ICE Pharma Group (IPG) is a generic pharmaceutical company with its own Marketing Authorisations (MAs) and experienced operational teams who can manage manufacturing through to final product release into European markets, as well as supply chain logistics all over the globe.

CASE STUDY

Summary

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

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.

Supply Chain Services

We specialize in providing the full spectrum of supply chain services to help distributors, wholesalers, pharmaceutical 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 optimizing 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 the supply chain, Annex 16 compliance and more. IPG is fully equipped to meet these challenges and ensure you can meet all QC & regulatory obligations.

ICE PHARMA GROUP HAS BEEN A SUPPLY CHAIN OUTSOURCING PARTNER SINCE 1999

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

NOTE: The product must be used 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 FDA identifying all firms that had possession of the product, including each processor, packer, distributor, or other firm that had possession of the product. This establishes 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.

With multiple pressures faced by pharma companies today, improving efficiency and managing cost remain high priorities. Finding a scalable supply chain solution, along with qualified personnel to handle it, can be a challenge.

ice pharma group

Atrium Court
The Ring, Bracknell, Berkshire
RG12 1BW, United Kingdom

+44(0) 845 453 1360
www.icepharmagroup.com
info@icepharmagroup.com

Summary

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

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

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, what days the product were being manufactured and note any losses or failed batches, so that these could be reported to the FDA.

We had to fully monitor the use of the API as import of fresh material could take up to 6 weeks to clear FDA, as they consistently work at their own leisure and will not be pressurized by out of stock issues we may have had, so we had to ensure we built this time lag into our lead time for the material to ensure no downtime on the manufacturing suite.

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, provide all documentation that confirmed every gram of API was used or destroyed, this had to be verified by the manufacturing site by way of signed confirmed letter.

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 letter direct from the FDA confirming that they accept the batch as been correctly imported and exported.

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

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.

www.icepharmagroup.com

Contact Us

Visit our website to learn more about our capabilities or get in touch to discuss your requirements:

Phone: +44(0) 845 453 1360

Email: info@icepharmagroup.com