GLOBAL
REGULATORY PARTNERS

COMMITTED TO YOUR SUCCESS IN JAPAN

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 Tokyo Japan and local team of regulatory affairs, medical, quality and pharmacovigilance professionals we provide tailored services to our clients in Japan in compliance with the Pharmaceutical and Medical Device Agency (PMDA) regulations, the Local Health Authority (HA) in Japan.

WE ARE LICENSED IN JAPAN

by the PMDA to:

1. **Act as your Local Representative in Japan** and handle all your local regulatory, clinical, quality and pharmacovigilance activities.
2. **Manage your your local clinical studies and PV needs** in line with PMDA requirements.
3. **Register your products in Japan** in compliance with PMDA regulations and Standards.
4. **Import and release** your products in Japan.

MARKET ACCESS

Our commercial team can help you define the perfect solution to access the Japan 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 AFFAIRS

- 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

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

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

GLOBAL
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