propharma

CASE STUDY

Restoring Inspection Readiness and Building a Long-Term Pharmacovigilance Partnership

Our Client

Our client is a mid-sized biotechnology company based in the United States with centrally approved (rare disease) products in the European Union. ProPharma have supported this organization since 2012 with our Qualified Person responsible for Pharmacovigilance (QPPV) solutions, making them one of our longest-standing partners.

Background and Challenges

This client had initially reached out to ProPharma based on the success of our previous partnership, where our experts had provided pharmacovigilance (PV) compliance support. They were already operating in the EU and had recently undergone an MHRA/EMA PV inspection that resulted in critical and major findings. Dissatisfied with their QPPV provider and facing an imminent follow-up inspection, the client urgently needed a reliable, experienced partner who could rapidly stabilize their PV system and restore inspection readiness.

Our Solutions

ProPharma appointed an experienced, senior EU QPPV with deep regulatory and life sciences expertise. As for the inspection: we saw this as an excellent opportunity to get to know the organization, its systems, and processes as quickly as possible. Using our expertise to be inspection-ready on a short notice, the client partnered with us.

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

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Expansion of Our Services

As trust in ProPharma's expertise grew, the scope of services expanded significantly over time to include:

- Deputy EU QPPV
- UK QPPV and deputy UK QPPV (after Brexit)
- Local Persons responsible for Pharmacovigilance (LPPVs) in most EU countries, almost all managed internally by ProPharma
- Local Literature Screening in most EU countries, fully managed by ProPharma
- Provision of Regulatory Intelligence on local requirements for Risk Management Plan (RMP) and additional Risk Minimization Material (aRMM) in over 50 countries and territories worldwide

This organic expansion was driven by consistent performance, reliability, and client satisfaction. Most recently, the client renewed their contracts with ProPharma for an additional multi-year period.

Our Approach

ProPharma tailored its operating model to meet the client's specific needs while maintaining robust oversight and efficiency:

- The EU and UK QPPVs operate fully within the client's Quality Management System (QMS), including internal procedures and training systems.
- LPPVs operate under ProPharma's QMS, ensuring consistency and compliance across countries.
- A gradual transition from alliance partners to internal resources improved system control and reduced costs for both parties.
- The EU/UK QPPV maintains oversight of all LPPVs and serves as a single point of contact for the client, simplifying communication and governance.
- All QPPVs roles are fulfilled by senior staff with life sciences backgrounds, so they have a full understanding of the client's processes, challenges and needs.
- For this client, the Deputy EU/UK QPPV is also the Project Manager, enabling short communication lines and more efficiency.
- ProPharma limits the number of primary QPPV roles per consultant to ensure sufficient capacity, timely responsiveness, and consistently high-quality delivery.
- Initially, the client required a fulltime QPPV, but with increased familiarity with the client, their PV system, and processes, now less QPPV time is needed. But of course, the QPPV is still full-time available in case of need.

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Results and Client Satisfaction

ProPharma's support delivered measurable and sustained results:

- Two successful European Medicines Agency (EMA) PV inspections by the Dutch inspectorate.
- Highly satisfactory client audits on the QPPV function.
- Timely retrieval of historical PV data that was difficult to retrieve due to the client's data retention policies. Using our robust archiving practices, we were able to forward the documents to the client.
- Recognition of the client with an internal quality award for the successful implementation of key initiatives to enhance the global additional Risk Minimization Measures (aRMM) process – an achievement to which ProPharma's EU/UK QPPV made a significant contribution.

Together, our expertise, fully qualified staff, single point of contact and range of services resulted in a long-standing relationship with this highly satisfied client.

Quote from Client

> "So, when I thought about what I value about working with ProPharma, several things came to mind. That includes reliability, compatibility, and creativity, but one of the most important characteristics is passion."

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.

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