GLOBAL
REGULATORY PARTNERS

COMMITTED TO YOUR SUCCESS IN USA

From Concept to commercialization and Beyond

WHO
WE ARE

We are a global consulting firm Headquartered in Boston Massachusetts USA that provides Regulatory Affairs, Quality, Clinical and Safety services to pharmaceutical and medical device companies worldwide to register their product with the Food and Drug Administration (FDA) the local Health Authority (HA)

WE ARE AN EXTENSION
OF YOUR ORGANIZATION

IN USA WE ARE LICENSED
by the FDA to:

1. **Act as your Local Representative in USA** and handle all your local regulatory, clinical, quality and pharmacovigilance activities.
2. **Register your products in USA** in compliance with FDA regulations and Standards.
3. **Manage your your local clinical studies** in line with FDA equirements.
4. **Import and release** your products in USA.
5. **Get immediate and direct access** to our experts at anytime and anywhere in the world.

MARKET ACCESS

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