Fifth Anniversary Meeting

Internal Session

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR

5 ANNIVERSARY

08 May 2025

Action Plan 2026 - 2030

INTER-AMERICAN COALITION FOR
REGULATORY
CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

ANNIVERSARY

Action Plan 2020 - 2025

1. Regulatory Process

Crisis Management Preparedness - Post COVID19 - Regulatory Framework
Prioritized use of international standards - baseline for new regulations - IMDRF, ISO, etc. (21st. Century Cures)
GRP implementation policy - RIA implementation
Agreement for Reliance - Approvals recognition
WTO - TBT Committee Commitments
GRP Legislation
Designation of a standards & conformity assessment: executive/program- Health Regulators
Designation of a standards responsible - MedTech Associations

2. Technical Regulations

Regulation of SaMD
Use of MDSAP / In-country Implementation
UDI/GMDN
Risk Classification of MDs
Labeling: Legal Manufacturer, Country of Origin, Physical Manuf., Storage Temp., Exp. Dates, local re-labeling
Electronic Submissions + eIFU + eSignatures
Medical Device Definition
Technovigilance

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Action Plan 2020 - 2025

Action Plan 2020 - 2025				Status
Emergency Procedures	Absence	Colombia	Crisis Management Regulatory Framework	
		Mexico	New normal Evolution	
	Outdated	Canada	Post Covid-19 Regulatory Framework	
GRP	Absence	Argentina	Creation of a local policy	
			Prioritized Use of International Standard	
		Ecuador	GRP Implementation	
		Colombia	Prioritized Use of International Standard	
		Chile	Prioritized Use of International Standard	
		Peru	Implementation of GRP	
	Implementation	All Countries	Implementation of MD RA Standards and Conformity Assessment Policy and Program	
			Designation of Coalition & Company Standards Strategies (AdvaMed Project)	
		Brazil	GRP (MDRC Project)	
		Argentina	MDSAP/ In-Country Implementation as Affiliate Member	
		Mexico	Generation of strategic standards	
			Infrastructure Law	
			T-Mec	
			COFEPRIS Implementation of GRP, WTO and MDSAP	

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Action Plan 2020 - 2025

Action Plan 2020 - 2025				Status
Regulation	Absence	Brazil	Non-sterile implants;	
			Technichal Service for MD	
		Ecuador	UDI	
		Colombia	eIFU	
			Electronic Signatures	
		Mexico	eIFU	
			Electronic Signatures	
		Peru	Customized implants registration requirements	
			Accesories Registration	
			eIFU	
	Country specific requirements	Brazil	Elimination of double GMP Fees	
			Brazil /Inmetro(Retesting, Recertification, Labeling)	
		Chile	Proposed Law (Pharma Law)	
		Mexico	Nom 241 - Good Manufacturing Practices	
		Peru	Sample Retains	
			Technical Documents - Handwritten signatures + Validity of 2 years	
	Outdated	Ecuador	Agreement of Reliance - Approval Recognition	
			Techno-vigilance	
		Peru	Local Labelling	
			Sanitary Licenses issued by Legal Manufacturer	
			Translation to Spanish	
		Mexico	Labelling	
Procedures	Digital infra-structure	Mexico	Evolution to new technologies	
		Colombia	Electronic Submissions	
	Customs	Ecuador	Counterfeit & Smuggling	

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Action Plan 2026 - 2030

Priorities 2020-2025	2026 - 2030
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Action Plan 2026 - 2030

New priorities 2026 - 2030	
Country	Topic

THANK YOU

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