CliniExperts | Your Regulatory Partner

Drug and Medical Device Regulatory Dynamics in India – CliniExperts is Acing the Ace

Following the firm's win of Best Pharmaceutical & Medical Devices Regulatory Solutions Provider for 2023, we heard from CEO Dr. Ashwini Kumar.

Dr. Ashwini Kumar, CEO of CliniExperts Services Pvt. Ltd.

With a decentralised framework engaging both federal and state authorities, and involvement of multiple agencies in the decision-making process, India has a complex healthcare regulatory environment. The ongoing reforms also make it dynamically evolving. If companies are not continuously updated about the latest changes or amendments in the guidelines and laws, independent filings can be counterproductive. This can lead to loss of time and business. With much on the line, it is recommended that experts manage your regulatory and compliance matters while you focus on other critical aspects of marketing your products in India. In my experience and opinion, there is one entity that aces regulatory compliance in India - CliniExperts.

CliniExperts - Regulatory expert trusted by over 25 global companies for India business

Since 2009, CliniExperts has stood out for its capabilities in seamless, end-to-end regulatory strategy and process management. In this entity, you have a serious case to consider for your India regulatory affairs management. Especially, if you have pharmaceuticals and medical device portfolios to offer to the Indian market. That's where CliniExperts aces the ace.

CliniExperts' deep service basket

With a comprehensive and inclusive offering, CliniExperts does put all its eggs in one basket. Once a partnership with a customer sets off, the company brings to the table all the services needed to initiate and establish a successful India presence.

On domain-specific offerings, here is the breakdown of CliniExperts 360-degree coverage:

Medical Device portfolio

Mandatory appointment of Authorised Agent

Medical device exporters to India must operate through an Indian authorised agent for all inland business. This dependency on an Indian entity makes it imperative for cross-border players to have a reputed, experienced, efficient, and resourceful Indian agent who can multitask as a facilitator, provider, trouble-shooter, and more, to ensure smooth, fast, and uninterrupted operations.

Obviously, this agent has to be best-in-class, someone like CliniExperts, someone who is an all-weather allrounder who gives 200% to their role and responsibilities.

Role of Authorised Agent

The agent is the company's proxy operator, fulfilling these needs:

- Product registrations with CDSCO
- Product supply to Indian distributors
- Post-marketing surveillance
- Handle custom clearances
- Full-spectrum compliance with regulatory mandates

To further detail the agent's responsibilities:

- Procure and manage the import license under Form MD-15, which can be issued only to this agent and NOT the overseas company
- Ensure full product compliance under the quality and other parameters set by the Indian regulator, and if needed, handle product recall procedure. These include, but are not limited to, adhering to quality management systems, ensuring patient safety, scrutinising material and design quality of devices, and other checkpoints throughout the device lifecycles.
- Provide full assistance for import compliance under relevant Acts, as also under Form MDR-17
- Provide logistical, supply chain, and inland transportation support to safely move products across the distribution and sales funnels. These include establishing inland storage infrastructure such as warehouse facilities.

First-hand customer feedback available with us confirms that as an authorised agent, CliniExperts has habitually provided exceptional services across the board. What makes it a preferred choice for so many overseas companies?

- Pan-India presence and coverage that offers unmatched ease of operation
- Single-window feature for all registrations and regulatory compliance under one roof
- Flexibility of appointing multiple sub-distributors, which prevents dependency on a single large distributor
- Pharmacovigilance - CliniExperts' elaborate market vigilance mechanism collects and collates market data and regularly shares with customers.
- Information and knowledge updates - Equipped with the latest knowledge of legal amendments and regulatory updates, CliniExperts is rightly called info-savvy! The client is thus always in safe hands.

This *video* provides insight into CliniExperts' capabilities as an authorised agent for medical device business.

Pharmaceutical Drugs portfolio

Regulatory snapshot

- Regulatory body: The Central Drugs Standard Control Organisation (CDSCO)
- Governing laws: The Drugs and Cosmetics Act of 1940, and the Drugs and Cosmetics Rules of 1945.
- Licenses required:
- Registration and Import license
- Form 10 for general and OTC drugs not listed in Schedule X, and Form 10-A for-prescription drugs listed in Schedule X. These licenses have to be renewed every three years.

- Form 20-B for wholesale license
- Repacking permission under Rule 37
- Additionally, to sell their products in the Indian market, companies need a registration certificate under form 40, which guarantees that products conform to Indian regulatory standards.
- And more. These two links to CliniExperts website provide detailed information.

With its experience and proven capabilities, CliniExperts covers all the above registration/licensing mandates.

CliniExperts' services as Authorised Agent

As I covered earlier, appointment of an Indian authorised agent is a blanket requirement for healthcare companies aspiring to be in the Indian market. It applies to the pharmaceutical drug category too. CliniExperts, as a reputed Indian drug wholesaler possessing Form 20B and 21B licenses, can provide you these standout services:

- Full-spectrum compliance with the Indian laws and regulatory framework
- Facilitate testing of drugs at central government laboratories and obtaining relevant clearances/permissions for their commercial use
- Filing form40 application and subsequently procuring Form41 drug registration certificate
- Issuing Form9 to exporters to facilitate drug imports to India
- Provide prompt and effective assistance in case of adverse event reporting and product recalls, if and when necessary
- New drug approvals
- Subsequent new drug approvals
- Post-approval changes, if needed
- Obtaining BE NOC

Critical certifications and accreditations

CliniExperts has earned these badges through sheer hard work and unwavering commitment to all-round excellence:

ISO 9001 - For maintaining impeccable quality management systems (QMS)
ISO 27001 - For hosting lean and robust information security management systems (ISMS)
ISO 13485 - For consistently maintaining a world-class QMS for design, development, and production of medical devices.
WHOLESALE 20B and 21B - For maintaining immaculate systems for procuring drug licenses in India.

Final word

I am positively biased towards CliniExperts for its meritocracy-based market standing, supported by the trust of a rapidly growing roster of overseas clients.

Go after CliniExperts!

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