propharma

outsourced regulatory department

Regulatory Sciences

Bespoke Regulatory Science Teams for Pharmaceutical Companies

Sometimes there is sound logic for a pharmaceutical company to outsource a significant part of their regulatory tasks to a stable and experienced team. ProPharma's team of Regulatory Sciences experts has been a trusted resource for a variety of companies looking to:

- Overcome a significant workload increase

- Place regulatory lifecycle management in safe hands while internal reorganizations take place

- Increase workflow efficiency

- Keep internal headcount to a minimum in small generics pharmaceutical companies

- Support non-EU pharmaceutical companies entering the EU market

We build bespoke regulatory teams for companies and provide a reliable regulatory workflow with appropriately qualified staff available for each task. The outsourced model can work as either dedicated Full Time Equivalent (FTE) or task-based contracts.

> "Our consultants' knowledge and expertise with large scale regulatory department planning and execution gives absolute reassurance to global pharmaceutical companies who need regulatory solutions while organizational restructures are ongoing."

Nick Littlebury
Vice President, Regulatory Sciences

propharma

ProPharma Group, LLC
Proprietary and Confidential

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.
ProPharmaGroup.com, info@ProPharmaGroup.com

challenge 🏔️

A major corporate restructure resulted in a shift in the European footprint. Several departments, including regulatory affairs, were impacted. A safe-harbor solution was required to support the restructure until a new European team could be built.

solution 💡

ProPharma provided a fully outsourced regulatory department to support the major corporate restructure.

- Team assembled with 1 director, 2 managers, and access to 5 officers

- 2-year project

- Full control of a portfolio of products

- Provided a safe harbor for product licenses and lifecycle maintenance during a restructuring exercise

- Upon completion, a shift in focus to ongoing Regulatory Department Overflow services as a fail-safe strategy against future organizational changes

results 📋

- On time Marketing Authorization submissions and approvals throughout the 2-year project

- Fully outsourced lifecycle management and publishing activities for Variation IA, IB, II, Renewals, Work-sharing, & PSURs

19 DCP   **6** National

MAA   **25** total

50 Type 1A   **22** Type II   **22** Worksharing   **14** Renewals

LIFECYCLE   **154** total

50 Type 1B (24 safety related)   **20** Article 61 (3)   **4** PSUR SUB

regulatory sciences

clinical research solutions

quality & compliance

pharmacovigilance solutions

medical information

R&D technology

propharma

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle. ProPharmaGroup.com, info@ProPharmaGroup.com