

# Accelerating Access to Health Products in the Americas

Regulatory convergence: Why it matters and the region's progress

The countries surveyed represent the 16 largest economies in the Americas, collectively accounting for roughly 95% of the region's GDP.

## Good Regulatory Practices (GRPs)

**69%** 

**Percentage of countries that have implemented "whole-of-government" foundational GRPs**

Foundational GRP policies help ensure technical regulations and conformity assessment procedures are appropriate, effective, transparent, and aligned with international standards, enabling medical innovations to reach patients.



**Percentage of countries with National Regulatory Authorities (NRAs) that have implemented the 'WHO good regulatory practices in the regulation of medical products' within their standard operating procedure for rulemaking**

**75%** Pharmaceuticals

**63%** Medical Devices



**Percentage of countries with NRAs that have implemented the 'WTO Technical Barriers to Trade Agreement' within their standard operating procedure for rulemaking**

**75%** Pharmaceuticals

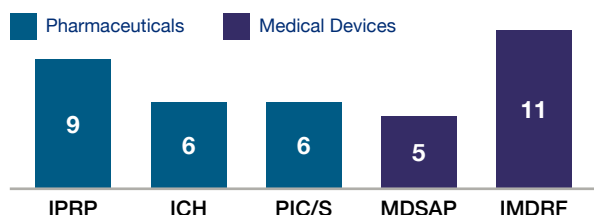
**75%** Medical Devices

## Convergence Forums



**Number of countries with membership in relevant international convergence forums**

Joining and participating in international convergence forums builds confidence among regulators and enhances the necessary capacity to undertake convergence.



## Building Trust to Enable Reliance

**69%** 

**Percentage of NRAs that publish and maintain data on product reviews, as well as inspection quantities and times**

Publishing and maintaining data enhances transparency and accountability while facilitating reliance for countries dependent on publicly available information rather than confidentiality commitments.



**Percentage of NRAs that have formally established regulatory reliance policies**

Reliance policies allow NRAs to use trusted assessments from other regulators, reducing duplication, enhancing efficiency, and freeing public health resources to focus attention on local priorities and health industries, ensuring timely access to safe and effective health products.

**63%** Pharmaceuticals **31%** Medical Devices

## Mutual Recognition Agreements (MRAs)

**56%** 

**Percentage of countries establishing MRAs<sup>1</sup>**

Participation in mutual recognition agreements (MRAs)<sup>2</sup> requires real, practical collaboration. Increases in MRAs over time is a hallmark of convergence.

## Medical Device Good Manufacturing Practice Alignment

**88%** 

**Percentage of NRAs substantially aligned with international standards for GMP inspections<sup>3</sup>**

Adhering to international standards for Good Manufacturing Practice (GMP) inspections helps ensure that products are consistently produced and controlled to meet quality and safety requirements, protecting public health.

<sup>1</sup> Relevant for pharmaceuticals, not medical devices

<sup>2</sup> Government-to-government arrangement whereby two or more economies agree to recognize each other's conformity assessment results. MRAs specify the conditions under which the conformity assessments performed by one party will be accepted as showing compliance with the other party's requirements and vice versa

<sup>3</sup> Alignment with international standards is measured by accepting MDSAP audit reports or ISO 13485 certifications for both domestic production and imports

# Accelerating Access to Health Products in the Americas

Regulatory convergence: How it benefits our region

## Protects people's safety



When we take advantage of testing, inspections, and reviews already done by high-performing regulators around the region, we can efficiently ensure approved products are both effective and safe, and work together to watch for safety issues in our collective population.

## Attracts investment



When we shorten burdensome procedures and adopt best practices by trusting the processes of high-performing regulators, we can reduce uncertainty and delays so that both local and international firms find it easier to do business in our economies, invest their capital, and create jobs.

## Makes products available



When we leverage the assessment work already done by high-performing regulators on a particular life-saving product, we can approve that product more quickly and ensure it is readily available on the market to those who need it.

## Promotes transparency



When we avoid duplicate inspections and lengthy approval procedures, we can reduce the time it takes to respond to an application and strengthen transparency in the process.

## Saves public resources



When we tap into the expertise and work of other high-performing regulators around the region, we can avoid unnecessary duplication and limit wasteful spending so we can save our precious public health resources for use elsewhere.

## Improves global standing



When we share the load with other regulators and join international initiatives, we show our willingness to cooperate and support best practices, which strengthen the global community and enable investment in our economies.

## Methodology

This survey was approved in February 2025 under the Regulatory Improvements Pillar Workstream led by Panama and was developed in collaboration with Americas RISE for Health stakeholders. To collect the data, Northeastern University distributed a survey to NRAs in the 16 largest economies<sup>4</sup> in the Americas (by GDP), representing approximately 95% of the region's GDP. Survey responses were complemented by desk research and validated by regional regulatory experts.

## About Americas RISE for Health

Americas RISE for Health is a health and economy public-private platform that identifies, catalyzes, and accelerates multisectoral collaborations that can be pursued on a voluntary basis to help bring about the resilient health ecosystems and economies that the Americas deserve. Americas RISE for Health works across five pillar workstreams: regulatory improvements, trade and investment, digital health, sustainable health systems, and ethics, to create a healthier more prosperous future for the Americas.

Learn more at [americasriseforhealth.org](https://americasriseforhealth.org)

<sup>4</sup> Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Jamaica, Mexico, Panama, Paraguay, Peru, and the United States  
The explanatory text on the benefits of regulatory convergence is sourced from the [APEC Regulatory Harmonization Steering Committee KPIs Infographic](#).