Regulatory Strategies

Catalyst Regulatory Services was founded to provide a wide range of high-quality Regulatory Affairs services to pharmaceutical and biotechnology companies. Services include ad hoc strategic consulting, "full-service" outsourced solutions for small-medium companies, as well as regulatory staff augmentation solutions

Catalyst Regulatory Services, LLC provides comprehensive services targeted to the needs of companies at all stages of development. Our goal is to work collaboratively with pharmaceutical and biotechnology companies to develop innovative, customized, strategic programs that help our clients obtain and maintain the regulatory applications necessary to study investigational drugs and biologics, in pursuit of market approval.

Aligning Regulatory Strategy to Product Objectives

Understanding the regulatory strategy for an exploratory product is a critical success factor in its development. Catalyst Regulatory Services' staff can assist clients in analyzing the key regulatory issues and navigating the complex path through development. These aspects include timing for regulatory authority engagement, the changing external regulatory environment, possible options for accelerating development and additional data exclusivity.

The regulatory team at Catalyst Regulatory Services has provided regulatory leadership to dozens of development teams, working in collaborative team environments at all stages of the project life cycle. We have detailed experience in regulatory due diligence to support decision making on licensing and investment opportunities. We also have the experience to provide expert input on a variety of regulatory topics such as QT prolongation, abuse liability, pediatric drug development and assessment of suicidality.

High-Quality Regulatory Authority Interactions

Through experience of countless regulatory authority interactions, the Catalyst Regulatory Services' staff each has a detailed understanding of building and maintaining effective relationships with regulatory agency staff at all levels. These relationships can help a company navigate a clear path through the daunting regulatory maze.

We have participated in hundreds of regulatory authority liaison activities and have the knowledge and expertise to prepare clients for critical agency interactions. Our experience includes leadership at FDA Pre-IND, End of Phase 2, and Pre-NDA meetings, Label negotiations, FDA Advisory Committees and European national regulatory interactions and CHMP meetings.

Value-Added Regulatory Submissions

The Catalyst Regulatory Services' team has made hundreds of submissions to regulatory authorities, ranging from routine IND updates to full-blown marketing applications in the US and EU. We understand the vital importance of high-quality documentation and the value of a customer-focused approach to regulatory applications.

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Catalyst Regulatory Services, LLC

Regulatory Services

Regulatory Strategy Consulting

- Critical program review and regulatory issue analysis
- Regulatory risk analysis and mitigation strategy planning
- Expert consulting on regulatory hot topics such as QT prolongation, suicidality assessment, abuse potential
- Due diligence for licensing and investment decision making

Regulatory Meeting Planning & Execution

- Initial meeting planning
- Meeting request and briefing document
- Rehearsals and team preparation
- Meeting conduct and follow up

Regulatory Submissions

- Prepare and submit initial INDs
- Maintain existing INDs
- Expert consulting on CTD build for US and EU NDAs
- Maintain existing NDAs and BLAs

Document Formatting and Publishing

- Compile composite reports
- Finalize reports with proper styles, tables of contents, headers, cross-references, footnotes etc.
- Render documents to PDF with bookmarks and hyperlinks suitable for electronic submission

Catalyst Regulatory Services partners with our clients to design and execute meetings that provide the results you need.

Regulatory Professionals

Average 15 years in Regulatory Strategy Role

- Small molecules and biologics
- From pre-clinical candidates through to marketed product maintenance

FDA Groups Worked With

- Division of Monoclonal Antibodies
- Division of Cardiovascular and Renal Products
- Division of Biologic Oncology Products
- Division of Oncology Products
- Division of Neurology Products
- Division of Psychiatry Products
- Division of Medical Imaging and Hematology Products
- Division of Dermatology and Dental Products
- Division of Metabolism and Endocrinology Products
- Division of Anesthesia, Analgesia and Rheumatology Products
- Office of Surveillance and Epidemiology
- Controlled Substance Staff
- Study Endpoint and Label Development Team
- Office of Compliance

Regulatory Authority Meeting Experience

- FDA Advisory Committee
- FDA Pre-IND, End of Phase 2, Pre-NDA
- Labeling and post-market commitment negotiations
- CHMP Oral Explanations
- Mutual Recognition Facilitation Group
- EU National Agency meetings

Geographic Scope

- United States
- Canada
- European Union

Therapeutic Experience

- Oncology
- Neurology
- Psychiatry
- Cardiovascular
- Endocrinology
- Dermatology
- Inflammation
- Critical care
- Addiction disorders
- Hematology

CONTACT

For more information about Catalyst Regulatory Services' consulting services, call us in the US at +1 (734) 253-2438. Or email us at mark.ammann@catalystreg.com

Catalyst Regulatory Services, LLC