COMMITTED TO YOUR SUCCESS

FROM CONCEPT TO APPROVAL

Early to mid-stage life science companies

GLOBAL
REGULATORY PARTNERS

WE ARE AN EXTENSION OF YOUR ORGANIZATION

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

GLOBAL
REGULATORY PARTNERS

WITH US YOU…

Respond quickly and efficiently
to changing regulatory environments.

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

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

Extend your business globally
with minimal risks.

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

Access investment sources
to finance your product development from concept to approval.

SERVICES

REGULATORY AFFAIRS

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 drug applications
- 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

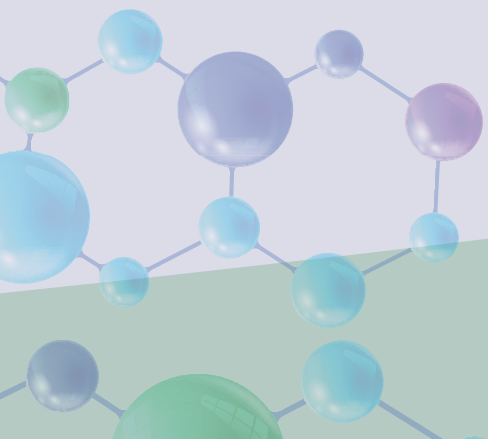
REGULATORY OPERATIONS & PUBLISHING

- 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

CLINICAL

Full-service management of national and/or international multi-site trials of pharmaceuticals, biologics and medical devices:

- Protocol development
- Site and investigator identification and qualification
- Site initiation and training
- Clinical monitoring
- Medical monitoring
- DSMB coordination
- Statistical analysis
- Electronic data capture
- Electronic Trial Master File
- Full service data management
- ClinicalTrials.gov registration and management
- Central lab oversight and coordination
- Site quality assurance audits
- Integrated final Clinical Study Report



SAFETY

Complete pre-marketing and post-marketing Safety services:

- Safety input to protocols, clinical study reports and investigational brochures.
- Safety reporting to competent authorities, ethics committees and investigators
- Medical safety assessment of individual case reports
- DSUR preparation and submission
- Medical literature screening
- Health authority PV database monitoring
- Products safety profile building and continuous updating

QUALITY

Complete Quality services to be and stay in compliance:

- GAP Analysis Audits
- Quality System Audits
- GMP Audits
- Due Diligence Audits
- FMA (Japan)
- SOPs

globalregulatorypartners.com

GLOBAL PRESENCE

GLOBAL
REGULATORY PARTNERS

400 Fifth Avenue, Suite 115, Waltham, MA 02451

781.672.4200 info@globalregulatorypartners.com globalregulatorypartners.com