

Clinical supply

Unlocking significant IGST savings and accelerating clinical supply timelines in India through SEZ operations

Comprehensive SEZ-based clinical supply strategy

A clinical research client came to Thermo Fisher Scientific to ask how they could accelerate study timelines while optimizing costs related to import duties and taxes. The challenge was navigating regulatory processes, particularly import licensing, while avoiding delays that could jeopardize First-Patient-In (FPI) milestones. The sponsor needed a solution that allowed for early preparation of clinical trial materials while still meeting all compliance requirements.

Streamlined SEZ operations to accelerate timelines

Thermo Fisher Scientific leveraged its facility within an Indian Special Economic Zone (SEZ) to manage the client's import, packaging, and export needs for comparator products, trial medications, and ancillary supplies.

The SEZ model offered several key operational advantages:

- **Regulatory efficiency:** No requirement for an import license for goods entering the SEZ.
- **Streamlined processes:** Single-window clearance with reduced paperwork and administrative burden.
- **Time savings:** Ability to commence kit packaging while the import license application was under review, avoiding idle waiting periods.
- **Financial benefits:** Exemption from GST on imports into SEZ enabling direct IGST savings, particularly for residual or destructed products.

Operationally, the SEZ location allowed the client to begin packaging activities while the import license application was still under review. This allowed the client to meet study timelines to stay on track, eliminating unnecessary waiting periods.

Financial and operational impact

The direct financial impact was significant for this client. The client achieved approximately \$91,000 in annual IGST savings from residual and destructed products on their mid-level product. This could potentially yield to greater savings when extrapolated across all clients and protocols. Also, the SEZ model safeguarded critical timelines. By enabling early-stage packaging and reducing customs clearance time compared to non-SEZ routes, the model ensured the sponsor did not have to give up FPI readiness and operational continuity.

Sustainability: Intention vs. action

This case study demonstrates how a strategic SEZ-based clinical supply model can achieve cost optimization and accelerated timelines in India. By combining deep regulatory expertise with a purpose-built SEZ model, Thermo Fisher enabled the client to meet aggressive timelines while achieving substantial cost savings, proving SEZ operations to be a powerful solution for clinical trial supply management.

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