

## **India Authorized Agent Representative for | medical device Companies**

Entellus Food & Drugs Regulatory Services Pvt. Ltd. representing medical device companies with no registered location in India must appoint an agent responsible for pre-certification and post-market surveillance inquiries. The Indian Agent must be a resident of India OR maintain a place of business there. Our office in Delhi (India), Entellus FDRS Pvt. Ltd. can act as your India Authorized Agent.

### **Responsibilities of the India Authorized Agent representative.**

The India Authorized Agent is a person/company responsible for Product registrations, acting as the liaison between the manufacturer and the CDSCO (Central Drugs Standard Control Organization). Foreign manufacturers of Products that are on the list of regulated products must appoint an Indian Authorized Agent.

The India Agent has significant responsibilities and is also legally liable for the product in India. The extent of responsibility is very different from the role of the "US Agent" representative required by the United States FDA. The India Authorized Agent is granted, through Power of Attorney by the manufacturer, authorization to submit Product registration documents and act as a point of contact for any inquiries related to the Product by the CDSCO. The Agent is also involved in vigilance activities and acts on the manufacturer's behalf if an onsite inspection of the manufacturer's facility is required.

### **Independent representation gives you full control over distribution.**

Before selecting Entellus FDRS Pvt. Ltd. as their independent in-country representative, some clients have considered appointing a distributor to serve as their Agent. Many distributors are happy to take on this role because they are fully aware that the appointed India Agent is identified on the CDSCO Product registration documents and tied to the product approval for its three year duration. That means if you appoint a distributor as your Indian Agent, you are "married" to them for at least three years. This can be problematic because if you decide to switch distributors because you will need to start the registration process over.

### **Medical Distributor Search and Evaluation:**

Entellus FDRS Pvt. Ltd. can assist you with identifying and evaluating medical device distributors across major regional market in India. We can also manage your ongoing distribution partner relationship when it comes to issues such as contract negotiations or validating agreed-upon services.

Entellus FDRS Pvt. Ltd. is a professional, independent in-country representative that specializes 100% in regulatory compliance. Appointing us as your Indian Agent allows you to select and change distributors whenever you wish. As noted above, it is also important to understand that the India Authorized Agent is responsible for your Products in India and therefore it is extremely important to be represented by a professional firm that specializes in regulatory issues and whose interests do not conflict with your company.

### **Tasks we perform as your India Authorized Agent**

As your officially designated India Authorized Agent representative, Entellus FDRS Pvt. Ltd. will:

- Provide authorization to place our name, local mailing address and phone/fax numbers on your Products submissions and registrations to the CDSCO;
- Upon request by the CDSCO provide information about your Products, and names and addresses of distributors established in India;
- Assist in coordination of an inspection if the CDSCO selects your company for an audit.

We are also available to perform a wide range of additional tasks such as post market surveillance including complaint handling, adverse incident reporting and product recall support. Entellus FDRS Pvt. Ltd. has been representing | medical device | Diagnostics | Cosmetics | Pharmaceuticals | Biological | Vaccine | Advanced Therapeutics | companies as a professional independent in-country representative and we are ready to act as your representative in India Market.

**Please contact us for additional information or a free proposal on India Authorized Agent representation services.**

### **Annexure- I**

#### **1.Responsibilities/Services of the India Authorized Agent representative.**

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### **Let us help you find and evaluate the best medical distributors in India.**

We help you identify and qualify appropriate medical distributors and marketing partners all over India. Our approach is systematic and effective. First, we develop a detailed medical distributor profile based on your needs. Starting with our local market networks and databases, this helps us quickly narrow the field of potential distributors throughout India. Next, we contact these distributors, introduce your company and provide product information, pricing, and samples (if applicable).

Interested medical device distributors will be interviewed, asked to provide details on how they intend to launch your products, and will be checked for references. Ultimately, the decision of which medical distributors to select is up to you but we can assist you at every stage of the process

### **Ongoing medical distributor management in India.**

Depending on your needs and local presence, we are also available to manage your ongoing relationships with your medical distribution partners in India. For instance, we can assist with contract negotiations or monitoring of your distributors to ensure that they are promoting your products as agreed. Our local office can also inform

you about new competing products entering the Indian market. We can have as much or little involvement as you need.

### **Benefits of Independent regulatory representation**

In the rush to introduce a new product, many companies give little thought to the appointment of their in-country regulatory representative and appoint a distributor to fulfill this important role. This can be a costly mistake.

### **Considering appointing a distributor as your in-country representative? Read this first.**

1. In markets such as India, the in-country regulatory representative controls the Product approval and/or Product registration. If you appoint a distributor to this role instead of an independent regulatory representative, switching distributors becomes extremely difficult and may require starting the product approval process all over again if your distributor is not willing to cooperate. This can be extremely expensive as you would not be able to sell in the market until re-registration is completed. You would also be required to pay a new registration fee.
2. In many markets your technical documentation, labeling, manuals and other information must include your in-country representative's name and address. If you elect to use a distributor and then decide to switch distributors, you will need to reprint labels, manuals, and deal with the issue of products already in the marketplace with that distributor's name on them. Plus, distributors do not like to see other distributor's names on your labeling.
3. Most distributors are not aware of the role of an in-country representative and the mandatory responsibilities that come with it and often elect to take on this responsibility to maintain control over your device on the market from a commercial point of view.
4. A conflict of interest may occur in the event of recall and/or incident reporting between you (the manufacturer) and the distributor. If the regulatory authorities question an incident or a non-compliance that occurred in the distribution system, will your distributor defend their company or yours?
5. The distributor is focused on sales and marketing, not on regulatory affairs. They may not keep you up-to-date on regulatory changes in the market and provide timely warnings when changes affect your Product.

**For more information email us on [vipin.kumar@entellusdrs.com](mailto:vipin.kumar@entellusdrs.com)**

**please visit our site on [www.entellusdrs.com](http://www.entellusdrs.com).**

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