

REGULATORY SERVICES

Achieve new or generic product submissions and approval by relying on our regulatory expertise



CASE STUDIES

Collaboration and strategic planning is key to bringing a product successfully to market. With a full complement of regulatory services, we can help you navigate the regulatory requirements throughout your product's lifecycle. From working in a focused area supplementing your internal team, or assuming a lead role in undertaking your entire regulatory planning, our team is ready to serve you.

Learn how three clients relied on Firma Regulatory Services to produce timely, quality, and successful regulatory submissions.

MEET TIMELINES WITH FORMAL AGENCY REPRESENTATION AND SUBMISSION SUPPORT

Client: Global, mid-sized pharma company

Project Focus: Regulatory submissions

Request: Firma was contracted to assist with an initial IND submission with expedited timelines. Services included:

- ▷ Providing a US agent
- ▷ Regulatory consulting and writing

Approach: Firma, acting as US agent, initiated communication with the FDA and established strategy submission. Regulatory writers were deployed to review and revise the regulatory submission documents for FDA compliance and clarity of a streamlined message.

Results: The client's IND was filed ahead of schedule and was accepted by the FDA.



ANTICIPATE HURDLES AND MAP A SMOOTH COURSE

Client: Mid-sized pharma company

Project Focus: Strategic development plan

Request: Firma was contracted to develop a strategic plan for a potential drug candidate to provide the optimal path to market. Services included:

- ▷ Target Product Profile (TPP) development
- ▷ Regulatory strategy and consulting

Approach: Firma assembled a cross-functional project team composed of medical, clinical, manufacturing, and quality members to assess the multitude of potential variables that affect a definitive strategy. After the TPP was developed, Firma implemented a regulatory strategy that identified the pathway and the potential risks, as well as proactively addressed any issues that arose.

Results: The strategic development plan created by Firma allowed the client to adjust their risk-based approach to successfully advance their product through development while lowering their development costs.

TECHNICAL INTELLIGENCE REFLECTING COMPELLING CONTENT

Client: Mid-sized pharma company

Project Focus: Regulatory operations

Request: The client identified a large number of documents to be prepared for an upcoming regulatory submission. The documents needed to be created using a standardized template to ensure submission-ready state. The standardization and conversion were due within 4 weeks. Services included:

- ▷ Clean document formatting/editing
- ▷ Providing and customizing templates

Approach: Our team of document specialists and electronic publishers directly navigated and edited documents, saving significant time while reinforcing and creating consistency among the portfolio. Undertaking document conversion and correction within templates increased efficiency and allowed for focused efforts within demanding time constraints.

Results: Implementation of a strong and comprehensive plan allowed the Firma team to complete the project one week ahead of schedule, allowing the client to focus their attention on other critical-path activities and achieve their submission on time.

FIRMA REGULATORY

For more information on how to achieve new or generic product submissions and approval by relying on our regulatory expertise, email sales@firmaclinical.com or visit firmaclinical.com.