

Global Logistics & Trade Compliance Services

Life sciences supply chains are growing in complexity whether they support preclinical, clinical, or commercial companies. Biopharma companies today work with a global network of suppliers, labs, and contractors, all while the industry continues experiencing after-effects of pandemic-related restrictions and disruptions. The need to manage this complex and evolving web of import/export, transport, and compliance regulations has never been more essential.

The mandates go beyond GMP. Non-compliance with multiple additional trade-related CFRs and international regulations can significantly impact your success through customs holds, shipment delays, penalties reportable on financial filings, stockouts, and in extreme cases the revocation of import/export privileges with criminal prosecution.

Converge Consulting's expert practitioners understand what constitutes reasonable care and compliant behavior as we guide clients through the logistics and trade compliance landscape. We collaborate closely with your team, as well as with the CMOs, carriers, freight forwarders, customs brokers, and attorneys who are critical to your success.

Executing Seamlessly

Preclinical companies focus primarily on conducting scientific R&D. The need for a seamless flow of research materials is critical, but there is often a knowledge and experience gap when it comes to the internal decision-making and documentation that ensures your partners and vendors are working effectively on your behalf to avoid disruptions.

Converge experts work closely with our client stakeholders in R&D, CMC, and Supply Chain to provide direct support for preparing shipment documentation, coordinating preshipment alignment with carriers and customs brokers, and monitoring customs and FDA release, ultimately ensuring delivery at designated locations.

Ensuring Compliance

As companies move into the clinic, the volume of shipments and regions involved in clinical studies increases. Operational focus often shifts to developing the appropriate procedures, systems, and repeatable processes that ensure logistics are executed consistently and in compliance to avoid disruption on the end-to-end logistics flow.

Our Logistics & Global Trade Compliance team helps companies establish trade compliance programs that are stage-appropriate and based on industry best practices. For some

clients, this may be the creation of an initial set of educational materials, procedures, and forms to collect information accurately and reliably. For others, we establish policies and centralized repositories across the extended organization that provide quick and easy access to information and ensure consistency for compliance.

Managing Growing Complexity

When biotech and pharmaceutical companies begin generating commercial product revenue, the risks increase further. Focus shifts again from developing the internal capabilities to ensuring compliance across an expanding organization, capturing efficiencies, and reducing cost.

We work with established commercial life sciences companies to evaluate and optimize shipping and logistics. By considering each supply node and shipping lane as part of the overall network, we uncover "hidden" efficiencies and then help our clients reap the benefits. Examples include evaluations of active vs. passive shipping container options, prelaunch logistics arrangements, as well as VAT optimization and alignment with legal entity and tax strategies.

Our Services

Our experienced consultants and practitioners work as either independent advisors or as closely embedded members of our clients' team in activities related to logistics and global trade compliance. Areas of support include:

- Best practices logistics assessment
- Trade compliance program design
- Logistics capabilities buildout & improvement
- Partner strategies & selection
- Day-to-day logistics management

Converge Consulting serves the Life Sciences industry with strategy, operations, and execution expertise. We collaborate with biotech, pharmaceutical, and cell/gene therapy companies to achieve important business objectives. The Converge approach focuses on bridging the gap between sound strategy and reliable execution.

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