

Regulatory Expertise for Business Success in India!



Optimus Pharma Consulting specializes in providing customers with expert solutions for the development of Therapeutics and Medical Technology (MedTech) based Products in India.

We provide Regulatory, Product Development expertise and resources through all stages of product development to enhance submission preparation and achieve faster product approvals leading to enhanced access to Markets and Opportunities.

Committed to Your Success !

We want your projects and your business to succeed !

We listen to your concerns, understand challenges, pay attention to details, give you the required expert advice and information while working with you to help reach your goal(s).

Developing and Implementing an optimal regulatory strategy is critical for efficient product development and successful approval of products. Optimus has significant experience in helping customers understand regulatory requirements along with developing and implementing regulatory strategies leading to first-cycle approvals in India.

Integrating Science, Regulations, Measurable Business outcomes and combining local knowledge with global standards, our team moves beyond providing expert advise to get your project off the ground, move at a fast pace and achieve faster product and product development approvals.

BETTER THE ROADMAP FASTER ONE GETS THERE !

Whether your company is global or a start-up, we provide the help you need for faster access to local Markets and Opportunities.

We have expertise with all products and development activities regulated by various Indian regulators.

We help you succeed throughout the product Lifecycle:



Service Focus

REGULATORY INTELLIGENCE

- Product specific requirements
- Precedents & current thinking
- Product specific RI Status Document

REGULATORY STRATEGY

- Scientific & Regulatory assessment
- Product Development Plan
- Regulatory Strategy & Roadmaps
- Risk Plans

REGULATORY SUBMISSIONS

- Preclinical & Clinical Development Plans
- Protocols, Investigator Brochures
- CTA, IND, BLA, NDA, MAA, CTD, DMF
- Approval, Maintenance

PROJECT MANAGEMENT

- Project Management Plan
- Outsourcing - identify, manage, optimise
- Analyse & optimise performance

ON-DEMAND CONSULTING

- Regulatory insight & Clarifications
- Strategies & Solutions
- Product Development Process optimisation
- Education and training
- Compliance Audit services

PRODUCTS

- Biologicals, Vaccines
- Pharmaceuticals
- Advanced Therapeutics
- Generics & OTC
- Veterinary Products
- Medical Devices
- Nutraceuticals
- Cosmetics
- Diagnostics
- Insecticides & Pesticides

Expert staff and over 50 years experience put to work for you and your company

We understand the Regulated Industry.

We at Optimus have a thorough understanding of regulations governing industries that manufacture and market medicine (Rx/OTC), biologics, medical devices, blood products, cosmetics, animal drugs, dietary supplements, food, and colors.

Our experienced senior regulatory professionals offer expert consulting and approach regulatory issues and processes in an innovative way and guide your organization throughout the life cycle of your regulated product.

Our overall experience includes over four hundred preclinical, clinical trial approvals, product registrations, marketing authorizations, import and marketing authorizations, manufacturing and marketing authorization and transactions covering a large number of therapeutic and product categories.

BETTER THE ROADMAP, FASTER ONE GETS THERE !

Science based perspective measured on Business Outcome

Our unique blend of science based backgrounds, business and pharma technology coupled with an in-depth knowledge of regulatory requirements and their local interpretations enable us to effectively analyze your regulatory concerns and provide you with optimized, practical solutions.

The business consulting approach and impeccable process implementation and delivery practices ensure that optimal business solutions are implemented to achieve specified, measurable business objectives.

Visit our homepage for more info :

<http://www.optimuspharmaconsulting.com/regulatory.html>



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OUR company

Optimus Pharma Consulting specializes in providing regulatory and product development advise to manufacturers and marketers of biopharmaceutical products used in prevention, cure and diagnosis of diseases.

Our team consists of experts in regulatory affairs, product development (medicines and devices), pharmacology, toxicology, preclinical and clinical trial design and evaluation, biostatistics, formulation development, each with extensive product development experience.

We are thus able to provide regulatory, product development consulting services through all stages of product development to enhance submission preparation and achieve faster product approvals leading to enhanced access to Markets and Opportunities.

OUR services

Product Registration (Medicines, Medical Devices)

Product Development (Medicines, Med. Devices)

Regulatory Submissions (Pre and Post)

Regulatory Intelligence

Product Labelling (Medicines, Medical Devices)

On-Demand Consulting

Regulatory Project Management

Regulatory Compliance

Avoid wasting time and money with our expert help, contact us :

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