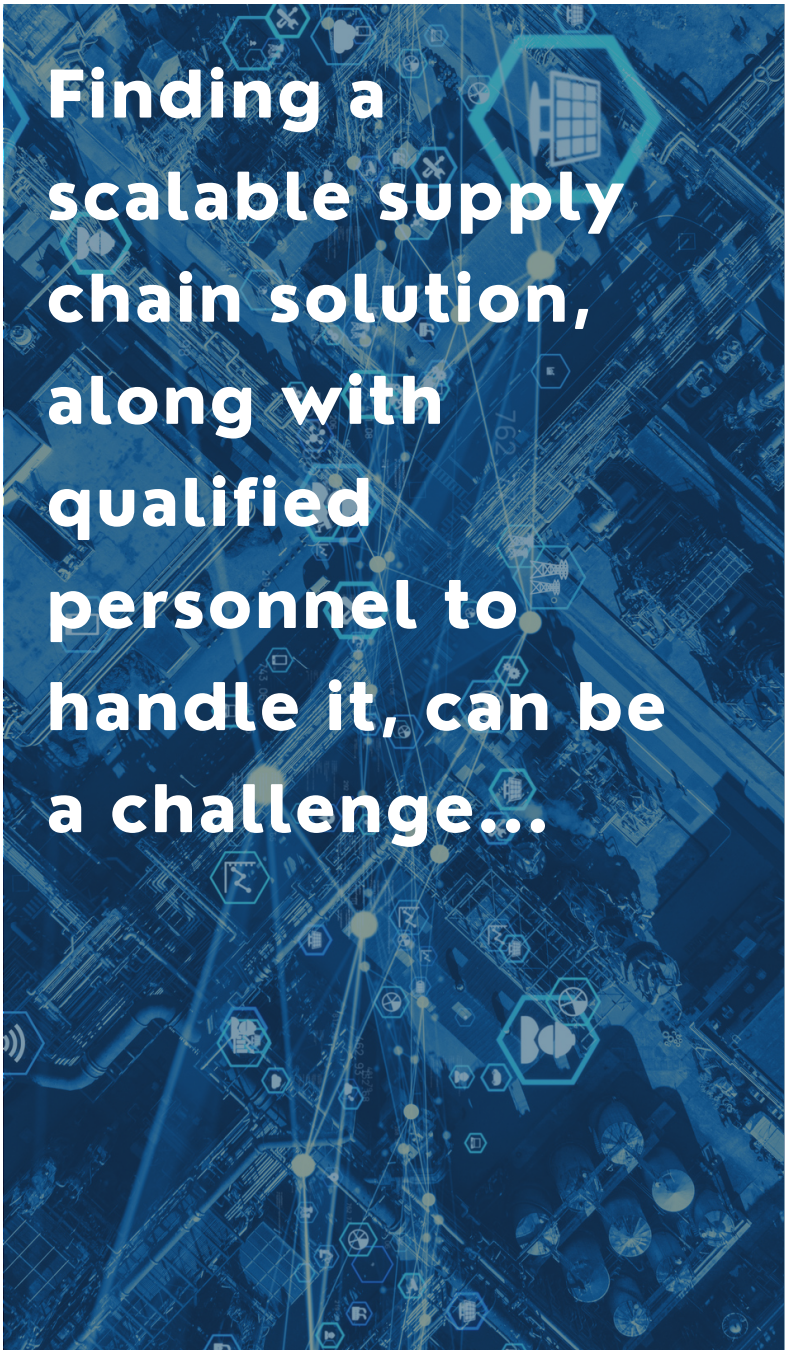
CLIENT STORY

Building a
Service Solution



With multiple pressured faced by pharma companies today, improving efficiency and managing cost remain high priorities.

Summary

European Licensed Product was being manufactured in the USA, the API was sourced in Europe and shipped to the USA. However, no licenses were held to supply product in the USA. So, we were governed by the FDA rules and regulation for Import for Export `IFE` regulations 801 (d) (3).

Occasionally for smaller markets we would import naked vials into our UK secondary packaging site and labe up full batched of product into smaller liveries. This was all done if course within the strict regulations and oversight of the registered QP.

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ipg
ice pharma group

We effectively released 40M units per year to customers in the UK, France, Spain, Germany and Scandanavia from this one manufacturing plant in the USA.

How was this achieved?

Supply chain would monitor the requirement of the API using production planning tools and forecasting models and would order the API from the European manufacturer and arrange the shipment to the USA. In order to import API for further processing into finished product for export back to Europe we had to provide the following information to the FDA for each importation of API.

Statement of Intent

Provide a letter to the FDA confirming the intent to process the product or to incorporate it into a final product. It should also state that the product would be exported by the initial owner or consignee from the US in accordance with section 801 (e) or 802 of the Act or section 351 (h) of the PHSA.

Note: The product must be use and exported by the initial owner or consignee in accordance with the statement of intent. Unused portions of the product must be destroyed.

Chain of Possession

Provide a statement to the FDA identifying all firms that had possession of the product, including each processor, packer, distributor or other firm that has had possession of the product. This established a chain of possession from the manufacturer to the importer. The statement should include information sufficient to identify the chain of possession of the article through each entity, which could include information such as product coding, lot, batch or other identification numbers.

Certificates of Analysis

Provide certificates of analysis that identify the product. Certificates of analysis or equivalent documentation should provide the product's formulation, ingredients, components, or results of analysis determining the presence of a substance and the amount (i.e. assay), as appropriate to the type of article.

We had to fully monitor the use of the API as import of fresh material could take up to six weeks to clear FDA. This is because they consistently work at their own leisure and will not be pressurised by stock issues that we may have had. Therefore, we had to ensure we built this time lag into our lead time for the material to make sure there were no delays on the manufacturing site.

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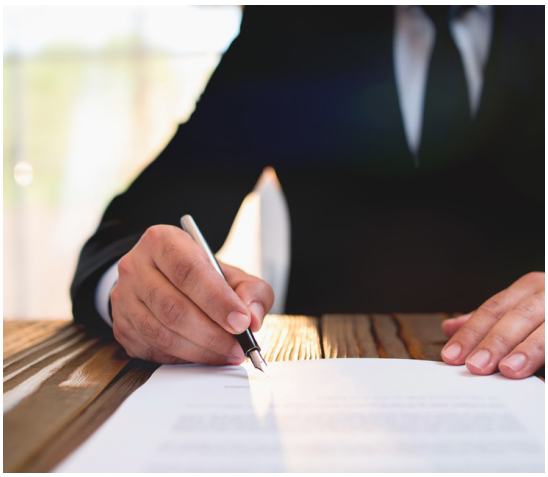
Once the FDA released the product to the manufacturing site, it was still considered in BOND, which meant we were still responsible to inform the FDA when the product was exported and provide all the documentation that confirmed every gram of API was used or destroyed. This has to be verified by the manufacturing site by way of signed confirmation.

Once all the export documentation was received and reviewed by the FDA, the open documentation on each batch of material was closed, and we received confirmation direct from the FDA that they accepted the batch as being correctly imported and exported.

We would arrange the export of the finished product by sea directly into our warehouses in France and the UK, ensuring that all the licenses required had correct storage locations listed. We would then make sure that testing was completed whilst stock was held in quarantine. Liaising with the registered QP at each stage for full compliance. Once the QP released each batch of product we would then forward the certificated onto the customers to effect full release of product to their market.



Supply chain had to maintain a full production schedule with the manufacturing facility showing how much active ingredient was being used in each batch of product, which days the product was being manufactured and note any losses or failed batched so that these could be reported to the FDA.

We specialise in providing the full spectrum of supply chain services to help distributors, wholesalers, pharmaceutical businesses and medical device companies transform their supply chains across Europe and around the globe. With every project and customer, we work with, we are committed to optimising and strengthening your supply chain.

Today's global pharma industry often extends across a myriad of transportation routes and regulatory jurisdictions which can present several challenges and risks to your business including falsified medicines entering your supply chain, Annex 16 compliance and more. IPG is fully equipped to meet these challenges and ensure that you can meet all QC and regulatory obligations.

Why Outsource?
Generic Pharma companies are aware of the need to be flexible, forward-thinking and have access to new skill sets. As such, there are many benefits to using outsourcing solutions for a range of operations.

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