FIRMA
CLINICAL RESEARCH
*Expert Insights | Quality Outcomes*

# REGULATORY SERVICES

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

Collaboration and strategic planning is key to bringing a product successfully to market. However, without experienced resources in-house to establish regulatory strategy and guide operational approach, you risk not meeting agency expectations and securing approval.

The Firma team understands challenges unique to ensuring successful regulatory submissions and approval. Our team members have direct experience presenting to and defending submissions in front of global regulatory agencies and advisory committees.

**50+**
**NDA submissions supported**

**30+**
**regulatory strategy plans developed**

**20+**
**NDA submissions directly managed**

## Proven regulatory experience you can count on

With a full complement of regulatory services and global experience, our team members leverage their expertise and knowledge of required regulatory pathways and approaches to advise, support, and operationalize your strategy. 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 provide value throughout each phase of your product's approval pathway.

## Expert team to navigate regulatory complexities

Count on our regulatory expertise and proven industry reputation to help you with:

- ▷ Regulatory strategic planning and consultation
- ▷ Target product profile (TPP) creation and review
- ▷ Regulatory/industry intelligence
- ▷ Gap analyses and due diligence
- ▷ Label creation and review
- ▷ Pediatric plan development
- ▷ Agency interactions
- ▷ US agent/authorized representative
- ▷ Regulatory writing
- ▷ Regulatory operations and publishing
- ▷ CRO and vendor oversight
- ▷ Ongoing post-approval support

## PRODUCE TIMELY, QUALITY, AND SUCCESSFUL REGULATORY SUBMISSIONS

Aligning our expertise by function, therapeutic area, or project phase ensures your strategic plan is applied to a dynamic environment, and flexibly adapts to changes in corporate strategy or development landscape. How can our expertise benefit you?

### Meet timelines with representation and submission support

Learn how we can help establish your submission strategy, review and revise compliance documentation, and support your drug approval.

### Anticipate hurdles and map a smooth course

Learn how our strategic development planning approach provides you the optimal path to market.

### Technical intelligence reflecting compelling content

Learn how our team implements a strong and comprehensive plan to drive completion at or ahead of schedule.

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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**.