propharma

CASE STUDY

An Inspection-Ready QMS Accelerates Product Introductions in Europe

Preparedness Pays Off with Successful Authority Inspections Resulting in MIA License Approval within 24 Hours

Accessing new markets in the European Union can be a challenge especially when having to navigate both specific country and general European regulations. ProPharma's deep understanding of local laws and extensive experience with local licensing agencies eliminated unnecessary time and effort. As a result, the inspection by local authorities was speedy and successful which helped expedite the MIA license approval.

A US-based client with products in various lifecycle stages from clinical to commercial sought market access to the European Union (EU) market as well as Switzerland. So, how do you navigate the complicated regulatory and compliance landscape across 44 countries and 21 supranational organizations in Europe?

Challenge

The initial request for support consisted of an appeal to set-up a Quality Management System (QMS) compliant with the European Union regulations as well as acquiring a Manufacturing & Importation Authorization (MIA) and a Warehouse & Distribution Authorization (WDA). Successfully passing Authority Inspections for MIA and WDA licenses in a timely manner is a crucial milestone given customary timelines for receiving such license approval can easily take up to 2 months if your organization is not inspection ready.

The client also requested to have their supply chain certified by a Qualified Person (QP) and felt it was important to have just one life science consulting partner to manage all requirements. Given the complexities of the various European markets and the pursued Swiss market, it can be difficult to source an experienced pool of QPs and Responsible Persons (RP) from one service provider.

Solution

In close collaboration with the client, ProPharma developed an initial gap assessment plan and license application plan. The client's existing global QMS was assessed for any gaps against EU Good Manufacturing Practice (GMP) regulations and was subsequently revised to suit all the EU and Swiss requirements. Where needed, new Standard Operating Procedures (SOPs) were drafted or current SOPs were revised to ensure compliance to the appropriate regulations.

As a single source service provider, ProPharma also provided the client two QPs to support the project and to certify the supply chain. The QPs combined their efforts and conducted supplier qualification audits. The QPs fully supported the initial authority inspection to obtain the MIA license and continue to support the client with batch release activities for Europe.

Results

The first milestone to obtain MIA licensure was completed successfully in a timely manner. In recognition of the diligent preparations for the inspection and ProPharma's excellent standing with the local inspectorate, the green light to provide an MIA license was granted within 24 hours upon completion of the inspection.

This was an exceptional result and provided the client an expedited path forward toward market access, producing faster returns on their investment. Furthermore, the increased productivity unlocked resources to focus on additional product development.

The feedback from the client remained very positive given the close collaboration and proactive approach of the ProPharma team. This further resulted in a new request to support the license application for the Swiss market, which was also successfully approved. As the truly global single source service provider, ProPharma continues partnering with the client on additional requirements of an application for a WDA license for other European markets, as well as providing QP and RP services for Europe and Switzerland. The client saved time and money by effectively and efficiently accessing various markets within Europe by partnering with just one company.

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