GLOBAL
REGULATORY PARTNERS

COMMITTED TO YOUR SUCCESS IN SOUTH KOREA

From Concept to Market

WHO **WE ARE**

We are a global consulting firm that provides **Regulatory Affairs**, **Quality**, **Clinical**, **Safety and local representation services** to pharmaceutical, biotech, Cosmetics and lifestyle consumer companies worldwide. **Global Regulatory Partners South Korea** has a local team of regulatory affairs, medical, quality and pharmacovigilance professionals we provide tailored services to our clients in South Korea in compliance with the Ministry of Food and Drug Safety (MFDS) regulations.

Please note that it is not possible for foreign companies to make administrative arrangements for issuing of pre-market approvals directly with MFDS. Foreign companies shall have partner companies legally constituted in South Korea that will be legally responsible for the products imported to and distributed in the South Korean territory.

IN SOUTH KOREA

WE ARE LICENSED

to act as your:

1

Act as your local representative in South Korea and handle all your local activities:

- **Regulatory Affairs**
- **Quality**
- **Pharmacovigilance**

2

Register your products in South Korea in compliance with MFDS regulations and Standards.

3

Import & releaser your products in South Korea.

REGULATORY **AFFAIRS**

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

PHARMACEUTICALS

- Regulatory Strategy
- Regulatory Intelligence
- Product Registration
- Preparation of consultation meeting with HA
- DMF registration
- Medical writing
- Regulatory operations and publishing
- Orphan drugs designation
- Fast track application
- Preparation and submission of Clinical Trial Application

MEDICAL DEVICES

- Regulatory Strategy
- Regulatory Intelligence
- Product Registration
- Preparation of consultation meeting with HA
- Medical writing
- Regulatory operations and publishing
- Orphan Device designation
- Fast track application
- Preparation and submission of Clinical Trial Application

COSMETICS

- Product Registration
- Ingredient and Formula Compliance Review
- Label Compliance Review

FOOD SUPPLEMENTS

- Product Registration
- Ingredient and Formula Compliance Review
- Label Compliance Review

SERVICES

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

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

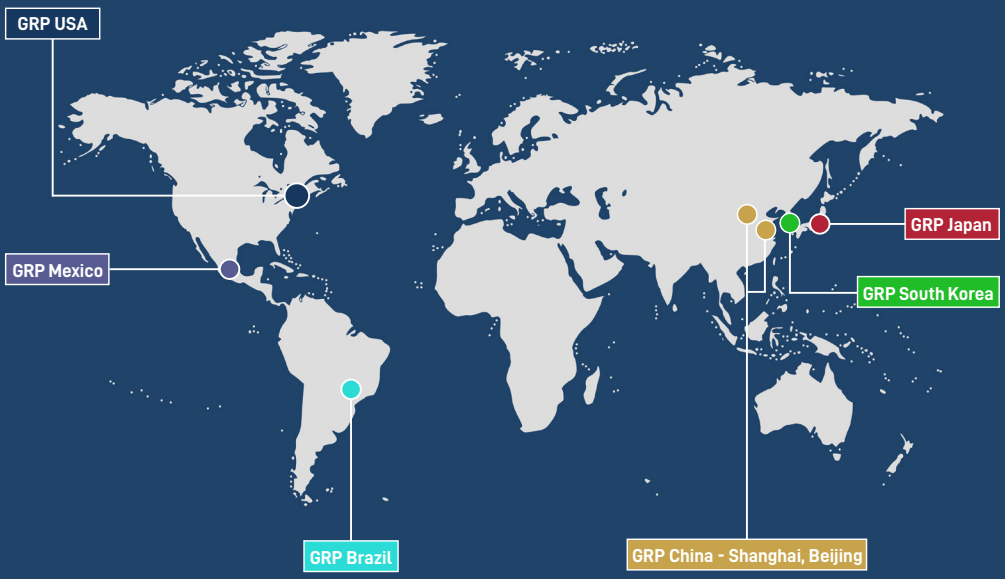
QUALITY

- 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

REPRESENTATION

- Products registrations
- lifecycle maintenance
- Application for products pricing
- Local product release
- Pharmacovigilance
- Recalls and complaints
- Communication with Health Authority

GRP LOCAL BRANCHES



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