propharma

case study

secure timely execution of your product launch by ensuring GDP compliance across European countries

Service Area: Life Science Consulting

ProPharma supported the successful launch of a centrally approved product.

After Marketing Authorization (MA) approval, we ensured the suggested distribution networks in the European Union (EU) were in compliance with national and EU-Good Distribution Practice (GDP) requirements for a safe and secure supply chain.

Our client was in the phase of submitting a Marketing Authorization Application (MAA) in the EU and needed to apply for a Wholesale Distribution Authorization (WDA).

After application and approval of the WDA, the next steps were qualification of the distribution network and development of a relevant Quality Management System (QMS).

ProPharma supported the client to meet its target timetable to launch the product in compliance with GDP regulations.

> “Serving as a true extension of your team, our consultants bring specialized expertise and knowledge of local regulatory requirements and have proven experience with local regulatory bodies.

challenge

The MAA is your first tollgate for bringing your biotech or pharma product to market in the EU. For post approval, there are multiple additional hurdles to clear before you can successfully dispense your product to patients. Application processes for WDA can take anywhere from 5 – 9 months depending on the country's availability of inspectors and the maturity of the QMS. Within that timeframe, there are many items that need to be accomplished before a WDA can be acquired such as: Standard Operating Procedures (SOPs) need to be written and approved, vendors should be audited, and a qualified health authority inspection needs to be completed. Furthermore, a Responsible Person (RP) with the appropriate credentials and experience is required to be assigned to the license.

One key element is compliance with all GDP regulations in each specific region in order to be able to distribute and sell your product in your target markets. This translates to multiple required activities, such as the verification of the correct licenses to procure and sell your product, the evaluation and risk assessment of your supply chain, the qualification of your vendors, and the affirmation your QMS is in place with accurate processes for the handling complaints, recalls, and other GDP-critical activities.

Our client was in the phase of submitting an MAA in the EU, with the possibility of an accelerated approval within 6-9 months. However, our client had no prior experience in commercial distribution and therefore did not have an existing supply chain in place. **This situation presented the risk of losing valuable time that could delay supplying medicines to patients. The challenge was to prepare the client to meet GDP compliance without compromising the quality of the product.**

solution

The ProPharma team of experienced Quality Assurance (QA) consultants started by **conducting a gap assessment of the existing QMS and the proposed distribution supply chain in the EU, including target countries. The team was then able to provide a road map and a project plan tailored to the client's expectation.**

The project plan included several key deliverables: SOPs that needed to be written or amended, the evaluation of countries where WDA license should be applied for
(including related timelines), guidance on local regulations in the key markets, as well as a plan for qualification and audit of vendors such as Third-Party Logistics (3PL) and transport providers.

A project lead was assigned to oversee all activities and worked in close collaboration with the client. A Responsible Person from ProPharma was assigned to execute the SOP updates and WDA application, and to host the competent authority inspection. ProPharma auditors where assigned to audit 3PL warehouses and transport companies. The team worked in close collaboration with regional experts, serialization experts, and GMP experts to provide a tailored quality system in order to meet the client's needs and efficiently launch its product within the targeted timeframe.

results

ProPharma supported the client to successfully launch the product upon MA approval through our holistic and agile approach. As a result, the setup of the distribution supply chain wasn't delayed and the launch to bring medicines to patients was completed on time.

Our European network of GDP experts and Responsible Persons enabled us to make sure the client was prepared to meet the compliance regulations to be able to distribute their product in all markets across the EU.

By being nimble, we were quickly able to tailor a robust quality system, meeting the compliance regulation for GDP and securing product quality in an efficient and simple way. This then allowed the client to focus on the path ahead, with built-in flexibility to make adjustments along the way and adapt to changes in future needs or regulations. By providing experts such as a Responsible Person, auditors, and project leads, the client received a tremendous strategic advantage with efficient and precise documentation as well as reports and processes.

improve the health and safety of patients.

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 goals are met, business objectives are achieved, and patient health and safety is improved.

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

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