Responses To Regulatory Challenges

Regulatory Solutions

Strategic, Execution and Project Management support for the submission lifecycle of drug, biologic, or regenerative products and vaccines, from pre-IND through licensure including the creation of and adherence to project timelines, monitoring of project resources, tasks, and budget, integration of multiple functional experts for application review and maintenance, attendance at FDA-Sponsor meetings, and experience with regulatory agency requirements and guidance.

Not infrequently, regulatory agency review of a submission leads to requests for additional data (technical, nonclinical, or clinical), re-analysis of existing development data, or clarification of information. These can hold up clearances to conduct clinical studies or marketing approval clearances or approvals. We have expertise in all aspects of healthcare product development and testing and can work with sponsors to develop responses to regulatory challenges or to implement programs necessary to collect information address data gaps.

- Advice on regulatory options and potential pathways
- Responses to Complete response letters (CRL) or clinical holds

Remediation Strategy and Execution

Adversarial relationships with regulators lead nowhere. DSI has helped numerous companies settle disputes with agencies by clarifying the design and/or interpretation of results as well as misconceptions implicit parties may possess. Should the FDA return an adverse opinion and/or non-approval, DSI expertly evaluates the technical and scientific details of FDA findings. We engage in a dependable process to identify issues and remediation strategies. Our team is proficient, for example, at transitioning programs off clinical hold to get NDAs submitted and filed, and then addressing challenges thereafter.

- Content review inquiries
- Clinical holds
- 505(b)(2) NDA non-approval/refuse-to-file
- Scientific dispute resolution

OUR PROJECT-BASED REGULATORY STRATEGY & SUBMISSION SERVICES

FDA Chemistry, Manufacturing and Controls Challenges

You can hear the fireworks, taste the champagne, all that's left is an Agency agreement on the clinical and/or commercial supply chain. Your success now depends on the flawless execution of your meeting strategy.

We have pioneered a unique technical approach to CMC meetings with the Agency to get you through this high-stakes interaction. Each program is different and has specific needs and concerns, and you must keep these in mind as you discuss your product.

After learning about key issues in your product's history and identifying critical issues in your current application, DSI will create a strategy for your meeting that is predicated on concerns likely to be raised by the Agency Reviewers, and the data necessary to address them.

With this strategy in place, we will help you to prepare a slide presentation that presents all information in a complete, understandable, and simple manner. Since most FDA reviewers will evaluate this information before the meeting, we must make it easy for them to understand why approval is rational. Next, we will make sure all participants are prepped for the meeting by conducting a rehearsal to train the speakers. Finally, we will attend the meeting with you, along with select Subject Matter Experts (SMEs), providing data and presentations, as needed during the meeting.

WHAT CAN DSI DO FOR YOU?

Regulatory Affairs

- Regulatory Agency Representation
- Regulatory Strategy Development
- Management and Preparation of Regulatory Submissions
- Responses to Regulatory Challenges
- Breakthrough Therapy Designation Requests
- Gene and Cell Therapy Product Review

CMC

- Integrated CMC Development
- Materials Characterization and Formulation Development
- Process Development, Optimization, And Validation
- Analytical Method Development, Optimization, and Validation
- Stability Program Design and Management

QA

- Design, Implementation, and Remediation of Quality Systems
- Compliance, Vendor Qualification, and Mock Pre-approval Audits (Mock-pais)
- Management of Compliance Situations

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