PROPHARMA GROUP®

Improving Patient Health and Safety

Ensure Regulatory Success Across the **European Medicines Agency (EMA)** and National Competent Authorities (NCAs)

Our aim is to make your business succeed. ProPharma Group's experienced team commands a breadth and depth of knowledge pertaining to the EMA's regulatory framework and can work with you to accomplish your regulatory and business objectives at every stage of the product lifecycle. We develop regulatory strategies for your product, providing a clear path forward through all the critical milestones to achieve a successful outcome. We can also help with your post-authorization regulatory needs, including the launch of your product, and managing post-authorization variations (including new indications and line extensions) and commitments for maintaining your product's optimal regulatory status throughout its lifecycle.

ProPharma Group: Helping Clients Achieve Successful Regulatory Outcomes at Every Stage in the Product Lifecycle.

PRE-AUTHORIZATION

Interacting with the EMA and NCAs can be a daunting task; we are here to help you every step of the way.

- Regulatory Strategy and Gap Analysis
- Medical Writing
- Scientific Advice
- Orphan Applications
- Pediatric Investigation Plans (PIPs)
- Marketing Authorization Applications (MAAs)
- Peri-Approval Services

REGULATORY OPERATIONS

After your data has been gathered and your submission has been compiled, if it is not submitted appropriately, all of your hard work could fall short and fail. We assist with all Agency communication and interaction to achieve successful outcomes.

POST-AUTHORIZATION

We understand your work does not end after EMA approval has been obtained, so neither does ours. Our expertise and experience extends well into the post-authorization phase to continue and ensure all European requirements are completed appropriately.

- Product Launch
- Project Lifecycle Management - variations and commitments
- Regulatory Project Management
- Regulatory Intelligence (RI)
- Promotional Material

Improving Patient Health and Safety. At Every Step.

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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