propharma

Accelerate Market Access to Europe with MIA License

Reduce Launch Timeline and Improve Business Efficiency

Accessing new markets for exporting pharmaceutical and biotech products or conducting clinical trials in Europe can be a complex challenge. There are many complexities that can impede your efficiency to market and attainment of your commercial goals, such as establishing a legal entity with a QP in the region and passing inspections to secure your own Manufacturing & Importation Authorization (MIA) license.

Partnering with the leading industry compliance expert will help unravel these complexities to improve business efficiency, shorten timelines, and reduce overall costs. This will allow you to further focus on clinical studies and product development to support patient access and safety.

Complexities of Accessing EU Markets

- Navigating both specific country and general European regulations
- Creating tailored market access strategies per country
- Establishing a legal entity with a QP in the region
- Passing inspections to secure your own MIA license

Immediate Market Access with ProPharma's MIA License

Our pharmaceutical and biotech clients save time and money when launching new products to the European market (Schengen countries) through the benefits of ProPharma's MIA license. Additional benefits to support your swift and compliant market access are:

- Ensures a licensed QP in the geographic area of choice
- Guarantees compliant QMS is already in place
- Expedites successful authority inspections
- Eliminates the need to hire in-house regulatory experts for local requirements
- Assures efficiency through proven experience with local regulatory bodies
- Allows for batch releases on your behalf

If you prefer to invest in securing your own license, we have the local expertise across Europe to help you with all the tasks to make it happen.

Contact ProPharma today for a complete evaluation and to explore your options for European batch release.

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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 setting up a limited company requiring a General Manager and a QMS	A well-established relationship with the local Health Authority is a key to success

Experienced Partners for EU Licensing and Compliance

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 to Europe.

Improving Patient Health and Safety

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory expectations are met, business goals are achieved, and patient health and safety is improved.

regulatory sciences | clinical research solutions | quality & compliance | pharmacovigilance solutions | medical information | R&D technology

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