

An alternative logistics approach realizes cost and performance efficiencies in Asia Pacific

Regional hub model delivers control, compliance & visibility

Our client, one of the top major pharmaceutical companies with research priorities aligned to significant global health needs had a high number of studies in progress in the Asia Pacific region. The Sponsor's focus on particular therapeutic areas indicated that many more studies would be planned for this region. Concerned about their current distribution approach, the Sponsor realized they needed to review their current model with a goal of achieving cost and performance efficiencies.

VIRAL VECTOR

SERVICES

API

BIOLOGICS

Country-specific affiliates

LOGISTICS

SERVICES

Traditionally all packaging and labeling functions were carried out in North American and/or European facilities, then transported as complete supplies to the many "country-specific affiliates" across the Asia Pacific region. One obvious concern was the varying levels of quality standards from one affiliate to another, as many did not consistently adhere to global GMP/GDP standards. In addition, this traditional model presented other challenges:

- High inventory overage & poor inventory visibility
- Investigational Medicinal Product (IMP) wastage
- Non-refundable up-front tax & duty payments
- Additional fragmented costs, e.g. emergency deliveries
- Exposure to risk of pilferage, order delivery accuracy and timeliness of shipments
- Varying destruction costs & processes for each country

COMMERCIAL

MANUFACTURING



Analysis

Historically there were many parties involved in managing the Asia Pacific trials – the Sponsor and Thermo Fisher Scientific teams globally and in the Asia Pacific region. A plan was established for all parties to work together as one team to conduct a detailed analysis of all current and planned clinical trial studies, evaluating all aspects of the trial from start to finish, including packaging, labeling, storage, distribution models, returns and destruction. The team was tasked with realizing cost and performance efficiencies across the entire clinical supply chain while adhering to trial timelines. This thorough analysis resulted in an alternative approach.

Regional hub approach

The new logistics model established an "Asia Pacific Hub" for the labelling and distribution of clinical supplies to all Asia Pacific countries. Thermo Fisher Scientific's Singapore team would provide the services. All IMP were sent directly to this GMP-compliant facility that provided all label printing, secondary packaging, ancillary supplies and comparator sourcing functions for clinical trials conducted in the Asia Pacific region. This approach gave the Sponsor great flexibility. Increasingly, the sponsor was conducting adaptive trials in the region. Establishing a Singapore hub allowed them to import pooled supplies for labeling at a later date. In addition, as we are is an approved member of the importer of Clinical Trial Medicinal, the Sponsor could be exempt from paying 7% GST (Goods & Services Tax) on all imported supplies. This represented significant savings for the Sponsor.

Benefits:

- Consistent and high quality standards of a cGMP facility
- Centralized inventory management
- Validated storage conditions for ambient and cold chain supplies
- Quick response to special trial requirements late stage customization, Just In Time labeling
- High level of control over distribution of supplies maximizing cost and performance efficiencies
- Proactive regulatory support and guidance speeds up study timelines in the region
- Simplified contract and invoice demands on the Sponsor
- Dedicated staff ensures high level of attention to detail on all studies

Ongoing monitoring

In order for this new Regional Hub Approach to work effectively it was important to clearly define roles and responsibilities of key functions – Account Management, Study Set-Up, Project Management, Warehouse Management and Transport Management. Dedicated Project Managers were assigned designated to the Sponsor's studies to oversee all aspects from start to finish. Logistics decisions are based on real-time and historical data on shipments and courier performance. This datadriven objectivity continues to drive optimized courier selection realizing cost and performance efficiencies.

Frequent monitoring of the defined Regional Hub Strategy ensures control, compliance and visibility of inventory at all times. The team continues to maximize On-Time In-Full delivery of supplies, reducing overall costs and mitigating risk across the supply chain.

