

# Faster Access to Markets & Opportunities...

**KNOWLEDGE, EXPERTISE, METHODOLOGY AT EACH PHASE OF PLANNING & IMPLEMENTATION TO MOVE YOUR PROGRAM FORWARD SUCCESSFULLY**

Authorised Agent



## India Authorized Representative

In order to legally register, import and market, sell medical products in India, a foreign manufacturer needs to be compliant to Indian regulations and legislation. When a company does not have a registered and physical office with statutory personnel and required licenses in India, a legal India Authorized Representative / Agent with the above, needs to be formally appointed.

Vyomus will represent your organization as your official Indian Authorized Representative / Agent in accordance with India applicable regulatory legislations. Only one Indian Authorized Representative office is needed for the whole country. Vyomus will represent you legally in India without any commercial conflict of interest activities like product distribution, product marketing, product sales etc.

## Retain full control over product distribution

Many product distributors are happy to take on the role of an official Indian Authorized Representative. This relationship would curtail the manufacturer's ability to work with multiple distributors in India or change distributor/s due to performance challenges.

Since the appointed India Representative is identified on the CDSCO product registration documents and tied to the manufacturing site and product approval for its three year duration, if a distributor is appointed as the authorized representative, this relationship cannot be changed at least for a period of three years.

The India Authorized Representative, through a legal Power of Attorney executed by the manufacturer, is authorized to submit product registration documents and act as a point of contact for any inquiries related to the product by the CDSCO. The Representative is also involved in vigilance activities and acts on the manufacturer's behalf if an onsite inspection of the manufacturer's facility is required.

## WHAT WE DO :

### AUTHORISED AGENT SERVICES

- Provide and maintain a registered and physical legal office with statutory personnel and required licenses in India
- Provide authorization to place our name, local mailing address and phone/fax numbers on your product submissions and registrations to the CDSCO;
- Upon request by the CDSCO provide information about your products, and names and addresses of Indian distributors;
- Assist in coordination of an inspection if CDSCO selects your manufacturing site for an inspection/audit.

### ADDITIONAL SERVICES

- Regulatory Strategy Consulting and Liaison
- Complete Product Life Cycle Management
- Compilation of India specific submission dossiers
- Submission management leading to approvals
- Labelling and Patient Information / Instructions for use leaflets
- Post marketing services including Complaint handling, Adverse incident reporting and product recall support as part of Product safety reporting, Query management, PSUR Writing & Submission activities
- Act as your India Regulatory Department by Applying and Maintaining required Authorizations, Prepare and review regulatory submission material for compliance to India legislation etc.,

## Why Vyomus ?

- Provides, localized strategic and process expertise to attain business competitiveness - delivering faster, quicker, approvable projects
- Projects tracked in real time, delivered on schedule within agreed service levels - reducing development costs
- Faster design, planning and implementation processes - leading to increased ROI.



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Regulatory & Commercialisation Experts

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