propharma

Successful Clinical Trials & Commercialization in EU/UK with Qualified Person Services

No matter where your product is in the lifecycle, we will work with you to maximize clinical and commercial value as well as accelerate and maintain market access.

Conducting clinical trials or launching products for commercialization in Europe can be a challenge. There are many complexities that can impede your efficiency to these markets, such as establishing a legal entity with a Qualified Person (QP) in the region, Brexit, and passing inspections to secure licenses. Whether you still need a license, or already have your MIA license in place, ProPharma can support you with strategic advice.

Preparing Your Product for Clinical Trials in EU/UK Markets

Partner with the leading industry compliance expert to prevent clinical trial failures in a late phase to shorten timelines and reduce overall costs. We will help establish a legal entity in EU/UK for your clinical trial and provide QP support via our established MIA license. This will allow you to focus on clinical studies and product development to support patient access and safety.

Launching Your Commercial Product to EU/UK Markets

Partnering with ProPharma and benefitting from our established MIA license will eliminate the need for you to navigate all the unique requirements across the European market. We support your swift and compliant market access by ensuring a licensed QP in the geographic area of choice and guarantying a compliant QMS is in place.

Full-Service Support to Help Entry to EU/UK Markets

We have the local expertise across Europe to help you with all the GMP/GDP tasks to make it happen.

Resources Required for European Market Access

A Qualified Person (QP) to oversee the entire chain of manufacturing (even if not in the EU), filling, shipping, packaging, etc.	A Manufacturing & Importation Authorization (MIA) and/or a Warehouse & Distribution Authorization (WDA) license	A legal entity for the QP-release. This means establishing a limited company requiring a General Manager & QMS	A Responsible Person, 3rd party logistics provider, serialization and QP certification

ProPharma's deep understanding of local laws and extensive experience with local licensing agencies eliminates unnecessary time and effort. Whether you need help establishing the right infrastructure or full-service support, our team of compliance experts can provide custom solutions to help you export your pharmaceutical or biotech product(s) to Europe.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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