propharma

case study

successful product launch with QMS and QP certification

Learn how ProPharma can support your organization with its own Manufacturing and Import Authorization (MIA) License for Qualified Person (QP) certification services.

ProPharma recently supported the go-to-market strategy for a client outside the European Union (EU) who was in the process of obtaining Marketing Authorization for a new product for commercialization in the EU.

As a MIA license holder and legal entity within the EU, ProPharma was able to provide QP certification of the product, eliminating the need for the client to obtain its own MIA license as an EU legal entity and successfully meeting the timeline for launch.

Reaching patients in the EU with needed medicinal products is a complex undertaking that not only requires knowledge of varied regulatory landscapes, companies must also have a MIA license, the services of a QP, and have a legal entity within the EU.

challenge

Our client is a biotech development company working on novel drugs for use in clinical trials. Following the successful completion of their Phase 3 trials, the product was ready for commercialization.

The company only had research labs in-house and, as a result, outsourced all manufacturing activities for their clinical trials.

As our client focused on developing novel drugs and outsourced all GMP activities, they had **no organization or staffing to support a MIA license.**

In addition, **their main facility was not located in the EU.**

Setting up a legal entity in the EU, completing the process to obtain a MIA license, and providing adequate staffing could **take six to nine months and lead to unavoidable delays in the go-to-market strategy for their novel drug.**

solution

As a MIA license holder, ProPharma Group, The Netherlands B.V., was able to provide QP batch certification services.

ProPharma worked with the client to ensure processes were aligned, and all required documentation was implemented to provide QP certification services.

Furthermore, ProPharma's extensive experience providing QP services allowed us to support the client with the activities required to transition from a clinical to commercially oriented company, ensuring agreements with the client's CMOs were in place and ensuring all regulatory requirements were met for the sale of the commercial product.

results

The client was integrated into the ProPharma Quality Management System (QMS), ensuring all required processes were in place to provide QP certification.

As the MIA holder, ProPharma will also take care of any future MIA license updates needed to add new medicinal products for the client.

With ProPharma's MIA structure in place, we were able to support the client in meeting all requirements for QP certification within a couple of months, and the entire process was completed well within the timeline for the client to execute their go-to-market strategy successfully.

Whether you are preparing to market your product for the first time in a European country or you want to expand your product's reach to more countries in the EU, ProPharma can support you in defining and executing your market access strategy throughout Europe.

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