Reduce Your Time to Market with an **Effective FDA Regulatory Strategy**

As experts in U.S. Food and Drug Administration (FDA) regulatory consulting, ProPharma will partner with your team to develop an appropriate and effective strategy to get your product to market as quickly and efficiently as possible.

Our team of experts will combine knowledge of your product with years of experience (including pre-clinical, clinical, chemistry, manufacturing, and controls (CMC), drug safety, and pharmacokinetics) and literature research on your product and similar approvals. The final regulatory strategy for your product will balance risk, speed to approval, and cost to provide you with a description of the most appropriate regulatory path and explain why this path is the rational choice.

We help clients achieve positive regulatory outcomes using a scientific approach as the driver of success. As the world's largest RCO (Research Consulting Organization) and leading provider of regulatory consulting services, we support our clients from pre- through post-approval for the FDA.

Our aim is to make your business succeed. ProPharma's experienced team commands a breadth and depth of knowledge pertaining to the FDA regulatory frameworks and will work with you to accomplish your regulatory and business objectives.

We develop regulatory strategies for your product, providing a clear path forward through all critical milestones to achieve a successful outcome. We will also help with your post-authorization regulatory needs, including the launch of your product, line extensions (LE) and variations, and maintaining your product's optimal regulatory status throughout its lifecycle.

www.ProPharmaGroup.com

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Helping Clients Ensure Regulatory & Development Success at Every Stage in the Product Lifecycle.

FDA SERVICES

DRUG DEVELOPMENT

From developing and executing your regulatory strategy to obtaining NDA approval, our regulatory and scientific knowledge combined with our experience and history of working with the FDA enables us to advance your product successfully.

- Regulatory Strategy/Gap Analysis
- FDA Meetings
- FDA Submissions
- Nonclinical Drug Development
- Chemistry, Manufacturing, and Controls (CMC) Advice and Management
- Clinical Pharmacokinetics (PK)/ Pharmacodynamics (PD)
- Regulatory Due Diligence
- Pre-Approval Audits

MEDICAL DEVICE DEVELOPMENT

From concept development through FDA approval and the Agency's post-marketing requirements, our team of specialists are highly qualified to assist you in all aspects of device regulation throughout the product lifecycle.

- Medical Device Regulatory Strategies
- Stand-alone Medical Devices or Combination Products
- Meeting and Submission Support
- Quality Management and Compliance
- Risk Management and Human Factors Engineering

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 expectations are met, business goals 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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