propharma

case study

effective lifecycle management within the European Economic Area (EEA) led by a dedicated project manager

Learn how our experienced regulatory consultants supported a pharmaceutical company with local lifecycle management activities for all 31 countries within the EEA.

A medium-sized pharmaceutical company requested assistance with local knowledge and execution of local Regulatory Affairs (RA) activities for all 31 countries within the EEA. ProPharma supported with regulatory intelligence and local strategic advice, launch preparations, maintenance activities, and interactions with local Health Authorities.

All activities were completed under the supervision of a dedicated project manager, who guarded deliverables, timelines, and ensured consistency and quality of service delivery across the region.

Serving as a true extension of your team, our consultants bring a deep understanding of effective lifecycle management and have the knowledge to offer a complete regulatory solution.

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

challenge

A medium-sized pharmaceutical company was working with a network of vendors for provision of local support and execution of local Regulatory Affairs activities within the EEA.

The company was struggling with cumbersome and redundant communication flows with many different contact points and was looking for a more efficient way of working.

Given the required follow-up regarding the status of projects and deliverables as well as handling multiple incoming invoices, working with several different vendors and managing communication amongst all of them proved to be an administrative burden for the company. As such, they were looking to find one vendor who could support them for the entire EEA.

solution

ProPharma assembled a team of regulatory consultants with relevant experience, language skills, and local knowledge for the countries concerned.

A project manager, as well as a back-up, was carefully selected to manage the workflow and be the main point of contact for the client.

The project manager was responsible for coordinating the start-up and training activities, as well as leading the on-going work and guarding deliverables, making sure timelines were met, and ensuring consistency of service delivery across the countries.

Regular meetings with the client were held to monitor progress.

results

Outsourcing the local Regulatory Affairs activities for all of the EEA countries to ProPharma rather than continuing to spread out the workload amongst several vendors resulted in effective and efficient lifecycle management, which in turn created a more expeditious regulatory process overall.

Communication was consolidated through one point of contact and the client's administrative burden was drastically reduced.

ProPharma provided a seamless interface between the client and the local dedicated consultants assigned for each country.

The client was very appreciative of the full-service support as well as the flexibility with resources that this partnership contributed to.

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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