WHITE PAPER

Resource savings through effective global trade compliance in drug development

A CDMO with expertise to support a (bio) pharmaceutical company's international trade compliance program is crucial to the success of a therapeutic product or medical device, starting during the earliest stages of drug development.

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Partnering with a full-service Contract Development and Manufacturing Organization (CDMO) that can handle all phases related to the development and manufacturing of a new treatment or medical device is crucial for the success of a drug development project. A CDMO helps (bio)pharmaceutical companies tackle early-phase challenges, meet clinical timelines, plan for future stages of development and ensure seamless tech transfers into the clinic.[1]

With competition rising due to the emergence of smaller biotech companies that may lack the resources to handle process development and meet regulatory guidelines, CDMOs play an increasingly important role in supporting their partners as they navigate through complex regulatory requirements and global compliance measures.[2]

Global Trade Compliance in Life Sciences

Intra-industry trade of pharmaceutical products such as APIs, raw materials and other goods and services continues to increase. As of 2022, 8 out of 10 top exporters in the world were cited to be among the largest pharmaceutical importers. With the increasing number of innovations in the pipeline, the value of (bio)pharmaceutical trade is expected to rise steadily in the industry, with a CAGR of 2.5% through 2035, exceeding $1 trillion by 2033.[3]

Consequently, (bio)pharmaceutical companies must consider how products are transported internationally in today's environment and should be knowledgeable on additional requirements that may be enforced for security reasons and due to sanctions/trade controls when transitioning APIs and raw materials, as well as other goods and services from one facility to another. Whereas pharmaceuticals were primarily transported by land in previous times, airborne and seaborne trade has increased.

Changes to the transport of (bio)pharmaceutical products have been based on various issues, including the necessity to have more timely access to medical breakthroughs, as was the case during the COVID-19 pandemic in 2020.[3]

"COVID-19 had an impact on the global economy, resulting in impacts to international trade of pharmaceutical goods," says Mariesa Coppola, JD, Vice President, Deputy General Counsel, Compliance Officer of Curia Global, Inc. Coppola comments that such impacts increased governmental audits by global customs and border control regulators. **"In addition to a financial impact related to fines or penalties for non-compliance, (bio)pharma companies serve a mission to bring medicines to patients that need them. Non-compliance with trade compliance could put that mission at risk,"** warns Stacie Phillips, JD, General Counsel, Corporate Secretary of Curia Global, Inc.,

encouraging companies to consider international trade requirements and collaborate with a CDMO experienced in material classification systems, valuation, and marking requirements used by the jurisdictions in which it operates.

"A strong international trade compliance program with the right CDMO drives consistent and accurate planning of costs and requirements related to imports. It builds credibility with regulators globally and is proven to enhance delivery timelines as materials are being shipped across borders," explains Phillips.

Not only is a robust compliance program necessary to reduce risk in the form of governmental investigations, fines and penalties given the complex global landscape of trade regulations, but it also offers a competitive and strategic advantage in the form of a comprehensive supply chain and cost management programs for various drugs and medical devices being developed and manufactured.

As highlighted by the US Department of Health and Human Services, "a comprehensive compliance program provides a mechanism that addresses the public and private sectors' mutual goals of reducing fraud and abuse; enhancing health care provider operational functions; improving the quality of health care services; and reducing the cost of health care." While positive results are shared across the entire industry, the (bio)pharmaceutical company will reap additional benefits crucial to the company's reputation and success in the industry.[4]

Establishing a robust compliance program

CDMOS AND TRADE COMPLIANCE TEAMS

The right CDMO has established a dedicated trade compliance team of experts who operate at the site level. The team is typically comprised of local import/export specialists with oversight from the CDMO's legal and compliance department. "Team members are experts in compliance with Customs regulations concerning classification, valuation, country of origin and marking of imported goods. They are also educated on compliance matters pertaining to sanctions/trade control regulations and restrictions that align to the individual needs of a (bio)pharmaceutical company," explains Swarna Shreenivas, Legal & Compliance, Senior Counsel III of Curia Global, Inc.

An import/export compliance manager oversees and coordinates with the supply chain, shipping/receiving and procurement departments, internally, and works with Customs brokers, externally, to ensure overall compliance and efficient handling of import transactions.[4]

Within the legal team, a senior legal and compliance counsel, with oversight from the compliance officer, is responsible for supporting the design and implementation of the trade compliance program, and responds to trade compliance issues that emanate from specific sites/locations.[4]

Especially for smaller-scale entrepreneurs, a team with such resources is an attractive option to navigating international trade, says Phillips. "A dedicated team brings an independent, holistic and focused approach to trade compliance with the resources and expertise to identify and mitigate compliance risks effectively. In today's dynamic global trade environment, a CDMO with a dedicated trade compliance team is attractive to small scale pharma/biopharma companies because it is better equipped to monitor domestic as well as international trade developments and strategically navigate resulting compliance challenges."

Elements of an effective compliance program[4]

A CDMO with a dedicated trade compliance team will be able to coordinate and implement a compliance program unique to the (bio)pharmaceutical company's medical device or drug product. The following elements are crucial when establishing an effective compliance program:

- Implementation of written policies and procedures.
- Designation of a compliance officer and compliance committee.
- Development of effective lines of communication with internal and external stakeholders.
- Regular internal monitoring and audits.

Standards provided via well-publicized disciplinary guidelines should be enforced and all team members are expected to be well-trained and educated on international trade matters and other legal aspects so they can serve as expert resources to internal and external stakeholders. The trade compliance team should respond proactively and provide solutions to address concerns and mitigate challenges from reoccurring.

Navigating trade compliance measures

TACKLING INFORMATION OVERLOAD

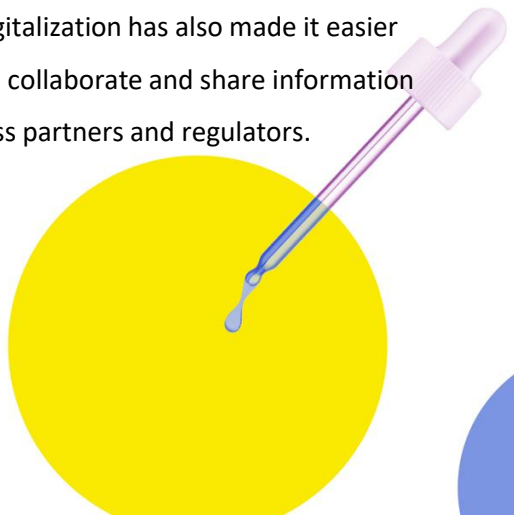
(Bio)pharmaceutical trade compliance teams are experts in navigating a complex industry. In addition to understanding global trade agreements and legal policies tied to global trade, trade compliance teams are equipped to navigate a complex (bio)pharmaceutical supply chain.

Coppola notes that the right trade compliance team can easily navigate changes in this complex industry because they have the most accurate knowledge pertaining to:

- Trade restrictions and prohibitions contained in sanctions;
- Import and export regulations;
- Licensing requirements applicable to certain products/end-users/end-uses;
- Customs regulations regarding duty drawbacks/anti-dumping/countervailing duties;
- Tariff classification and updates to harmonized tariff schedules;
- Free trade agreements;
- Rules and country of origin matters;
- Marking/anti-transshipment requirements;
- Valuation;
- Supply chain security, transportation, shipping terms (Incoterms);
- Trade documentation and record-keeping requirements; and,
- Environmental and social compliance regulations including, but not limited to, those related to labor/human rights, pollution control/hazardous substances, etc.

"**Our team [Curia] maintains a curated list of publicly available and subscription-based resources that are monitored for regulatory updates**. These include government/federal agency websites, US Federal/EU regulations, Federal Register notices, Customs bulletins, Informed Compliance Publications, HTSUS, the CBP Cargo System Messaging Service, Customs broker updates and trade publications," says Shreenivas.

Shreenivas credits the emergence of digitalization as an enabler of cost-effective, timely access to the large amounts of information that enable the trade compliance team as they navigate complexities in the industry. Digitalization has also made it easier for teams to collaborate and share information with business partners and regulators.



MAINTAINING PROPER DOCUMENTATION, RECORD KEEPING, REPORTING AND REVIEWS

In addition to regularly monitoring the industry for updates that may impact the import/export of (bio)pharmaceutical products, the trade compliance team is responsible for maintaining complete, accurate, and well-organized documentation necessary to streamline transactions and the delivery of information as well as transit of products and services tied to a drug product or medical device.

All supported by the CDMO, these actions help place a (bio)pharmaceutical company "in the best possible position to benefit from favorable treatment under applicable regulations," says Phillips.

Proper documentation enables effective reporting and reviews that, in turn, help identify trends and provide insights that inform enhanced future decision-making in the industry, says Phillips.

TEAM TRAINING AND COMPLIANCE REVIEWS

In addition to ensuring that a CDMO's international trade compliance team is operating based on the most current information and resources available, a team should be assessed regularly and receive periodic training on trade compliance issues relevant to individual roles and job functions.[4]

At Curia, for example, a general training module focused on sanctions compliance is administered on an annual basis to all team members to equip them with the information they need to identify, manage and report, as appropriate, sanctions compliance risks/issues. The all-employee training module is supplemented by specific and targeted training for high-risk groups actively involved in trade transactions, focused on a broad range of trade compliance issues including import/export controls, customs regulations, tariff classification, valuation, supply chain security, etc.

Annual compliance audits and periodic reviews of customs/trade documentation are also performed, and the findings from such audits/reviews help inform the design and content of future training and communication to employees.

In addition to audits/reviews, Phillips highlights their form of a Supplier Due Diligence checklist/questionnaire as another important resource to collecting important information relevant to trade compliance and overall industry performance. "Be it sanctions regulations or other import/export controls, the quality and effectiveness of our compliance program is heavily dependent on the quality and extent of trade compliance in our supply chain. Through our supplier due diligence processes, including the [Supplier Due Diligence] checklist/questionnaire, we attempt to gather information on our suppliers' business operations – nature, geography, compliance processes, etc. – which helps us identify gaps in their programs and the resulting risks to our business activities, enabling us to proactively devise suitable mitigation strategies."

Collaborating with a well-trained trade compliance team

In today's dynamic global trade environment, a CDMO with "a sophisticated trade compliance team is better equipped to monitor domestic as well as international trade developments and strategically navigate resulting compliance challenges to support customer timelines and goals," says Phillips.

"Our trade compliance control framework [at Curia] includes key components designed to mitigate possible customs risks such as supply chain due diligence to discourage transshipment and encourage compliance with Country-of-Origin marking requirements. We enforce continuous and automated screening of all suppliers/customers to prevent dealings with sanctioned/denied parties. We have established tariff classification processes in consultation with technical groups to ensure proper and accurate classification under HTSUS and we make value determinations for imported merchandise based on guidance contained in CBP's Informed Compliance Publications. We recently completed our recertification and are proud to report that we are a member of Customs Trade Partnership Against Terrorism (CTPAT)."

Phillips encourages (bio)pharmaceutical companies, especially those of smaller scale, to investigate their options and pursue a partnership with a CDMO such as Curia to support international trade of high-quality products designed to accelerate the development, manufacture, and commercialization of medical devices and potentially life-saving drugs.

About Curia

Curia is a Contract Development and Manufacturing Organization with over 30 years of experience, an integrated network of 29 global sites and over 3,500 employees partnering with customers to make treatments broadly accessible to patients. Our biologics and small molecule offering spans discovery through commercialization, with integrated regulatory and analytical capabilities. Our scientific and process experts and state-of-the-art facilities deliver best-in-class experience across drug substance and drug product manufacturing. From curiosity to cure, we deliver every step to accelerate and sustain life-changing therapeutics. **To learn more at curiaglobal.com**

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