COMMITTED TO YOUR SUCCESS IN CHINA

FROM CONCEPT TO COMMERCIALIZATION

GLOBAL
REGULATORY PARTNERS

WHO WE ARE

Global Regulatory Partners is a consulting company that provides a full spectrum of regulatory affairs, quality, clinical and safety services to pharmaceutical and medical device companies worldwide.

With offices in Shanghai and Beijing we can be your local agent in china and handle all your regulatory affairs and compliance activities in China.

Our team of professionals has over 15 years of experience working with CFDA registering multiple drugs and medical devices in China for multiple life science companies and assisting them during the local testing of their imported products.

MARKET ACCESS

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

- Market-access, pricing, reimbursement strategies
- Due-diligence and asset evaluation
- Evidence-based portfolio prioritization
- Review of Target Product Profile (TPP) and label claims
- Economic needs assessment and evaluation
- Distributor selection
- Commercial and marketing strategies

SERVICES

REGULATORY AFFAIRS

- Regulatory Strategy
- Preparation of Meeting with CFDA
- Medical Device Registration
- Medical Device Classification
- Drug Registration
- Orphan Drug Application
- Medical Writing
- Project Management
- Drug and Medical Device Local Testing
- License Renewals
- Regulatory Compliance
- China Labeling Compliance
- Medical Device CCC Marking

QUALITY

- FDA and CFDA Inspection Preparation
- ISO 13485 QMS Audit and Gap Analysis
- ISO 13485 QMS Implementation and Monitoring
- ISO 13485 QMS Training
- QMS SOPs Writing and Implementation
- Quality Manual Writing
- Local Product Release

SAFETY

- Receipt, Review and Coding of Adverse Events
- Safety Reports to CFDA
- Post-Marketing Surveillance (PMS) Studies
- Development of Safety Data Base
- Safety Data Management

CLINICAL

- CRO Oversight and Management
- Clinical Trial Application (CTA)
- Clinical Trials for Medical Devices and IVD
- Pre-Clinical Investigation of Medical Devices
- Clinical Trial Protocol Design and Writing
- Clinical Trials Auditing and Quality Assurance
- Data Management and Statistical Analysis
- Clinical Studies Reports Writing

We offer the perfect solution for you in China

- Regulatory affairs and clinical services that meet your needs and fit your budget.
- Efficient product registration.
- Compliance with CFDA regulatory requirements.
- Quick access and extension into Chinese market without local investment.
- Effective commercial and marketing strategy for your products in China.
- Control of your product registration and license.

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