Regulatory Strategy Development

A regulatory strategic plan is critical to defining the overall product development plan and the fastest path to marketing. It considers regulatory agency expectations and precedence for the technical, nonclinical, and clinical data necessary to support a regulatory action. The strategic plan provides timelines and milestones for necessary activities and the implications of delays.

Regulatory CMC 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.

Whether this is the first or tenth product you have brought to market, careful preparation for each milestone and possible challenge is necessary or your entire development strategy could be derailed. Planning is key to this process, and knowledge of each regulatory agency's intricacies is a major plus.

Whether you need help executing your entire chemistry, manufacturing and controls (CMC) strategy, producing an FDA briefing package, or conducting a "Development Milestone" Meeting, DSI's experience and positive working relationship with the FDA means we will get the job done right. We work with you to do what is necessary to move to the next milestone.

Our Project-Based Regulatory Strategy and Submission Services Include:

- Pre-IND Meeting – To the best extent possible, any meeting with the Agency should end in clarity. During the Pre-IND Meeting Sponsors have the chance to discuss the CMC requirements for opening an IND with the Agency.
- End of Phase 2 Meeting – During this meeting, you need to effectively present your Phase 3 and development strategy and ensure that you are aligned with the FDA prior to the start of Phase 3.
- Pre-NDA Meeting – When you leave your Pre-NDA Meeting, you should have an understanding of the FDA's expectation for content. During the Pre-NDA Meeting, you must make the most of the opportunity to solicit comments and clarification from the Agency on the acceptability of data required.
- NDA Submission: 505(b)(1) and 505(b)(2) Assistance – As you can imagine, this type of submission requires extensive research, including both clinical and nonclinical studies to prove the product's safety and efficacy for the indication being sought.

OUR PROJECT-BASED REGULATORY STRATEGY & SUBMISSION SERVICES

Regulatory Strategy & Due Diligence:

- Evaluate and provide guidance on all aspects of regulatory CMC strategy for product development
- Support clients developing biologics, small molecules, devices, biosimilars and combination products
- Advise on CMC compliance with Orphan Drugs Designation, Fast Track, Break-through Therapy, Accelerated Approval, ANDA and 505(b)(2) submissions
- Conduct due diligence assessments

Strategic CMC Assessment

When beginning with a concept drug candidate, the first important step in an efficient drug development path is to determine its feasibility. For New Chemical Entity (NCE) drug pathway candidates, a strategic assessment is especially important. This is where DSI can help by utilizing their strategic assessment services.

Done right, a strategic assessment determines the key components of the drug development plan, like a roadmap for a trip. Without a roadmap, it is possible to reach a desired destination. But with an informed roadmap, it is possible to reach a desired destination by planning for efficiency from the beginning, spending the least amount of time and money to get there.

Here at DSI, we believe a strategic assessment is the first key to a drug candidate's success, making go/no-go informed decisions at the beginning, and evaluating and planning for the scientific, technical, regulatory, and commercial aspects of a product's development.

Scientific Viability

Does the science make sense? For instance, is the formulation stable and readily prepared? Is manufacturing scalable? Are active and inactive ingredients available and affordable?

Regulatory Viability

What data will be required to gain approval? Can development be expedited? Would exceptions or commitments ("be negotiated") be available? What distinguishing information can be presented within the negotiation for eventual binding agreement?

Commercial Viability

Is there a viable supply chain for the product? What is the potential for future competition or substitution?

DSI offers the strategic assessment, scalable to fit each program's needs.

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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