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Free trade area attracts zone sponsors to India

Our client, a leading pharmaceutical company, focused its attention on India to conduct bioequivalence studies with clinical end points. The prevalence of disease indications and the ability to recruit patient numbers within an appropriate timeframe were two important factors of influence for the Sponsor. In addition, the increased pressure on today's pharmaceutical companies to realize cost efficiencies prompted this Sponsor to conduct clinical trial studies in this region.

Realizing tax efficiencies

While India had traditionally been considered as a difficult location from a logistics point of view, the strategic location of a Thermo Fisher Scientific Clinical Supply Distribution Center, India in one of India's Free Trade Zones, also known as Special Economic Zones (SEZ), offered many advantages:

- A duty-free enclave, deemed to be a foreign territory for the purposes of trade operations, duties and tariffs
- No import license required
- No applicable import/export taxes (service tax, VAT, Excise & Custom Duty)
- No routine examination by customs officials of import or export cargo

The Sponsor also needed to evaluate the breadth of services that could be provided by Thermo Fisher Scientific to facilitate clinical trial supplies in this region. To this end, the Sponsor and Thermo Fisher Scientific met for detailed discussions regarding the Sponsor's immediate and long term strategy for India.

Reduced inventory and shipment costs

The team analyzed the Sponsor's proposed distribution model and expected shipping requirements in order to deliver clinical trial materials on-time and in-full to investigator sites across the region. The team determined the best route to market for this Sponsor was to have a central hub where all products could be dispatched at appropriate times to accommodate clinical trial timelines. The Sponsor would send bulk shipments of clinical supplies to this hub, reducing inventory and shipping costs to the region. Thermo Fisher Scientific worked closely with the Sponsor validating the proposed logistics plan to ensure remotely located investigator sites would be well served.

Regulatory support

The strategic location of our facility in the Free Trade Area and the regulatory expertise of the local team facilitated the import of clinical trial materials into India. As a result, the Sponsor realized an immediate time savings of up to eight weeks. Additionally, the simplified regulatory processes allowed the team to finish a packaging project in advance of expected timelines, allowing the Sponsor to accelerate the start date of their trial.

Cold chain compliance

The Sponsor was particularly concerned that its temperature-sensitive clinical supplies would not be compromised in any way. It was important that its compounds would be maintained at their specified temperature during storage and transportation. Our facility at Ahmedabad was chosen because it is GMP-compliant, with redundant compressors and back-up power generators to ensure strict temperature management, whether ambient, refrigerated or frozen. In addition, all shipments were tracked and traced giving visibility of all supplies in motion and at rest.

Visibility

Having total visibility of all supplies was of utmost importance to the Sponsor in order to ensure its Investigational Medicinal Product (IMP) was maintained across the supply chain. To this end, the Sponsor received customized monthly reports from the Thermo Fisher Scientific Global Logistics Help Desk demonstrating chain of custody across the supply chain.

New studies

This leading pharmaceutical company continues to deploy clinical end point bioequivalence (BE) studies in India in partnership with the experts of choice – Thermo Fisher Scientific team.

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