TAKING YOU TO NEW HORIZONS IN LIFE SCIENCE

GLOBAL
REGULATORY PARTNERS

WITH GLOBAL REGULATORY PARTNERS YOU WILL:

Get immediate and direct access to our experts at anytime and anywhere in the world.

Build flexibility in your operation by using our services as needed.

Respond quickly and efficiently to changing regulatory environments.

Focus on your core business and let us take care of the rest.

Extend your business globally with minimal risks.

WE ARE AN EXTENSION OF YOUR ORGANIZATION

At Global Regulatory Partners we provide **tailored** and **personalized** regulatory affairs, clinical, quality and safety services that meet your business needs.

GLOBAL
REGULATORY PARTNERS

SERVICES

REGULATORY AFFAIRS & CLINICAL

REGULATORY STRATEGY

Global Regulatory Partners develops the appropriate regulatory strategies that:

- Lead to a more predictable product development process
- Bring new products to the market faster
- Meet your business goals
- Maximize your progress toward success
- Reduce your risk of failure
- Help you respond quickly to the changing regulatory environment

PRE-MARKETING ACTIVITIES

- IND, CTA, IB, IMPD, IDE and PIP
- NDA, ANDA, BLA, MAA, CE Marking, 510(K) and PMA
- Fast track applications
- Orphan drugs application
- Annual report production
- Medical writing
- Regulatory project management
- CROs oversight and management
- CMC writing and compilation
- FDA and other health authorities meeting preparation

POST-MARKETING ACTIVITIES

- NDA, ANDA, BLA, MAA, 510(K), PMA and design dossiers amendments
- License renewals
- Line extensions
- Annual report production
- Post-approval commitments monitoring
- Advertising and promotional material review and approval

REGULATORY OPERATIONS & PUBLISHING

- Submission-ready documents creation
- Dossier lifecycle management and version control
- Thorough QA/QC of submission's dossier
- eCTD compilation and submission
- CSR publishing
- eCTD XML backbone creation
- SPL and PLR labeling conversion
- esubmission to FDA and Health Canada via gateway

QUALITY

GAP ANALYSIS AUDITS

Routine quality audits performed on regular basis as required by quality system regulation

QUALITY SYSTEM AUDITS

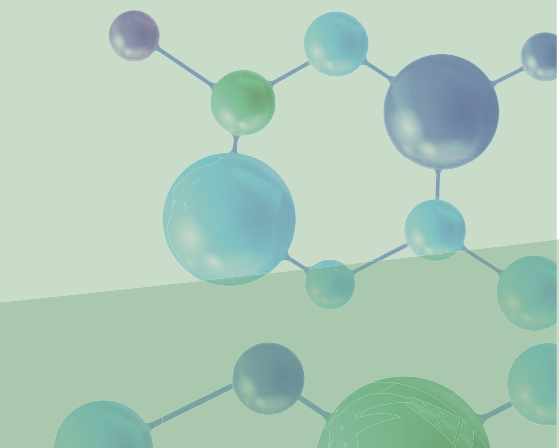
Audit performed against FDA CFR 820 and ISO 13485 as preparation for FDA quality system inspections and ISO 13485 certification by notified bodies

GMP AUDITS

Audits performed against FDA 21 CFR 211 as preparation for FDA current GMP inspections

DUE DILIGENCE AUDITS

Audits performed against predefined standards to identify non-compliances before acquisition, merger or licensing agreement



SAFETY

PRE-MARKETING SAFETY

- Receipt, data entry, review, analysis, coding and follow-up on serious adverse events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSAR) from clinical studies
- Safety input to protocols, clinical study reports and investigator brochures
- Safety data reporting to competent authorities, ethics committees and investigators

POST-MARKETING SAFETY

- Complaints collection, evaluation and review
- Medical safety assessment of individual case reports
- Adverse events reporting to health authorities
- MedWatch 3500A reports completion and submission
- PSUR preparation and submission
- Medical literature screening
- Health authority PV databases monitoring
- Products safety profile building and continuous updating

With offices in the United States, Europe, Latin America and Asia, Global Regulatory Partners can meet your regulatory affairs, clinical, quality and safety needs anywhere in the world.

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