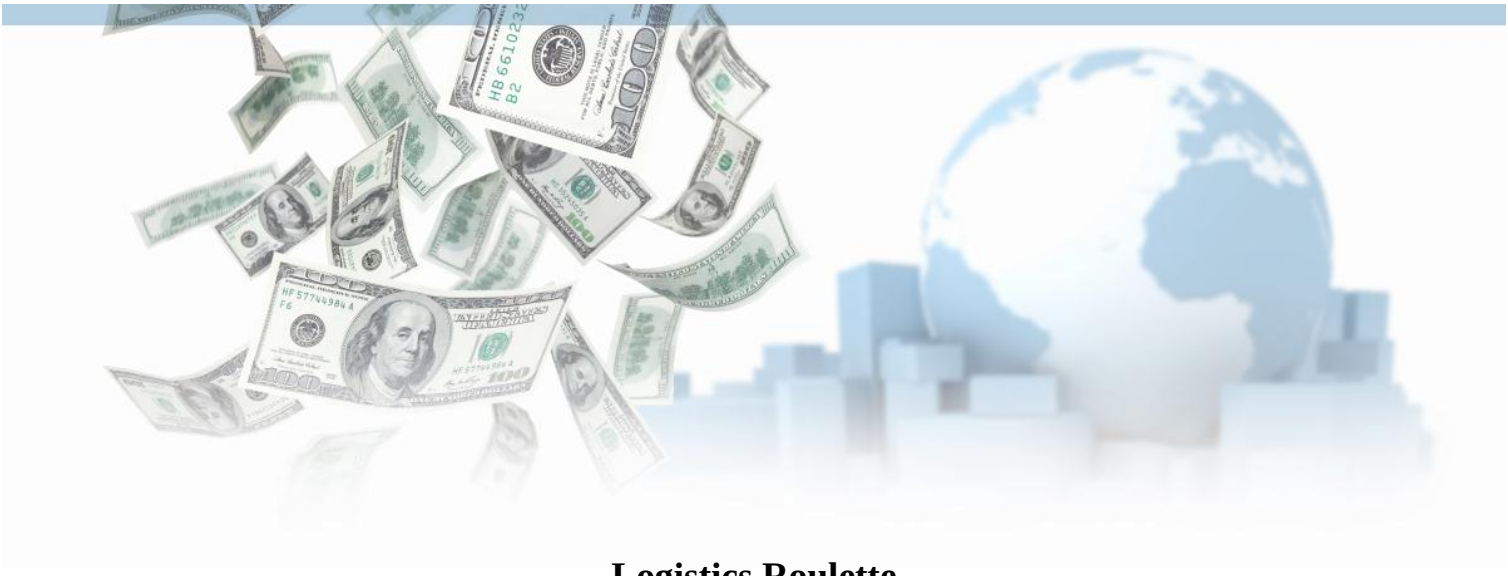

Logistics Roulette

Some clinical trial sponsors are taking chances with global shipping compliance and getting fined millions. Don't be one of them.

A Q&A with Steve Balk, CFO of Imperial, a Clinical Research Support Organization

Global expansion of clinical trials has elevated several areas of risk for sponsor organizations, underscoring the need for logistics suppliers who are both versed in and compliant with taxes and duties, and federal and international regulations. Revenue avoidance has come under increased scrutiny within European Union (EU) member countries. As such, value-added tax (VAT) compliance has become a requirement for the international shipment of study materials and study-related supplies. In addition, delays in customs related to harmonized tariff schedule (HTS) codes, importer of record errors, and shipments to denied parties present obstacles to maintaining study timelines on a country-by-country basis. In this scenario, site initiation materials may not be allowed entry into all countries participating in a clinical study.

Companies face three key challenges in global shipping and compliance, including: 1) raising awareness and appreciation for the risks associated with shipping products and materials domestically and internationally; 2) delivering accurate information and documentation for shipments in a fast, efficient and compliant way; and 3) managing extensive filing responsibilities with United States and international authorities.

These challenges can be overcome through people, processes and technology. It is also essential to instill an appreciation for compliance among employees and clients, and to raise awareness of potential issues so they can be anticipated and averted before they arise.

So what steps can companies take to ensure compliance with global shipping regulations? Steve Balk, CFO and Global Compliance Officer of Imperial, a Clinical Research Support Organization in Grand Rapids, Mich., provides the following insights.

Q: For perspective, what U.S. regulations govern global logistics?

A: The U.S. Federal Regulations are primarily derived from:

- The Export Administration Act of 1979 authorizes the Department of Commerce to regulate the export or re-export of U.S.-origin dual-use goods, software and

technology. The Department of Commerce implements this authority through the Export Administration Regulations (EAR).

- The Department of Commerce imposes certain export and re-export controls for foreign policy reasons, most notably against countries designated by the U.S. Secretary of State as state sponsors of international terrorism, as well as certain countries, entities and individuals subject to domestic unilateral or United Nations sanctions.
- The Department of Commerce administers and enforces regulations that prohibit certain trade and transactions with certain countries, entities and individuals by U.S. persons or from the United States under the Trading with the Enemy Act and the International Emergency Economic Powers Act.
- U.S. Customs officials (now part of the Department of Homeland Security) have the authority to check any export or import against its license at the borders.

There are 45 states that require businesses to collect and remit sales and use taxes. Of these states, 36 have local sales and use tax requirements. In all, there are a daunting 9,600 sales and use tax jurisdictions throughout the United States. For the most part, all of the states have their own unique tax laws.

Individual countries generally have their own customs laws, rules and procedures. Additionally, there are numerous treaties and agreements within the international community, the European Union and between countries to further regulate import and export activities.

Q: What are some recent regulatory changes that clinical trials sponsors should consider?

A: Export compliance is a dynamic discipline that evolves with our changing business environment, client needs, new product offerings, material content changes, and changes related to increasingly complex global situations. To that end, we are shipping new product classifications, adding to lists for denied parties, persons and entities, anti-boycott country lists, etc. There is no such thing as a static system that can be developed and used for any amount of time where an assumption of compliance can be held.

Regarding pending legislation, a recent communication received from Alston and Bird, LLP stated: "On October 15, 2013, the first of many Final Rules required to advance the Obama Administration's Export Control Reform (ECR) initiative will take effect. …Their publication also represents a significant milestone in the overall regulatory reform effort that began almost four years ago and is now finally on the brink of implementation. Indeed, a hearing on the future of ECR held last week by the House Foreign Affairs Committee suggests that further progress lies ahead for the reform effort, as the Administration's representatives from the Commerce, State and Defense Departments received a noticeably cooperative reception despite the concerns expressed by some Members. Thus, while the "four singularities" vision of ECR first announced by the President in 2009 remains an ambitious work in progress, a framework and path forward for what we now know to be achievable regulatory reform is finally clear. Accordingly, industry can begin to genuinely evaluate the challenges and opportunities ECR presents."

Q: What specific penalties do suppliers and clients face for logistical missteps?

A: Violations of the Export Administration Act of 1979 may be subject to both criminal and administrative penalties. Criminal penalties can reach 20 years of imprisonment and $1 million per violation. Administrative monetary penalties can reach $11,000 per violation, and $120,000 per violation in cases involving items controlled for national security reasons. When the EAA is in lapse, the criminal and administrative penalties are set forth in the International Emergency Economic Powers Act (IEEPA). On October 16, 2007, President Bush signed the IEEPA into law. The Act enhances criminal and administrative penalties that can be imposed and also amends IEEPA to clarify that civil penalties may be assessed for certain unlawful acts. Criminal penalties can reach $1,000,000 and 20 years of imprisonment per violation, and the administrative penalties can reach the greater of $250,000 per violation or twice the amount of the transaction that is the basis of the violation.

Violators also may be subject to denial of their export privileges. A denial of export privileges prohibits a person from participating in any transaction subject to the EAR. Furthermore, it is unlawful for other businesses and individuals to participate in an export transaction subject to the EAR with a denied person.

Q: With a myriad of governing bodies and regulations, and in light of stiff penalties for noncompliance, what are some general standards that companies should follow?

A: Adherence to the following standards (i.e., "Core Elements of an Effective Export Management and Compliance Program") set by the Bureau of Industry and Security, Department of Commerce is essential:

- Management Commitment: Senior management must establish written export compliance standards for the organization, commit sufficient resources for the export compliance program, and ensure appropriate senior organizational official(s) are designated with the overall responsibility for the export compliance program to ensure adherence to export control laws and regulations.
- Continuous Risk Assessment of the Export Program
- Formal Written Export Management and Compliance Program: Effective implementation and adherence to written policies and operational procedures
- On-going Compliance Training and Awareness
- Pre/Post Export Compliance Security and Screening: Screening of employees, contractors, customers, products, and transactions and implementation of compliance safeguards throughout the export life cycle including product development, jurisdiction, classification, sales, license decisions, supply chain, servicing channels, and post-shipment activity
- Adherence to Recordkeeping Regulatory Requirements
- Internal and External Compliance Monitoring and Periodic Audits
- Maintaining a Program for Handling Compliance Problems, including Reporting Export Violations
- Completing Appropriate Corrective Actions in Response to Export Violations

Q: What should clinical trial sponsors look for when evaluating a logistics supplier?

A: First and foremost, executive management must be fully committed to risk management both in international export compliance and domestic tax and reporting compliance. Having an experienced global logistics compliance officer is tangible evidence of that commitment. Other things to look for include:

Education

- Internal knowledge about new and existing requirements
- External efforts to inform customers of compliance requirements and potential risk in this area

Systems

- Keeping abreast of constantly changing legal and tax environments
- Incorporating changes into efficient and seamless systems processes for shipment documentation, product valuation, tax reporting and others

Filings

- Ensuring awareness of the states in which they have nexus, as they will be responsible for taxes in that state
- Having a global footprint, yielding the benefit of production and distribution capabilities requiring VAT return filings, which can facilitate EU VAT recovery for clients
- Understanding of how to process electronic filings with the U.S. Census Bureau for qualifying shipments

Audits

- Increasing number of customer compliance audits
- Growth in audits by regulatory and taxing authorities

Technology

- Custom applications to support logistics activities
- Software support to provide appropriate taxing applications for state and local sales-and-use taxes on domestic shipments
- Software that produces automated monthly state and local tax returns

Unique Shipment Requirements

- Processing of shipments using Delivered Duty Paid (DDP) incoterms, allowing the end user to pick up the import with minimal red tape and no duty or tax payment requirement
  - Not every supplier is able or willing to carry the risk and responsibility of shipping DDP for their clients. For the client, however, it is the most preferable method as it is the least complicated.

- Experience shipping to several countries

- Demonstrated shipping efficiency as evidenced by the number of shipments done annually

- Documented procedures and instructions, as well as a classification manual for identification of special requirements

Global logistics is a heavily regulated industry environment where compliance is simply not optional. Penalties for non-compliance could include loss of export privileges, monetary fines, unexpected duties and VAT assessments, adverse state sales and use tax audit assessments, and even criminal charges. It is, therefore, vital for sponsors to hire vendors with a comprehensive program to facilitate time-saving and cost-effective shipping solutions within the legal framework of U.S. agencies, foreign customs authorities, state and local taxing jurisdictions, company management, and client legal and compliance officials.

In addition to developing a formal, written policy for facilitating and sustaining compliance, standards must be communicated throughout the organization and all employees must be trained continuously. While individual shipments may present unique challenges, having an established framework of behavior helps identify issues and provide solutions. Having a supplier that is familiar with lean strategy and process mapping is invaluable, and serves to both enhance the supplier-client relationship and ensure successful delivery of clinical trial materials.

About Steve Balk
Steve brings 31 years of experience in all aspects of financial management to his role as CFO and Global Compliance Officer for Imperial. He leads the financial management and reporting responsibilities of the finance and accounting departments, and is intricately involved in risk management, mergers and acquisitions, global compliance, and strategic planning.

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