



# **COMMITTED TO YOUR SUCCESS IN MEXICO**

From Concept to commercialization and Beyond

# WHO WE ARE



We are a global consulting firm that provides **Regulatory Affairs, Quality, Clinical** and **Safety services** to pharmaceutical and medical device companies worldwide.

With local Office in Mexico City and local team of regulatory affairs, medical, quality and pharmacovigilance professionals we provide tailored services to our clients in Mexico in compliance with the Federal Committee for Protection from Sanitary Risks (Cofepris) regulations, the Local Health Authority (HA) of Mexico.

## IN MEXICO

### WE ARE LICENSED

By COFEPRIS to:



1

Act as your Local Representative in Mexico and handle all your local regulatory, quality and pharmacovigilance activities.

2

Register your products in Mexico in compliance with COFEPRIS regulations and Standards.

3

Import, release, store and distribute your products in Mexico.

Our commercial team can help you define the perfect solution to access the Mexico market by providing the following services:

- ✓ Market-access Strategy
- ✓ Pricing & reimbursement strategies
- ✓ Application for pricing
- ✓ Quantitative & Qualitative market research
- ✓ Due-diligence and asset evaluation
- ✓ Evidence-based portfolio prioritization
- ✓ Review of Target Product Profile (TPP) and label claims
- ✓ Evidence and economic needs assessment and evaluation
- ✓ Commercial and marketing strategies



- ✓ Regulatory Strategy
- ✓ Regulatory Intelligence
- ✓ Registration of drugs and biologics
- ✓ Preparation of consultation meeting with HA
- ✓ DMF registration
- ✓ Medical writing
- ✓ Regulatory operations and publishing
- ✓ Orphan drugs designation
- ✓ Fast track application
- ✓ Preparation and submission of CTA
- ✓ Nutraceuticals and vitamins claims' review
- ✓ Nutraceuticals and vitamins formulation review
- ✓ Cosmetic packaging and labeling review & Registration



# SERVICES



Global Regulatory Partners develops the appropriate regulatory strategies that:

## CLINICAL

- ✓ Local sponsor service
- ✓ PI recruitment
- ✓ Contracts with sites
- ✓ Protocol development
- ✓ eCRF and EDC
- ✓ IRB approval
- ✓ Import investigational products.
- ✓ Site initiation meetings
- ✓ Monitoring of clinical studies
- ✓ Data management Statistics
- ✓ Clinical study report (CSR) writing
- ✓ GCP audits

## QUALITY

- ✓ Quality System Management (QMS) implementation
- ✓ Preparation for HA inspection
- ✓ Standard Operating Procedures (SOP) writing
- ✓ Quality manual writing
- ✓ Due diligence audits
- ✓ GXP quality audits
- ✓ CAPA management
- ✓ Mockup quality audits

## SAFETY

- ✓ Receipt, review, and coding of adverse events
- ✓ Safety reports writing
- ✓ Safety reporting to different health Authorities
- ✓ Good Vigilance Practice (GVP)
- ✓ Product safety profile writing and updates
- ✓ Post-Marketing Surveillance (PMS) Studies
- ✓ Safety annual reports
- ✓ Medical literature screening
- ✓ Health authority PV database monitoring
- ✓ Risk Management Reports writing & submission to HA

## REPRESENTATION

- ✓ Products registrations and lifecycle maintenance
- ✓ Application for products pricing
- ✓ Local product release
- ✓ Pharmacovigilance
- ✓ Recalls and complaints handling D Distributors selections
- ✓ Local Labeling
- ✓ DMF registration and maintenance



## Corporate Office

**Address:**

550 Cochituate St, East Wing, Suite 25, Framingham, 01701, MA

**Email:**

[info@globalregulatorypartners.com](mailto:info@globalregulatorypartners.com)

**Website:**

[www.globalregulatorypartners.com](http://www.globalregulatorypartners.com)

**Telephone:**

781.672.4200



### Brazil

Avenida Frei Caneca,  
no. 486  
Bairro Nossa Senhora  
das Graças  
Uberlândia-Minas Gerais  
(MG)  
CEP: 38402-282  
Telephone:  
(+55) 34-3235-1971

### Mexico

Lake Alberto 442 –  
5th floor  
Tower A – Office 509  
Col. Anahuac 1st  
Section  
Delegation Miguel  
Hidalgo, C.P. 11320  
Telephone:  
(+52) 55 7312 4169

### Japan

Toranomon  
40MT Buildings 7th  
floor  
Minato-ku, Tokyo,  
105-0001 Japan  
Telephone:  
(+81)-3-4530-9824

### China

Hang Seng Bank Tower 9F  
No.1000 Lujiazui Ring  
Road,  
Pudong District, Shanghai,  
200120  
Telephone:  
(+86) 021-517-27278