Consulting Practice

Go to Market Case Study

Vyomus® Consulting
Regulatory & Commercialisation Experts

Case Study

Client

A business conglomerate based start-up, wanted to launch a patented, chemistry based New Drug Product in the Indian market and then extend this launch to penetrate the European and US markets.

Challenge

The CEO was challenged by management to provide a strategic regulatory development pathway to conduct proof of concept, pivotal studies (Preclinical and Clinical) which could be used to garner marketing authorizations in India, Europe and the US.

Solution

Vyomus Consulting (Vyomus) provided Strategic Regulatory Consulting services and assisted the customer by creating a regulatory development roadmap for a global presence of the patented product. The following approach was executed :

- Vyomus created a team of senior regulatory practitioners (with experience in registering products in Indian, Europe and the US) under a Project Manager who acted as the point of focus for this engagement
- Vyomus assisted the customer in identifying the optimal regulatory development strategy and the exact regulatory and clinical categorization of the product which would facilitate a faster regulatory review and approval
- Vyomus assisted the customer in creating a Risk Mitigation Matrix based on both internal and external factors which could affect the proposed regulatory development strategy.

Results

Vyomus delivered a detailed Project Plan which indicated the steps (preclinical, clinical, regulatory, formulation development, manufacturing) required to implement this strategy and associated timelines and budget details required to garner regulatory approvals.

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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.