WELCOME

RegEnd Solutions

Who we are

RegEnd Solutions is an established venture founded by team of experienced professionals of pharmaceutical industries who will provide end to end solution to your regulatory needs.

More than 13 years of experience in field of Regulatory affairs, we, as an individual have established ourselves as an expert in various regulatory activities and serving the markets worldwide. A passionate team of dedicated people with clear vision, accurate planning and immaculate execution process help client for early access of the market of the product by providing tailored made solutions and diverse regulatory tactics.

RegEnd Solutions

About us

Mission

- To maintain high standards of business ethics and good management practices.
- To emerge as a caring regulatory service provider for all its constituents.
- To help client for early access of the market through diverse regulatory tactics.
- Quality deliverables of services and adhering strictly to our values.

Vision

- To carve its mark as a distinguished entity in the field of regulatory consultancy with its principles and customers promising swift service everywhere and to cultivate an environment of excellence, entrepreneurship and team work for its members.

RegEnd Solutions

SERVICES we offer

Regulatory Services

- Regulatory Affairs
- Publishing and Submission
- Regulatory strategy
- Regulatory medical writing
- Regulatory labelling

Legal and Patent Services

- Patent searches with analysis report and Legal opinion
- Patent Analysis Reports
- Patent Drafting, Filing & Prosecution

Toxicological Assessments Services

- Pharmaceutical and Chemical industries

GXP Compliance

- Good Manufacturing Practice
- Good Clinical Practice
- Good Laboratory Practice

RegEnd Solutions

SERVICES we offer

Regulatory Affairs - USA

Pre-Submission:

- Controlled correspondences
- Meeting requests with agency
- Pre-submission activities like (facility identification, request for DUNS/FEI /ANDA Application numbers)
- Gap analysis of source data for dossier compilation/preparation

Submission Phase:

- Application submission (505j,505(b)(2))
- Preparation, review and submission of applications in line with refuse to receive (RTR) requirements.
- Structured Product Labelling (SPL) preparation and review
- Submission management through FDA ESG portal

Post-Approval:

- Transfer of ownership application
- Any changes to existing Dossier – Annual Report Filling
- Change being effective in 0 Days – CBE0
- Change being effective in 30 Days – CBE30
- Prior approval supplement – PAS

RegEnd Solutions

SERVICES we offer

Regulatory Affairs - EUROPE and United Kingdom:

Pre-submission:

- Dossier submission strategy
- Scientific advice
- Reference product evaluation
- Due diligence support
- Product information preparation (QRD)
- Orphan drug registration
- Brexit support

Submission Phase:

- Review, Preparation and Submission of MAA (MRP/DCP/CP/Reliance/RUP/Duplicate)
- Regional guidance/support as and where applicable.
- National phase management.

Post Approval Phase:

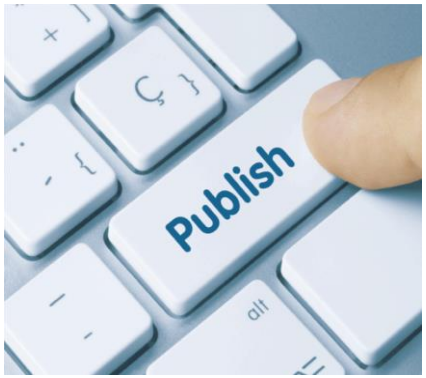
- Variation support (Type IA/IB/II), MAT application
- Line extension application
- Labelling management
- Sunset clause application
- Renewal application

RegEnd Solutions

SERVICES we offer

Regulatory Strategy

RegEnd solutions provides end-to-end Regulatory solutions and services.
With good understanding of global life science industry and regional Regulatory pathway, RegEnd assist organizations to define successful strategies for different Regulatory authority submission to get quick market approvals.



Publishing and Submission

Submission in electronic format becomes the mandatory tool for all regulated countries along with some of semi regulated countries.

RegEnd solutions ensures error free Regulatory submission with utmost quality for each region wise specific requirement and format.

RegEnd Solutions

SERVICES we offer

Regulatory medical writing

Medical writing is a critical segment of clinical research. With a team of experienced medical writing professionals from pharmaceuticals and clinical research industries, **RegEnd Solutions** provide quality clinical documents in described format by Regulatory authority.

Regulatory labelling

RegEnd Solutions has qualified personal who prepare and review of product labelling requirement for submission to the Regulatory authority.

RegEnd Solutions

SERVICES we offer

Legal and patent services

Patent searches with analysis report and Legal opinion include

- Prior art searches for patentability
- Prior art searches for invalidation
- Searches for Infringement
- Freedom to operate / practice (FTO)

Patent Analysis Reports

- Preparing patent invalidation strategies
- Providing Invalidation opinion report
- Patentability search reports
- Preparation of Infringement analysis report
- Suggestive analysis including Proposing Patent design around strategies

RegEnd Solutions

SERVICES we offer

Legal and patent services

Patent Drafting, Filing & Prosecution

- Drafting provisional & complete patent specifications as per Indian and as well International standard
- Filing and prosecuting applications at the Indian Patent Office and under the PCT includes Response to Office Action, Patent hearings, Pre Grant Opposition, Post Grant Opposition and other proceedings.
- Filing and prosecuting applications internationally in association with foreign attorney
- Convention Patent Filing in other countries
- PCT National Phase Application
- Convention Patent Application in India

Non patent literature searches include

- Prior art searches for patentability
- Prior art searches for invalidation

RegEnd Solutions

SERVICES we offer

Legal and patent services

Preparation and assistance to foreign attorney for Paragraph IV certifications and section VIII statements for US market.

Patent Maintenance and Tracking all activities after patent filed

- Form 3 updation to IPO
- Reminder for all upcoming activity
- Portfolio Management
- Patent Journal watch services
- Patent renewal
- Patent Working statement
- Foreign Filing License
- IP strategy for Pharmaceutical Products

RegEnd Solutions

SERVICES we offer

Toxicological Assessments Services

RegEnd Solutions provide services for preparation of toxicological assessment report as per the Regulatory authority requirement. We have expert personals having wide experience in toxicological department in various institution.

Pharmaceutical and Chemical industries

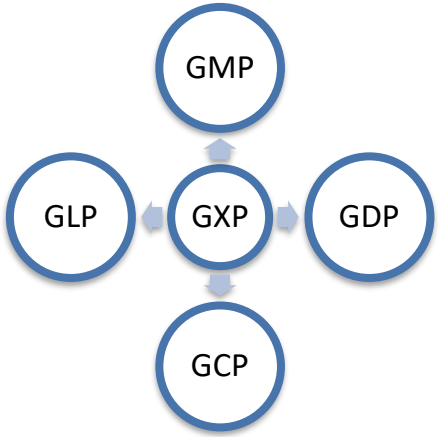
- PDE/ADE Monographs
- Risk Assessment of impurities in Pharmaceuticals
- Toxicology literature search
- Manual material safety data sheet (MSDS)
- Chemical Hazard and Risk Assessment
- Genotoxic Impurity Risk assessment in Pharmaceutical Products
- Literature Search Report

RegEnd Solutions

SERVICES we offer

GXP Compliance

RegEnd Solutions has team of expert professionals who performs third party evaluation (Gap analysis) of pharmaceutical manufacturer. We offer a full range of services in GCP, GLP and GMP compliance from development through commercialization. We help pharmaceutical company to implement comprehensive CAPA and prepare them for various Regulatory authority inspection.



RegEnd Solutions

WHY partner with us?

We work together closely with client to strategize the submission pathway of the product, and provide complete regulatory solution throughout the lifecycle management, such as due diligence of dossier, regulatory strategy preparation, module writing, agency submissions, assessment phase support and Post approval activities. We help client to implement the regulatory updates in timely manner and ensures that the applications remain up to date as per regulatory perspective.

Few key philosophies to which RegEnd team believes ….

- Uniting science with regulatory to achieve goal
- Leveraging strong industry experience & expertise to provide best solution for client's regulatory needs.
- Serving the healthcare fraternity with customized registration pathways.
- Helping to launch the products in shorter time span.
- Compliance to regulatory norms.

RegEnd Solutions

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