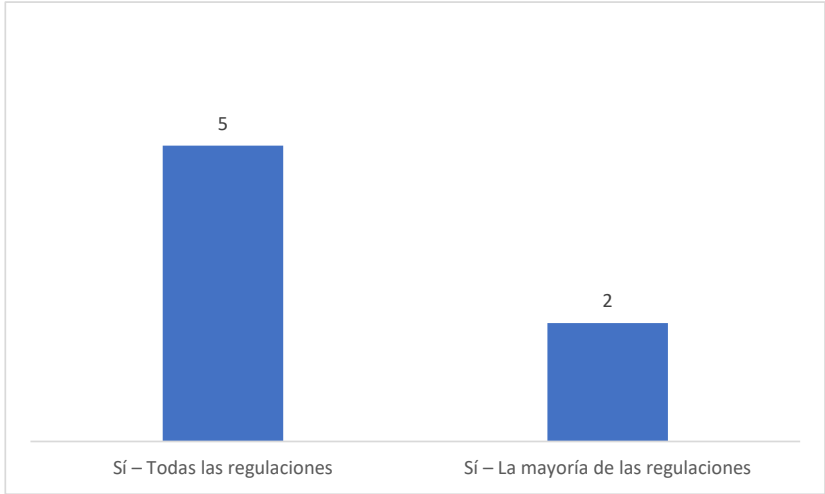
¿La autoridad reguladora de dispositivos médicos publica evidencia y/o análisis regulatorio para sustentar un proyecto de norma (reglamento técnico)?



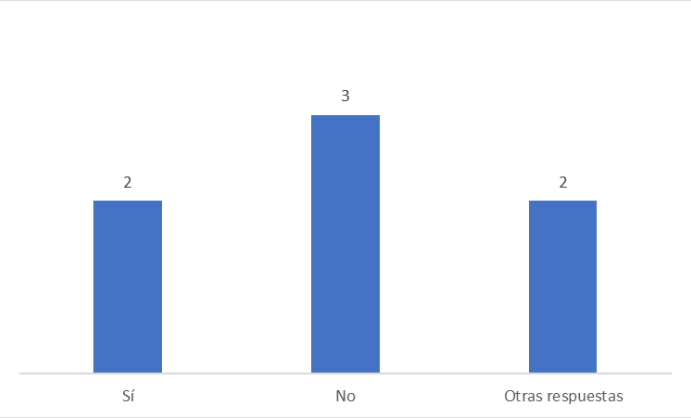
¿Se da un período entre la publicación de las regulaciones y su entrada en vigor?



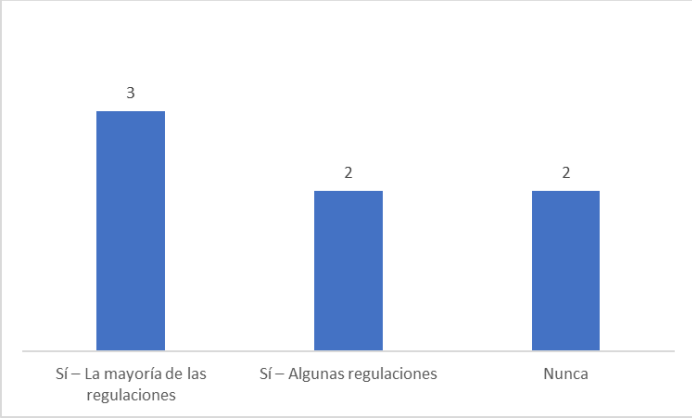
¿Las regulaciones publicadas se basan en información válida y confiable, y en ciencia sólida para guiar el proceso de elaboración de la regulación?



¿Existen lineamientos escritos para las autoridades reguladoras sobre cómo recopilar información de calidad, que apliquen a todas las áreas del gobierno?

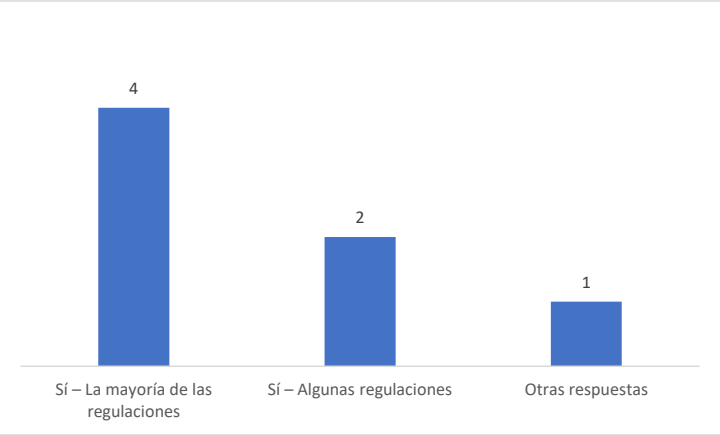


¿Se solicita la evaluación de riesgos para el desarrollo de regulaciones?

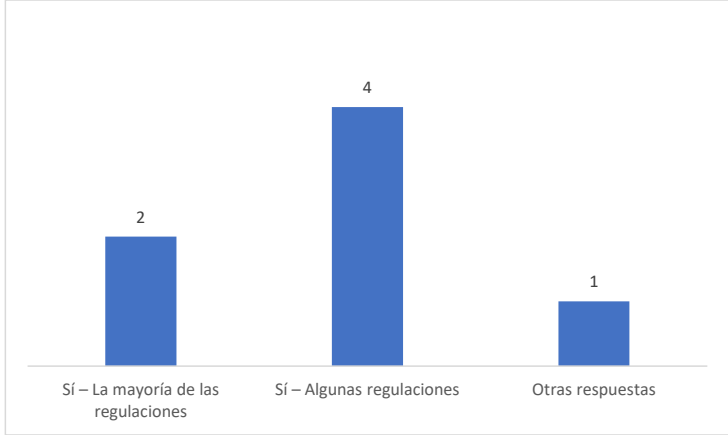


INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

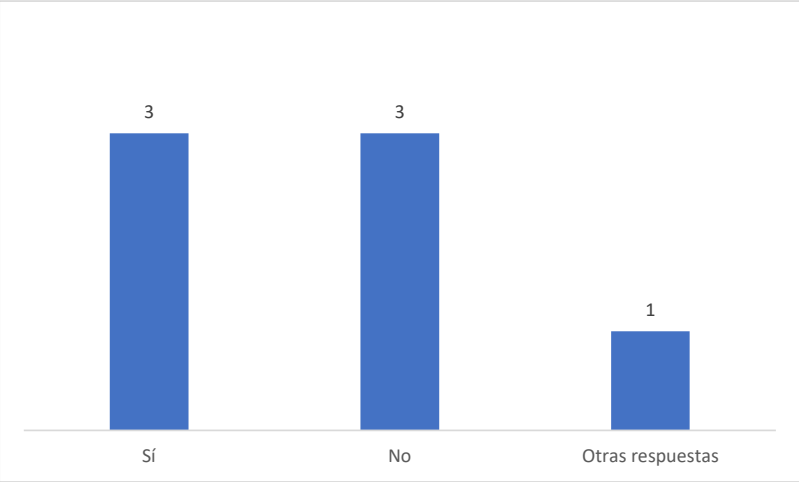
¿Existe un requisito para conducir una Evaluación del Impacto Regulatorio (RIAs) ex-ante en proyectos de regulaciones (ej. previo a la publicación de la regulación)?



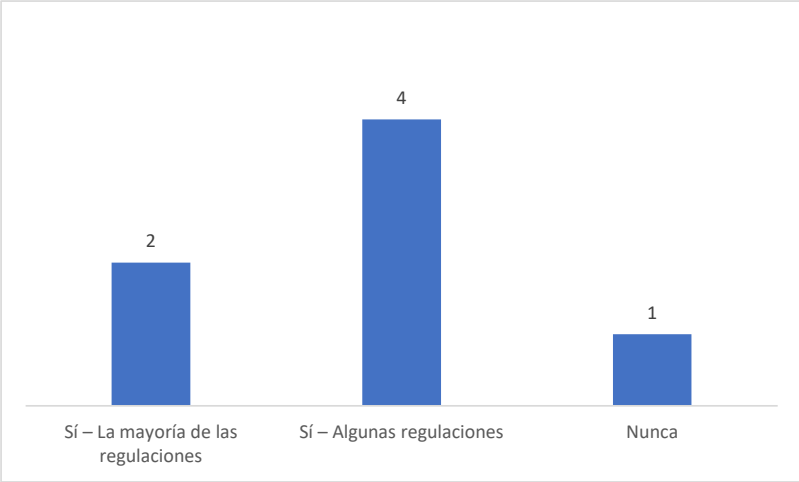
¿El proceso regulatorio solicita que las regulaciones se basen en normas internacionales?



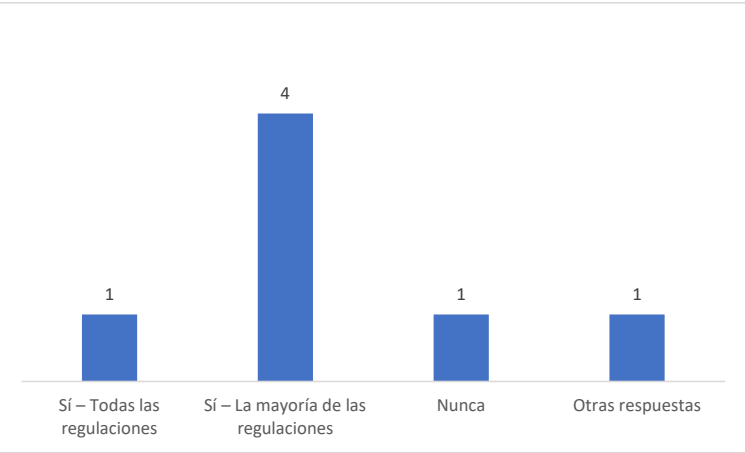
¿Existen parámetros escritos para las autoridades reguladores sobre cómo asegurar el cumplimiento del Acuerdo de la OMC sobre los Obstáculos Técnicos al Comercio, que apliquen a todas las áreas del gobierno?



¿Existe un requisito para conducir evaluaciones posteriores a la implementación para informar sobre el éxito de las regulaciones y sobre los esfuerzos para manejar las duplicidades e inconsistencias?



¿Existe un organismo o mecanismo central de coordinación regulatoria que sea capaz de asegurar la implementación en la totalidad del gobierno de las BPR (no solo en el sector salud)?



Next Steps

- **Further discussion on the responses: support regulations / SOPs**

- **Define additional capacity building needs**
  - Regulators
  - Coalition Members

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Q&A

INTER-AMERICAN COALITION FOR
REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

INTER-AMERICAN COALITION FOR BUSINESS ETHICS
MEDICAL TECHNOLOGY SECTOR

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Remarks by the U.S. Food and Drug Administration (FDA) on Regional Medical Device Regulatory Convergence Efforts in 2022

Mark Abdoo
Associate Commissioner for Global Policy,
U.S. Food and Drug Administration (FDA)

Virtual

INTER-AMERICAN COALITION FOR BUSINESS ETHICS
MEDICAL TECHNOLOGY SECTOR

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Remarks by the Pan American Health Organization (PAHO) on PAHO / WHO Efforts to advance convergence through Good Regulatory Practices and Good Reliance Practices

Alexandre Lemgruber
Regional Advisor, Health Technologies
Pan American Health Organization (PAHO)
Virtual

Status Updates by Coalition Members

Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector
Los Angeles | 6 June 2022

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

BRAZIL
Angelica Marques, ABIMED

International Standards – Checklists Update

- Acompanhamento CB-26
- Acompanhamento CB-36

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Novas Publicações

- Aprovada a Regulamentação sobre Dispositivos Médicos Usados e Recondicionados, RDC 579/2021.
- Aprovada a Regulamentação sobre Identificação Única de Dispositivos Médicos, RDC 591/2021.
- Aprovada a Revisão da Regulamentação sobre Agrupamento de Materiais Implantáveis em Ortopedia, RDC 592/2021.
- Aprovada a nova Instrução Normativa referente às Normas Técnicas para a certificação de conformidade dos equipamentos sob regime de Vigilância Sanitária, IN 116/2021.
- Aprovada a regulamentação sobre regularização de SaMD, RDC 657/2022.
- Aprovada a norma com os critérios para concessão e renovação de CBPF, RDC 687/2022.

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Em processo (Agenda Regulatória)

- Análise de petições de dispositivos médicos com aproveitamento de análises de Autoridade Reguladora Estrangeira Equivalente (reliance)
- Reprocessamento de dispositivos médicos
- Revisão dos requisitos essenciais de segurança e eficácia para dispositivos médicos
- Revisão da RDC 185/2001 e RDC 36/2015

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Q&A

INTER-AMERICAN COALITION FOR
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INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Medtech Canada

remarks by Greg LeBlanc

INTER-AMERICAN COALITION FOR
REGULATORY
CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

International Standards – Checklists Update

- **Health Canada is planning to change the way Recognized Standards are published.**
  - Generally, no version number or date will be listed – this means the latest version is accepted with a 3-year transition period
  - If a version or date is listed – only that version is acceptable
  - If a safety issue is concerned – no transition period
- **Medtech Canada continues to participate in ISO 13485 TC210 Mirror Committee through Canadian Standards Association and Standards Council of Canada**

Key Achievements

- Continuing to provide comments on proposed Health Canada guidance/policy/regulatory changes
- Engagement on Post-market Regulatory Changes including requirements for Summary Reports
- Continuing to monitor Trade Agreements and barriers to trade – work with Global Affairs Canada, COCIR and other agencies/associations to raise issues
- IMDRF: Continuing to monitor and engage on activities including MDSRP, UDI, SaMD, AI etc.
- Continuing to pursue IMDRF issues with GMTA and DITTA

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SETOR DE TECNOLOGIA MÉDICA

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Colombia

Marisol Sánchez – ANDI

Medical Device and Health Resources Chamber

International Standards – Checklists Update

Working Comittees

USAID – ANDI Project

Regulatory Affairs

Pacific Alliance

Working sub-comittees:

Electronic IFU

Medical Device Software

European Regulation

Semantic Standard

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

International Standards – Checklists Update

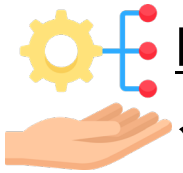
Semantic Standard

- ✓ Pending publication of public policy for consultation
- ✓ Finalization of the pilot with GS1 and Fenalco
  - More than 30 companies participating
- ✓ Position paper with ADVAMED
  - The coalition is supporting Colombia in the accomplishment of Good Regulation Practices
  - Presented to governmental entities

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

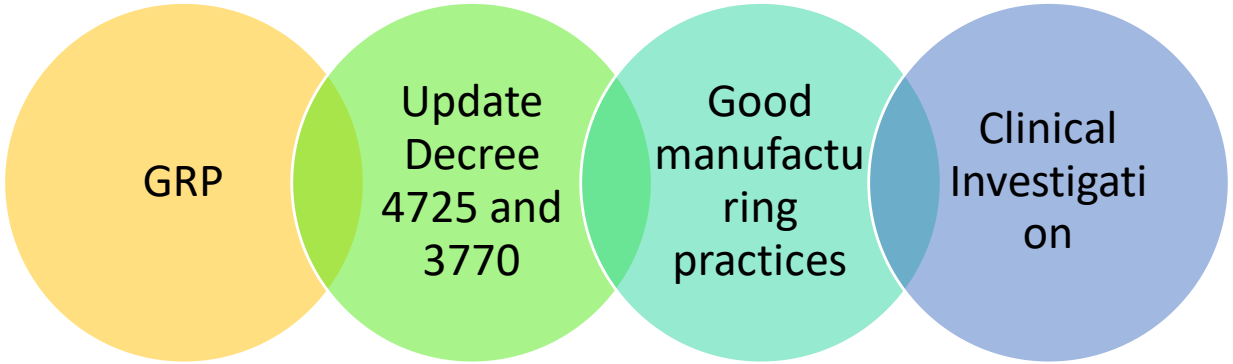
Key Achievements

Standards Alliance – USAID project



Proactive actions:

- ✓ Training public and industry personnel in good regulation practices
- ✓ 27 companies participating
- ✓ Government for the construction of the problem tree



Chamber's action plan:

- ✓ Pre-alignment meetings with industry
- ✓ Meetings of understanding with government

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Key Achievements

Simplification of procedures in INVIMA

- ✓ Minor changes are accepted as attachments to the dossier (characteristics of label)

INVIMA CYBER ATTACK

- ✓ Prioritization of procedures
- ✓ Problem solving with industry and government
- ✓ Communication of ANDI with Government (Trade and Health Minister and INVIMA)

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

CHALLENGES

- To achieve re-establishment of all INVIMA procedures.
- To target operational efficacy and unity of criteria within INVIMA.
- To align all pertinent requirements for the new European sanitary regulation
- To achive all USAID projects successfully.
- To establish rules of Good Manufacturing Practices fully aligned with ISO1340 and MDSAP.
- Alignment between semantic standard regulations and updates of sanitary standars to reflect the needs of the sector

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Q&A

INTER-AMERICAN COALITION FOR
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SECTOR DE TECNOLOGÍA MÉDICA

COALIZÃO INTERAMERICANA PARA CONVERGÊNCIA REGULATÓRIA
SETOR DE TECNOLOGIA MÉDICA

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

ECUADOR
Cristina Murgueitio, ASEDIM

INTER-AMERICAN COALITION FOR
REGULATORY
CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

International Standards – Checklists Update

Health Law Project:	Price regulation	Mandatory government's approval to introduce new technology in health system	Reverse bidding only mechanism to purchase Medical Devices	The Project is still in veto – no activity
Traceability Regulation	Regulation was derogated on December 2021	Traceability was introduced as requirement in the Public Procurement Regulation System – ARCSA has not created yet a regulation		
Relliance – Expedited Process for Approval Recognition IMDRF (2019) :	Expediated process for medical devices risk I and II	ASEDIM sent proposal to extend to medical devices risk III & IV		
Counterfeit & Smuggling	Authority has agreed to have workshops between Customs, ARCSA & COMEX (Foreing Trade office)	Workshop to 200 public employees of ARCSA regarding MD and counterfeit	Promote control of sanitary registration´s control by customs Designing media campaing with ARCSA to the public regarding MD and to purchase in authorized establishments	
Good Regulatory Practices	GRP was introduced in the economy urgent Project in the Production Code	Need to work in secondary regulation in order to have applyed	Design of strategy to perform workshops for the public sector	

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Key Achievements

Traceability Regulation with UDI requirements	Expedite approval process for Risk	Sanitary Document Control of MD by Customs	Good Regulatory Practices	Implementation of GMP for local manufacturer
• Allow more access to medical devices to Ecuador	• Acelerates process of Sanitary registration and generate more access to MD	• Reduce illegal market of medical devices	• Regulate the authorities to create regulations with the participation of industry	• Regulate the market to have manufacturers to comply with the law

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Reto
ECUADOR ES
SALUD

¿Qué proponemos?

Organizado por:

ASEDIM | Asociación Ecuatoriana de Distribuidores e Importadores de Productos Médicos

Auspiciado por: Boston Scientific — Advancing science for life™

En alianza con: ecuaSurgical s.a.

Elaborado por: Purpose ALLIANCE

Reto ECUADOR ES SALUD

OBJETIVO

Innovar el Sistema Nacional de Salud mediante soluciones construidas por los actores en equipos de trabajo colaborativo.

Reto ECUADOR ES SALUD

¿EN QUÉ SE ENFOCARON LAS PROPUESTAS?

- Fortalecimiento atención primaria (incluyendo telemedicina)
- Potencialización del Talento Humano ámbito técnico y servicio al paciente
- Articulación de la Red Pública Integral de salud y la red privada para atención oportuna al paciente
- Dinamizar la investigación en salud entre los actores

EQUIPO 01 ¿CÓMO OPTIMIZAR EL MODELO DE GESTIÓN DEL SISTEMA NACIONAL DE SALUD?

EQUIPO 02 ¿CÓMO MEJORAR LA COBERTURA Y PRESTACIÓN DE SERVICIOS DE SALUD?

EQUIPO 03 ¿CÓMO OPTIMIZAR LA CALIDAD EN LOS SERVICIOS DE SALUD?

EQUIPO 05 ¿CÓMO REDUCIR LA INCIDENCIA DE LAS ENFERMEDADES TRANSMISIBLES?

EQUIPO 06 ¿CÓMO REDUCIR EL IMPACTO DE LAS ENFERMEDADES NO TRANSMISIBLES CRÓNICAS?

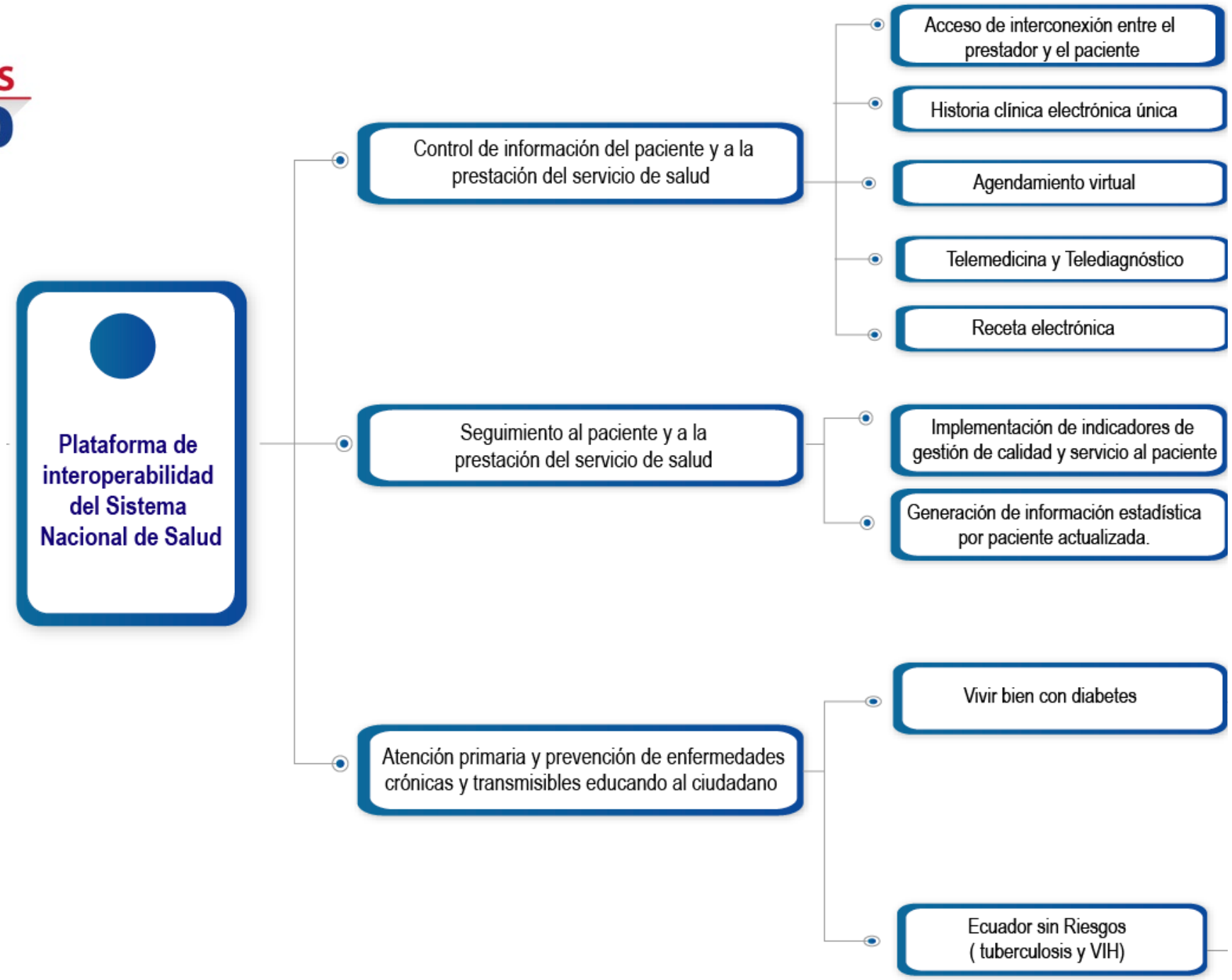
Plataforma de interoperabilidad del Sistema Nacional de Salud

- Control de información del paciente y a la prestación del servicio de salud
- Seguimiento al paciente y a la prestación del servicio de salud
- Atención primaria y prevención de enfermedades crónicas y transmisibles educando al ciudadano
  - Vivir bien con diabetes
  - Ecuador sin Riesgos (tuberculosis y VIH)

Integrar el 100% de los actores del SNS y generar un impacto positivo en la salud de población ecuatoriana.

Reto ECUADOR ES SALUD

Reto ECUADOR ES SALUD



Reto ECUADOR ES SALUD

Vivir bien con diabetes

- Detección oportuna: prediabéticos y diabéticos pues existe el 60% retinopatía + 30% pie diabético
  - Reducir amputaciones y pérdida de visión en un 50% en pacientes pre diabéticos y diabéticos
  - Reducir el gasto público al disminuir la atención en el tercer nivel
  - Medir ahorro en la disminución de condiciones de retinopatía y pie diabético
- Educación especializada y herramientas a los profesionales de la atención primaria para mejor diagnostico y tratamiento necesario para prevenir úlceras a los pacientes con condiciones detectadas.

Ecuador sin Riesgos (tuberculosis y VIH)

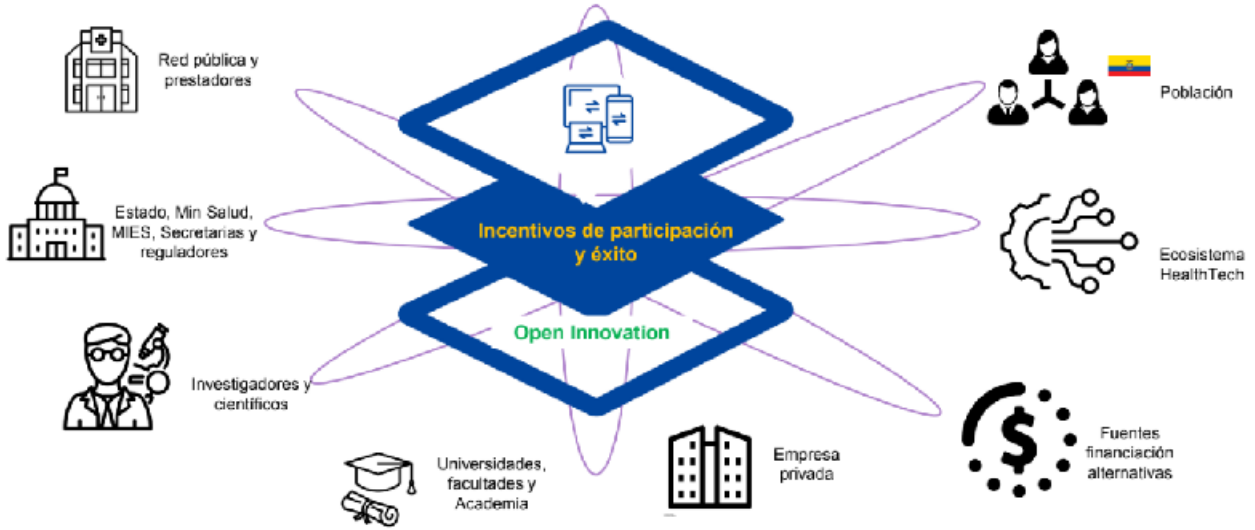
- Prevención y detección oportuna de tuberculosis y la incidencia de VIH
  - Reducir al 2030:
    - La incidencia de tuberculosis a 40 casos por cada 100,000 hab.
    - La incidencia de VIH a 6% de crecimiento anual.
  - Al disminuir la atenciónen en el tercer nivel, se reduce el gasto público

EQUIPO 04

¿CÓMO PROMOVER LA INVESTIGACIÓN EN SALUD?

- Dificultad para encontrar las necesidades de investigación sobre la cual enfocar sus aportes
- Recursos están alejados del ecosistema directo de salud
- No hay un adecuado mecanismo de relacionamiento entre el sector público y privado
- Poca promoción, incentivos o reconocimiento para el desarrollo de investigación

Plataforma de investigación híbrida (Digital y No Digital) repositorio de retos y necesidades de investigación en salud



Fomentar la investigación en Salud del Ecuador

Reto ECUADOR ES SALUD

Reto ECUADOR ES SALUD

07 EQUIPO

¿CÓMO GESTIONAR LA ATENCIÓN PARA ENFERMEDADES CATASTRÓFICAS, HUÉRFANAS Y RARAS?

Padecer una enfermedad catastrófica, huérfana o rara

Observatorio interdisciplinario de enfermedades raras, huérfanas y catastróficas

Centro de salud móvil al alcance de cada paciente

Visualizar y mejorar la atención primaria para pacientes que tienen enfermedades catastróficas, huérfanas y raras en Ecuador para 2030

EQUIPO 08

¿CÓMO IMPULSAR LA GESTIÓN DEL CONOCIMIENTO DEL TALENTO HUMANO EN SALUD?

- Débil relacionamiento entre el sector público y privado
- Personal de primer nivel de contacto con el paciente, es quien define la experiencia del servicio de salud
- No existe formación continua del personal en el sector salud
- Falta de mecanismos de comunicación acertiva
- Constante rotación de personal

CAPACITAMED

Plataforma digital de capacitación continua para formar profesionales que puedan trabajar tanto en el sector público como privado

Tener el 100% de profesionales del sector salud formados en:

- Fortalecimiento de competencias
- Potencialización de habilidades y destrezas
- Conocimiento técnico actualizado

Reto ECUADOR ES SALUD

AGRADECIMIENTO A LOS PARTICIPANTES

GRACIAS POR ASUMIR EL “RETO: ECUADOR ES SALUD”

EQUIPO 1

- Alexandra Mantilla
- Cristina Murgueitio
- Daniel Hidalgo
- David Rúales
- Fernando Gavilánez
- Juan Jara
- Rodrigo Cargua

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- Erika Monteros
- Valentina Agudelo
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- Laura Rodriguez
- Ruth Jimbo
- Lorena Ortiz
- Edison Osorio

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- Jennyffer Soto
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- Esteban
- Nancy Stortoni
- Claudio Gutierrez
- Lilia Ushiña
- Verónica Ushiña
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- Diego Ayala
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- Diana Idrovo
- Elizabeth Pauker
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- Andrés González
- Juan Francisco Viteri
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EQUIPO 6

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- María Elizabeth Malla
- Nataly Andino
- Priscila Escala
- Joanna Maldonado
- Camilo Arenas
- Giordano Poletto
- Edward Merizalde

EQUIPO 7

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- Félix Galarza
- Jaime Godoy
- Yadyra Ludeña
- Carol Moreno
- Eliecer Quispe
- Karen Vaca

EQUIPO 8

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- Evelyn Escalante
- Lissette Hidalgo
- Walter Lopez
- Michael Álvarez
- Mishael Sangoluisa

Status Updates by Coalition Members

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INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

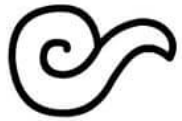
Mexico
Verónica García, AMID

INTER-AMERICAN COALITION FOR
REGULATORY
CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

International Standards – Checklists Update

Engagement as KOL

- Ministry of Economy
- Ministry of Foreign Affairs
- Ministry of Health
  - COFEPRIS



Shaping the Environment

- GMP
- Techno-Surveillance
- MD Labelling
- SaMD

Building Capabilities

- Authorities
- Academy
- Private Sector

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Key Achievements

Good Regulatory Practices (GRP)

Quality Infrastructure Law: Member of the group for the review of the new Rules.

Implementation:

- **GRP:** IACRC has held meetings with the Mexican authorities (COFEPRIS)
- **MDSAP:** IACRC has provided training for the private sector

Regulation

- **Creation of:**
  - Software as Medical Device
- **Updating:**
  - Labelling: NOM-137
  - Techno-surveillance: NOM-240

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Q&A

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SETOR DE TECNOLOGIA MÉDICA

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

PERU
SANDRO STAPLETON P.
Presidente Del Gremio de Salud-CCL
COMSALUD

INTER-AMERICAN COALITION FOR
REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

DIVERGENCIAS Y VACIOS LEGALES IDENTIFICADOS EN LA REGULACION DE DISPOSITIVOS MEDICOS

Check list update:

En el año 2020, con la Coalición Interamericana para Convergencia Regulatoria de dispositivos médicos, se identifico 10 inconvenientes :

1.-elFU electrónico, no se permite la presentación del manual de instrucciones de uso e inserto en forma electrónica.

2. Etiquetas de origen: La Autoridad exige que se coloque el nombre del país de origen del fabricante.

3.Los equipos y sus accesorios deben registrarse por separado.

4. .-La autoridad requiere la traducción completa de documentos técnicos al español

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5. Presentar validación y verificación en formato especifico emitido por la Autoridad Sanitaria.
6. Validez de los documentos técnicos deben tener una fecha de emisión no mayor a dos (2) años
7. Implantes personalizados se registran presentando los mismos requisitos que para un dispositivo medico normal.
8. Digemid autoriza el Registro Sanitario de dispositivos médicos, basados en clasificación de riesgo y por país y fabricante.
9. Aprobar un nuevo Proyecto de Reglamento de Dispositivos Médicos de Reactivo de Diagnostico Invitro
10. Revisión del proyecto de Reglamento de Cambios mayores y menores de dispositivos médicos

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1. Pendiente
2. Etiquetado de origen, se acepta al rotulado de “Hecho en … o Made in …” o “Country of Origen” en relación a la regulación arancelaria y que no necesariamente se vincula al sitio de fabricación, las empresas deberán presentar una carta del fabricante que explique el país de origen.
3. Pendiente
4. Traducciones de documentos técnicos, se aceptan las traducciones resumidas que incluyan : a. Introducción, Metodología, Conclusiones , y adjuntar el documento completo en idioma original.
5. Requisito para DM clase III y IV, documento de Verificación y Validación, se acepta en formato del fabricante.
6. La Autoridad Sanitaria, acepta los documentos técnicos de acuerdo con la fecha de emisión del fabricante.

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7. Dispositivos Médicos Implantes a medida o personalizados, se podrán tramitar a través de autorizaciones excepcionales para tratamiento individual; la solicitud debe incluir la receta médica del dispositivo a importar y el rotulado del dispositivo debe incluir la leyenda “Hecho a medida del paciente o frase similar”, esta aprobación será rápida, y se deberá incluir información general de seguridad y eficacia
8. DIGEMID está participando activamente en Alianza del pacifico en el plan de reconocimiento del Registro Sanitario en los países miembros, esto permitirá incluir en un mismo registro varios sitios de manufactura para estar alineados con los otros países miembros.
9. La Autoridad Sanitaria reconoce la importancia de la aprobación de este nuevo Reglamento de Dispositivos Médicos de Reactivo de Diagnostico Invitro.
10. La autoridad Sanitaria revisara el Proyecto de Reglamento de cambios mayores y menores de dispositivos médicos y si es necesario incluirá los cambios producidos en la normativa europea.

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PRIORIDAD A LOGRAR 2022-2023

1. Que La Autoridad Sanitaria tenga una estructura estandarizada de acuerdo a Normas Internacionales, siendo necesario la aprobación de un Reglamento específico para la Regulación Sanitaria de dispositivos médicos., a fin de evitar que se generen dificultades para llevar nuevas tecnologías al mercado en el país

2. Se apruebe un Reglamento específico para dispositivos médicos, reactivos de diagnostico invitro, por ser necesario e importante hacer un cambio normativo y de esta manera estar alineados a las Normas Internacionales, armonizado con Estándares Internacionales

3. El Gremio de Salud –Comsalud, solicita a la Autoridad Sanitaria se revise el Proyecto de Reglamento de cambios mayores y menores de dispositivos médicos, a fin de incluir los cambios producidos por el cambio de normativa de la Regulación Sanitaria de dispositivos médicos en Europa.

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Q&A

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Status Updates by Coalition Members

Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector
Los Angeles | 6 June 2022

COALICIÓN INTERAMERICANA PARA LA CONVERGENCIA REGULATORIA
SECTOR DE TECNOLOGÍA MÉDICA

COALIZÃO INTERAMERICANA PARA CONVERGÊNCIA REGULATÓRIA
SETOR DE TECNOLOGIA MÉDICA

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United States
AdvaMed

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International Standards – Checklists Update

- Medical Device User Fee Amendments 2023 (MDUFA V)
- Verifying Accurate, Leading-edge IVCT Development (VALID) Act
- Food and Drug Administration Safety and Landmark Advancements Act of 2022 (FDALSA)
- FDA transition from QSR to ISO13485
- Revision of WHO GMRF
- Engagement with ANSI, ISO, IEC, AAMI, ASTM, CLSI, MITA
- Ecuador Traceability
- Mexico NOM241
- Colombia Semantic Standard

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Key Achievements

- Updated U.S. MD regulatory framework and agreement on how user fees will be used
- Updated U.S. In Vitro Clinical Tests requirements
- Increased alignment of U.S. MD GMP requirements with ISO13485
- Participation in the public consultation on international MD reference documents towards convergence
- Engagement with NSBs and SDOs on MD technical standardization
- Development of Specific Trade Concern casework to facilitate convergence

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INTER-AMERICAN COALITION FOR BUSINESS ETHICS
MEDICAL TECHNOLOGY SECTOR

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MEDICAL TECHNOLOGY SECTOR

Action Plan Review & Closing Discussion

Sandra Ligia Gonzalez
Executive Secretary, Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector

INTER-AMERICAN COALITION FOR BUSINESS ETHICS
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Joint Coalitions and Delegation Reception

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