Regulatory Practice

Marketing Authorisation Case Study

Vyomus® Consulting
Regulatory & Commercialisation Experts

Case Study

Client

An India based marketing company wanted to leverage the USP of a Multinational Product and introduce an innovative treatment segment in the Indian market for the first time.

Challenge

Their previous vendor had created extreme challenges by not categorizing the product appropriately and by not delivering regulatory documents within committed deadlines even after unreasonable extensions.

The Indian partner of this JV Firm was challenged by management and the markets to get the product to the market at the earliest and hence Vyomus was asked to rescue the project and help bring the product to market at the earliest.

Solution

Vyomus Consulting (Vyomus) was engaged to provide Regulatory Consulting and Project implementation services to assist the customer in bringing the product to the market at the earliest. The following approach was executed :

- Vyomus assisted the customer in identifying the optimal regulatory strategy and the exact categorization of the product which facilitated Indian regulatory authorities to reconsider the market authorization application
- Vyomus also conducted an audit of all Preclinical, CMC and Clinical information available on file and identified gaps.
- Vyomus assisted the manufacturer and the marketing organizations in generating the required information to fill the identified gaps
- Vyomus compiled the regulatory submission dossiers in-line with agreed upon submission strategy and according to regulatory requirements.

Results

Vyomus Consulting assisted the customer in registering his manufacturing sites (outside of India), garnering Import and Marketing Authorisations for a product which was rejected during its initial submission.

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