Case Study

Global Trade & Logistics: The Other Side of Compliance

Service Areas: Commercial Launch, Global Trade Compliance, Manufacturing, Supply Chain, Supply Planning
Lifecycle Stage: Clinical

An innovative pharmaceutical company was awaiting FDA approval to launch its first commercial product. They were also increasing their clinical trial activities globally and advancing other programs into the clinic. The complexity of their global supply network was increasing, but they lacked processes, knowledgeable resources, and organizational understanding of global trade and logistics requirements which was causing unnecessary costs and risks.

Fortunately, one of their executives understood the high risk of operating without a Global Trade Compliance (GTC) program. GTC is not just about tax collection; it is now considered a critical part of national security. Non-compliance can result in being flagged for more investigation of risks compromising product integrity and causing stockouts or service delays. Companies may lose their import/export privileges and be prosecuted for fraud, negligence, or gross negligence.

Although our client had obtained some government permits and was working with a customs attorney, there were significant compliance gaps. The individual responsible for logistics only focused on domestic carrier management, and responsibility for international shipping documentation was unclear. It generally fell to whoever was making a shipment. Additionally, no one was providing oversight or central management for customs brokers and key vendors. The paperwork was managed and stored by dozens of employees across the organization.

Many emerging and growing biopharmaceutical companies face similar situations because their Regulatory focus is on compliance with CFR 21 - the FDA. They are typically unaware of the six other CFRs that govern import and export activities, and which play a larger role as companies advance pipeline programs toward commercialization.

The company also needed help conveying to senior management the importance and urgency of developing and executing a GTC strategy as they prepared for commercial operations.

Gap Assessment Builds Business Case for Full GTC Program

The VP of Global Supply wanted to prevent delays to production, research and commercial launch due to key materials held up in customs. Nor did he want to incur unexpected fines, duties, and tariffs that could number in the hundreds of thousands of dollars.

The company initially engaged Converge to provide a team of experienced industry practitioners to conduct a Global Trade Compliance Gap Assessment and make recommendations.

The assessment included:

- Evaluating the organization's capabilities across seven dimensions of logistics and trade compliance best practices,
- Reviewing historical documents and records for accuracy of information, valuations, and tariff codes,
- Identifying compliance gaps and risks, along with a comprehensive set of recommendations,
- Developing a roadmap for what the company should do prior to and after launch.

The GTC Gap Assessment is designed to build a business case for action, and it summarizes the results in terms of where the greatest compliance risks lie. Conducting the assessment before product approval is a high impact and low investment effort that provides an organization with direction and clear priorities, allowing them to move quickly with both pre- and post-approval initiatives when appropriate.

Pre-approval recommendations included developing a central function focused on GTC, closing critical gaps in broker activities, developing policies, and creating training materials. Post-approval, the focus shifted to building out procedures, more actively managing vendors and partners, and conducting training across the company.

Completion of the assessment coincided closely with receiving FDA approval, so Converge and the client transitioned quickly into implementing recommendations and building out the GTC program.

The program included creating procedures that detailed documentation requirements for individuals involved in transportation, purchasing, and clinical research.

Simultaneously, we developed training on basic GTC and customs law, covering important concepts including reasonable care, valuation practices, and product ownership. The initial training was delivered to 180 employees involved in GTC-related efforts, across the company.

External Support Shifts to Day-to-Day Operations

As the company grew, they hired an internal Director of Trade Compliance with responsibility for documentation management and the GTC program going forward. The role of the Converge team shifted from program design and buildout to supporting day-to-day GTC operations, particularly on the clinical and R&D sides of the business.

These execution activities include assistance with evaluating new vendors and conducting vendor audits. Our work has resulted in cost and material savings and avoiding delays and penalties, that can then be reinvested into further product development.

Status Today

Three years into the relationship, our work together continues to add value. Converge provides both GTC leadership assistance and a team of day-to-day trade compliance execution resources. There is a high level of respect between the Director of Trade Compliance and her peers. They value her work and bring her into planning conversations at earlier stages. Senior management also entrusts her with a larger scope of logistical responsibility.

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