

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

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

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

Our team consist of former FDA officials & industry executives who have deep knowledge & More than 20 years of experience in your industry , it moves beyond providing expert advice to get your project off the ground, move at a fast pace and achieve faster product and product development approvals.

Our Services include:

REGULATORY INTELLIGENCE	REGULATORY STRATEGY	REGULATORY SUBMISSIONS	ON-DEMAND CONSULTING	PROJECT MANAGEMENT
Product Specific Requirements	Scientific & Regulatory Assessment	Preclinical & Clinical Development Plans	Regulatory insight & Clarifications	Project Management Plan
Periodic Regulatory Updates	Product Development Plan	Protocols, Investigator Brochures	Strategies & Solutions	Outsourcing - identify, manage, optimise
Precedents & Current thinking	Regulatory Strategy & Roadmaps	Dossier Preparation (For all kind of submissions)	Product Development Process optimisation	Analyse & optimise performance
Product specific Status Document	Risk Plans	Review, Approvals, Maintenance	Compliance Audit Services	Education and training

We at Entellus have a thorough understanding of regulations governing industries that manufacture and market medicine , biologics, medical devices, blood products, cosmetics, animal drugs, dietary supplements, food.

PRODUCTS : All Products and Product Development Activities regulated by various Indian Regulators (Eg : Biologicals, Vaccines, Pharmaceuticals, Advanced Therapeutics, Generics & OTC, Veterinary Products, Medical Devices, Food & Nutraceuticals, Cosmetics, Diagnostics)

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.

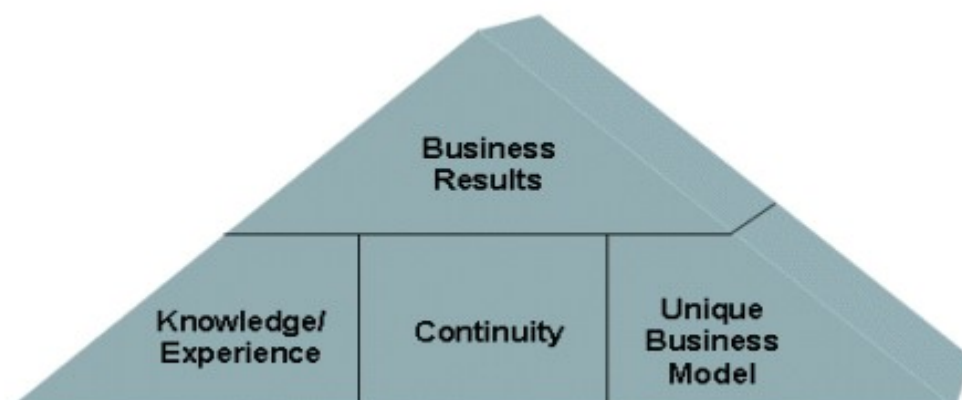
We anticipate pitfalls before they occur, outline a clear pathway for advancement, and maximize your investment and program success. Our regulatory group specialises in rescuing regulatory projects which need specific consultation in restructuring, re-strategising and or re-implementing.

Our expert services can begin early in development with preparation for filing the initial regulatory submission (Dossier Preparation For all kind of submissions)) 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 Services team at Entellus is flexible to fit your needs. We can provide selected or comprehensive services either from our facility or onsite at your facility as required to meet your specific program needs.

4-Why Entellus Food & Drugs Regulatory services?

We believe that you should choose Entellus Food & Drugs Regulatory Services. for the four following reasons:



First, we have extremely deep experience and knowledge in your industry and on your issues.

Our team consist of former FDA officials & industry executives who have deep knowledge & experience in your industry

Second, we focus on developing long-term relationships and creating continuity with our clients.

We are believes in performance and achieving the results & maintain the high standards and integrity so why our Clients feels to develop long term relationships.

Third, we have an innovative business model that minimizes risk and maximizes value for our clients.

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Fourth, we have demonstrated success in helping our clients reach their goals.

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