Industry knowledge, Process expertise Working for you.....

TRAINED, EXPERIENCED RESOURCES & CUSTOMISED, TIME TESTED PROCESSES AT EACH PHASE OF PROJECT IMPLEMENTATION

Regulatory Services

Vyomus Consulting is a Regulatory Science and Product Development Consulting firm, serving Business to Business (B2B) Customers in highly regulated industries. Our services help Biopharmaceuticals, Medical Devices, Diagnostics, Cosmetics & Wellness, Food & Nutrition organisations Commercialise products, Reduce time to market, Achieve compliance and Grow their business efficiently and effectively.

Integrating Science, Regulations and Business outcomes, at Vyomus, our experienced senior regulatory professionals offer expert consulting and approach regulatory issues and processes in a innovative way to provide business solutions to operational problems.

We design, develop and implement distinctive and compelling regulatory strategy to facilitate execution of smart and effective regulatory approval projects by working hand in hand with operational teams and organisations involved in drug discovery and development – right from discovery leading to commercialization.

We anticipate pitfalls before they occur, outline a clear pathway for advancement, and maximize your investment and program success.

Our expertise services can begin early in development with preparation for filing the initial regulatory submission (such as review of existing data and filing an IND/CTA/NDA/CTD/eCTD) and can continue through product launch. Post-marketing regulatory services include post-approval periodic reporting as well as managing developmental programs for new or extended indications, new dosage forms, variations, renewals.

The Regulatory team at Vyomus is flexible to fit your needs. We can provide selected or comprehensive services as required to meet your specific program needs.

Regulatory Consulting Services

STRATEGY

- Due diligence & gap analysis
- Regulatory strategy development
- Project management

STUDY APPROVALS

- Preclinical approvals
- Clinical Trial (Phase I to III) approvals
- INDs , NDA's
- Drug, Site Master Files
- Electronic publishing (CTD's, eCTD's)

MARKET AUTHORISATIONS

- Marketing Authorizations NDAs, BLAs)
- Import and marketing (NEW DRUG)
- Manufacturing and marketing
- Drug, Site Master Files

POST MARKETING APPROVALS

- Safety reporting (PSUR's)
- New indications
- Variations and Renewals
- Export, Product Registration dossiers

Industry Focus

- Biopharmaceuticals, Medical Devices & Diagnostics, Cosmetics & Wellness, Food & Nutrition;
- Biologicals, Vaccines, rDNA products, Small molecules, Biotechnology products, NBE's, NCE's, NME's, API's (Chemistry & Biotechnology) Generics and Formulations;

Customer Focus

- R & D (Ideation & Development), Manufacturing, Marketing, Service Providers;

Business Focus

- Start-ups, Small Businesses, Medium Businesses, Large Businesses;

Why Vyomus ?

- Overall experience includes over 400 preclinical, clinical trial(I to IV) approvals, product registrations, marketing authorisations, import and marketing authorisations, covering a large number of therapeutic and product categories,
- Project manager lead customer focus teams,
- **Improved drug development productivity, risk mitigation, increased revenue.**

Vyomus® Consulting

Regulatory & Commercialisation Experts

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