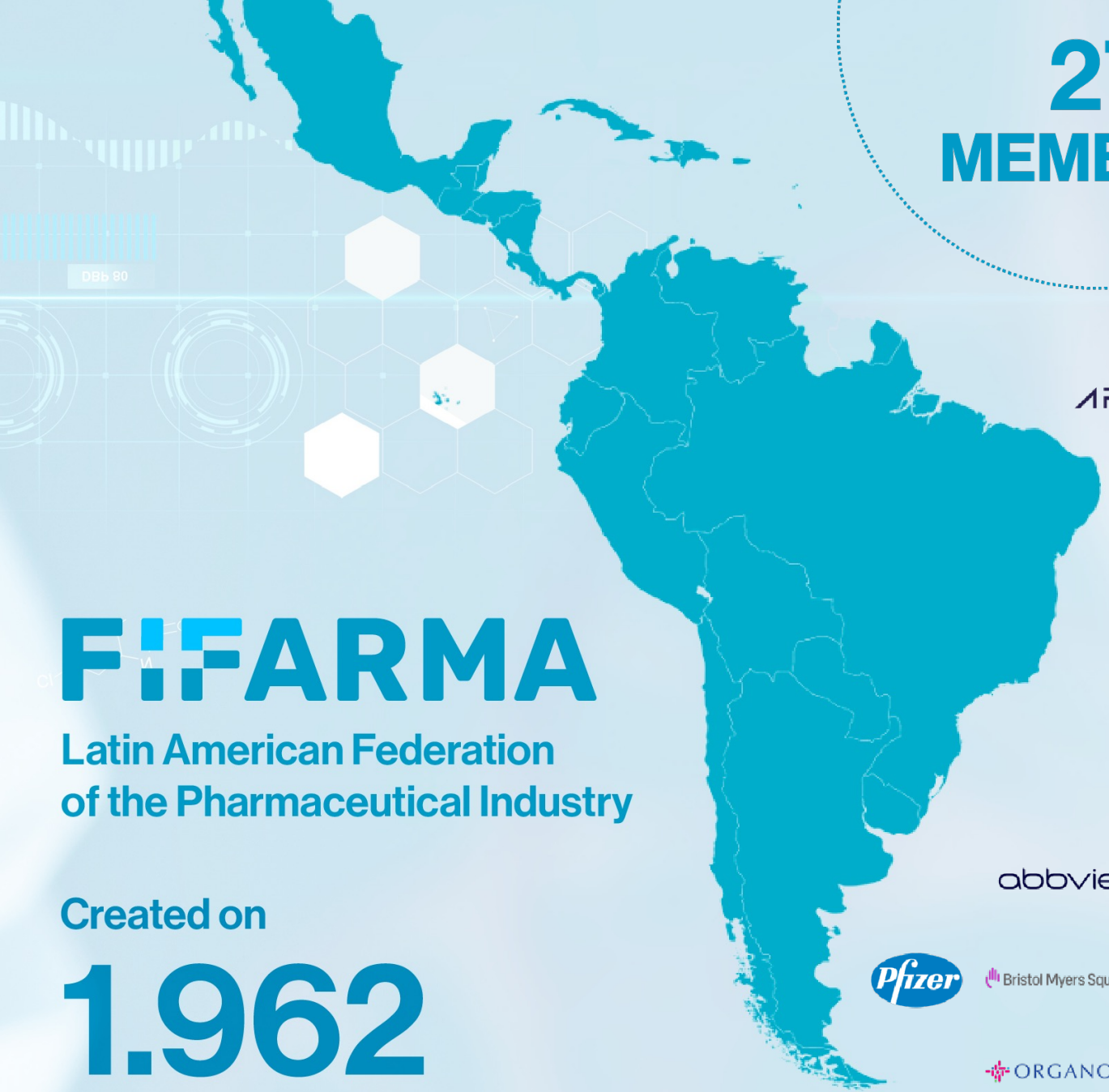
FIFARMA

LATIN AMERICAN FEDERATION OF THE PHARMACEUTICAL INDUSTRY

# Webinar - Implementation of Good Regulatory Practices



# 27 MEMBERS

## LOCAL ASSOCIATIONS • 11

AFIDRO · ALAFARPE · AMIIF Innovacion para la vida · ARAPF · CEFA Cámara de Especialidades Farmacéuticas y Afines

CAVEME Investigación para la vida · cif Cámara de la Innovación Farmacéutica · Fedefarma · Ifl

interfarma · caeme innovación para la salud

# FIFARMA

**Latin American Federation of the Pharmaceutical Industry**

**Created on**

# 1.962

## COMPANIES • 16

abbvie · AMGEN · astellas · AstraZeneca · Biogen

Pfizer · Bristol Myers Squibb · GILEAD · J&J · MERCK · MSD

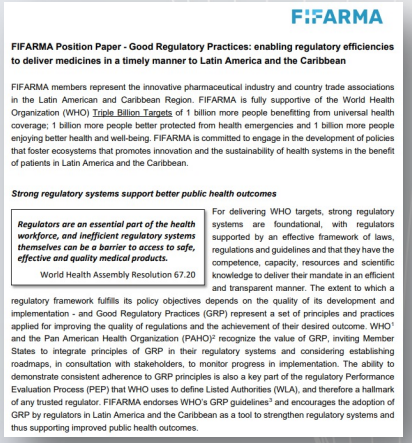
ORGANON · NOVARTIS · Roche · sanofi · Takeda

# GRP - Related activities in Latin America and the Caribbean

FIFARMA **supports the adoption of Good Regulatory Practices** as a tool to strengthen health systems in Latin America and the Caribbean, in order to achieve better health outcomes

**Strategic Objective**
Promote and support, in coordination with Local Associations, that Regulatory Authorities of the region advance in the implementation of GPR in the regulation of pharmaceuticals

1. GRP as a priority for the regional activities **Embedded in PAHO-FIFARMA Triannual Work Plan**
2. Support to local associations in activities with local regulators*
3. Participation in regional conferences and events
4. Collaboration with academia to develop a study on the experience of industry with the practical implementation of GRP by 8 countries in Latin America



FIFARMA

**FIFARMA Position Paper - Good Regulatory Practices: enabling regulatory efficiencies to deliver medicines in a timely manner to Latin America and the Caribbean**

FIFARMA members represent the innovative pharmaceutical industry and country trade associations in the Latin American and Caribbean Region. FIFARMA is fully supportive of the World Health Organization (WHO) Triple Billion Targets of 1 billion more people benefitting from universal health coverage; 1 billion more people better protected from health emergencies and 1 billion more people enjoying better health and well-being. FIFARMA is committed to engage in the development of policies that foster ecosystems that promotes innovation and the sustainability of health systems in the benefit of patients in Latin America and the Caribbean.

***Strong regulatory systems support better public health outcomes***

***Regulators are an essential part of the health workforce, and inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products.***
World Health Assembly Resolution 67.20

For delivering WHO targets, strong regulatory systems are foundational, with regulators supported by an effective framework of laws, regulations and guidelines and that they have the competence, capacity, resources and scientific knowledge to deliver their mandate in an efficient and transparent manner. The extent to which a regulatory framework fulfills its policy objectives depends on the quality of its development and implementation - and Good Regulatory Practices (GRP) represent a set of principles and practices applied for improving the quality of regulations and the achievement of their desired outcome. WHO[1] and the Pan American Health Organization (PAHO)[2] recognize the value of GRP, inviting Member States to integrate principles of GRP in their regulatory systems and considering establishing roadmaps, in consultation with stakeholders, to monitor progress in implementation. The ability to demonstrate consistent adherence to GRP principles is also a key part of the regulatory Performance Evaluation Process (PEP) that WHO uses to define Listed Authorities (WLA), and therefore a hallmark of any trusted regulator. FIFARMA endorses WHO's GRP guidelines[3] and encourages the adoption of GRP by regulators in Latin America and the Caribbean as a tool to strengthen regulatory systems and thus supporting improved public health outcomes.

**Position paper** "Good Regulatory Practices: Enabling regulatory efficiencies to deliver medicines in a timely manner to Latin America and the Caribbean"

## Future plans

- GRP Q&A document
- Face-to-face GRP workshop with regulators

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- DIGEMID – ALAFARPE (Peru). Reliance and GRP Workshop - June 2023.
- COFEPRIS - AMIIF (Mexico). Reliance and GRP Encounters with other Associations in March and September 2023.
- Central America NRAs – FEDEFARMA (Central America and Caribbean). Webinar on Reliance and GRP in June 2023.

# GRP- Related activities in Latin America and the Caribbean

**FIFARMA's Commitment to Increasing Regulatory Efficiency and Transparency:** Examples of Industry Practices

- Responsibly share clinical trial data, continuously collaborate with researchers, and facilitate public access to clinical trial results
- Collaborate with regulators to anticipate trends by providing information related to new technologies and best practices implemented by the regulated sector
- Training in globally recognized guidelines and standards
- Provide timely information to regulators on safety and quality issues
- Participate in pre-submission meetings to proactively provide input on product development


We are *the voice* of the R & D pharmaceutical industry in the region that work every day
to have better health
for Latin America
better health
better health
better health