

**Fifth
Anniversary
Meeting**

**Internal
Session**

08 May 2025



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



Action Plan 2026 - 2030



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

Action Plan 2020 - 2025

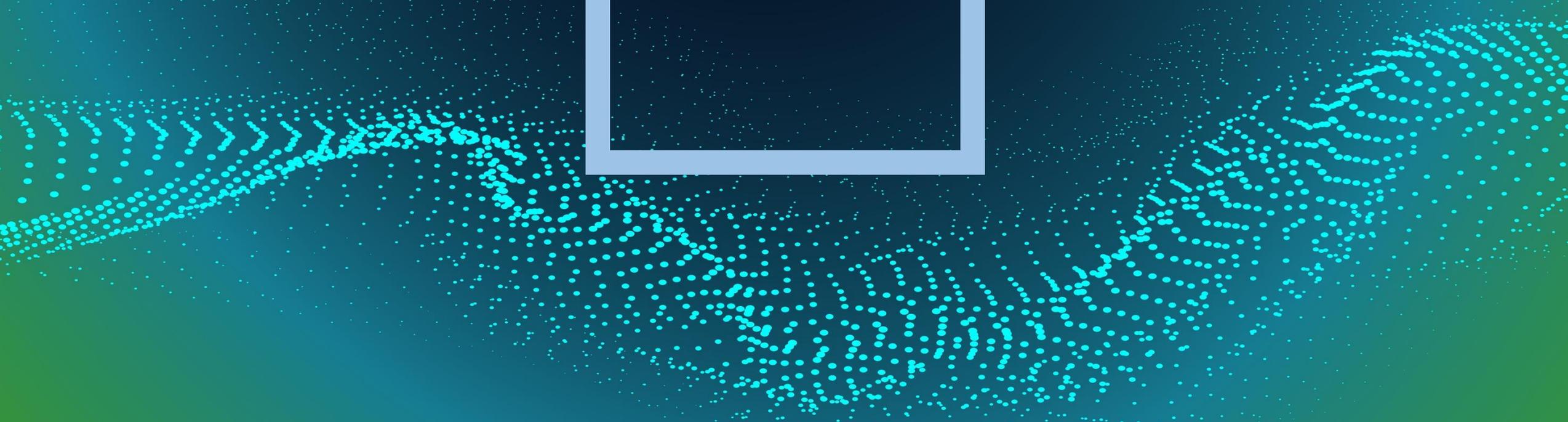
Action Plan 2020 - 2025				Status
Emergency Procedures	Absence	Colombia	Crisis Management Regulatory Framework	
		Mexico	New normal Evolution	
	Outdated	Canada	Post Covid-19 Regulatory Framework	
GRP	Absence	Argentina	Creation of a local policy	
			Prioritized Use of International Standard	
		Ecuador	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				

Action Plan 2020 - 2025

Action Plan 2020 - 2025			Status		
Regulation	Absence	Brazil	Non-sterile implants; Technical 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		

Action Plan 2026 - 2030

Priorities 2020-2025	2026 - 2030
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Medical Device Definition	
Technovigilance	



THANK YOU

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