#### Unveiling the Cross-Border Maze: Demystifying Tax, Importation, and VAT in Clinical Trial Supply Management

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We had the opportunity to sit down with Rognvald Lamb, an expert in clinical trial logistics, to gain valuable insights into the complexities surrounding tax, importation, and value-added tax (VAT) in the management of clinical trial supplies. Here are some highlights from our conversation:

#### Q.1 When do you recommend using a specialized courier over a standard courier?

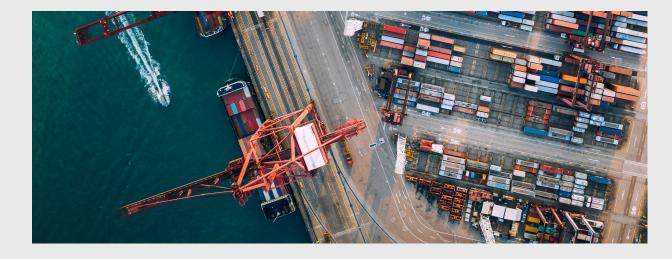
Generally, for US domestic or Canada to US, intra EU or UK, and parts of Asia, I would recommend using an integrator like UPS or FedEx. For high volumes, challenging destinations, or where there are customs challenges, specialty couriers are a better choice. Factors such as product volume, temperature control, and customs impact play a role in this decision, but ultimately, the route and customs requirements determine the best approach.

## Q.2 Would importing into Europe have different taxes depending on which country you import into?

There are two factors to consider: custom duty and import taxes. When importing into the EU, the same customs tariff applies to every country, regardless of which one you import into. However, variations arise in import VAT. Rates differ from country to country, ranging from as low as 7% to as high as approximately 25%. Nevertheless, the same laws apply across Europe, and in most cases, you can reclaim the tax. In Ireland, medication for human oral delivery is free of VAT, so there can be an advantage there.

#### Q.3 What is the most complicated country to export or import products to and from?

While I wouldn't name a specific country, Eastern Europe and South America present challenges. South America, especially Argentina, has stringent regulatory environments that require import permits and specific import permissions from customs. Asia is gradually becoming more accommodating, and developing countries within Asia and parts of Africa have fewer constraints. The real challenge lies in regions where the laws are either too ambiguous or poorly defined. In such cases, you rely heavily on the customs officers' understanding of the laws. Currently, South America has the toughest regulatory landscape, making it crucial to establish the right connections and find reliable importers.



## Q.4 What are the advantages of bonded warehouses?

Bonded warehouses, also referred to as custom warehouses or free ports, allow you to land products into a country and move them into the warehouse without the need for immediate import or export processes. Free zones and free ports effectively serve the same purpose. When a bonded warehouse is also a Good Manufacturing Practice (GMP) facility, it offers additional advantages. For example, in the EU, you can bring products into a bonded warehouse, store them, repack them into new containers and packaging systems, and ship them out without the necessity of separate import and export procedures. While proper process management can minimize the difference, utilizing a bonded warehouse simplifies landing products into a country with minimal documentation required.



# Q.5 If you are purchasing products and packaging in the EU and then shipping them into Switzerland, are there any additional taxes, and can they be reclaimed?

When purchasing items in the EU, the ability to reclaim or avoid VAT depends on the location and purchasing process. However, when shipping into Switzerland, there is import VAT, which can be reclaimed in certain circumstances. It's important to note that when shipping to clinical sites in Switzerland, the VAT is often charged back rather than directly to the site, which can make the reclamation process more challenging. However, when moving products into wholesaling within Switzerland, importers can reclaim the VAT. Overall, very similar import, export, and VAT laws that apply in the EU also extend to Switzerland, Norway, the UK, and other EU member countries.

### Q.6 What is the difference between an integrator and a speciality courier?

Integrators such as UPS or FedEx have integrated networks that offer end-to-end visibility and cost-effective services. They operate efficiently by combining multiple shipments, which may not allow for extensive intervention or customization. On the other hand, specialty couriers provide a bespoke approach, offering services like specific pickup times, customized packaging, and direct notifications on transit points. They may provide GPS tracking on boxes and allow customers to choose specific airlines. Specialty couriers can even tailor routes based on requirements, such as choosing airports where Customs staff are experienced in handling pharmaceutical imports. Integrators, on the other hand, stick to their standardized routing for all products. The choice depends on whether cost-efficiency or personalized service is the priority.

#### Navigating the Complexities for Successful Clinical Trials

This insightful interview with Rognvald Lamb provides a deeper understanding of the intricacies surrounding tax, importation, and VAT in clinical trial supply management. It highlights the need for careful consideration of various factors and the importance of staying informed about regional regulations and best practices. Navigating these complexities effectively will undoubtedly contribute to the success of clinical trials and the advancement of medical research.



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