

**UNITED
WITH**
RELIABILITY &
RELATIONSHIPS

Expert handling of high-risk clinical trial product in Mexico

A multinational Sponsor needed to choose a reliable provider with a wealth of expertise in delivering highly complex products from point of origin to patients at investigator sites, on time and in perfect condition. The Mexico-based Thermo Fisher Scientific team was chosen to provide the distribution and logistics services needed to successfully handle and transport its controlled drugs (PICSC) across the supply chain to investigator sites in Mexico.

COFEPRIS

The Mexico-based Thermo Fisher Scientific team worked closely with COFEPRIS – Comision Federal para la Proteccion contra Riesgos Sanitarios – to ensure the smooth running of the Sponsor’s clinical trials. The team ensured full compliance with all directives, regulations and guidelines related to the handling of all medication containing controlled drugs. Thermo Fisher Scientific acquired the relevant approval documents and authorization certificates allowing us to release clinical trial materials to our state-of-the-art facility in central Mexico City within one day of their arrival into customs.

Distribution model

The distribution options across Mexico are immense, with over 1,724 airports and a ground transportation network of over 132,000 km throughout the country. The Thermo Fisher Scientific team worked with the Sponsor to fully accommodate the unique requirements of its trial and to define a distribution model that would meet its needs. As this Sponsor was targeting a large number of patients in Mexico, they required scheduled distribution of clinical trial materials to investigator sites in the city as well as in remote locations.

Having established a presence in 2000, the Thermo Fisher Scientific team has developed close working relationships with international and local logistics service providers. In support of this Sponsor’s trial, all approved couriers were evaluated and the best couriers were chosen for each specific route, realizing cost and performance efficiencies and mitigating risk across the supply chain. A distribution model was defined and scheduled to ensure the delivery of adequate supplies to investigator sites at all times, on-time, in-full, at temperature and without damage.

Cold chain compliance

The Sponsor wanted to ensure that all temperature sensitive clinical supplies would not be compromised either in storage or in transportation to the investigator site. Thermo Fisher Scientific conducted a risk analysis study in advance of the trial to eliminate potential risks across the supply chain.

The Sponsor selected our facility because it is GMP compliant. Additional security measures were put in place with back-up generators on stand-by to accommodate power outages - ensuring temperature compliance, whether ambient, refrigerated or frozen, at all times.

Track and trace

All clinical trial materials were carefully packed in appropriate shippers for secure transportation across the supply chain at the right temperature. Our team carefully scheduled delivery times to accommodate opening hours at the investigator sites, especially for those located in more remote areas. All shipments were tracked and traced and closely monitored by the Thermo Fisher Scientific Global Logistics Help Desk team. Any alerts activated to highlight potential temperature excursions along the route to the investigator sites were pro-actively addressed to achieve a 100% on-time, In-full delivery of all clinical materials in perfect condition.

Control and visibility

As this clinical trial included high risk products, the Sponsor wanted to maintain visibility of its inventory at rest and in motion across the supply chain. To this end our team provided the Sponsor with direct access to its inventory stock information via a secure web portal. The Sponsor was able to independently review its stock inventory at any time, and to generate reports.

Other studies

The Mexico-based Thermo Fisher Scientific team continues to provide support to multinational and local pharmaceutical and biotech companies from importation to secondary packaging, regulatory support, comparator sourcing, storage and distribution, all the way through to destruction.