

# CMC Regulatory Affairs Support

As an investigational product moves closer to commercialization and final to market, the CMC information is collected, maintained, and updated for both the drug substance and drug product. We have prepared numerous successful CMC and quality sections of regulatory submissions including meeting packages, INDs and CMC Amendments, DMFs, NDAs, postapproval CMC Supplements, Canadian NDSs, BLAs, European IMPDs and MAAs, and postapproval variations IMPDs.

## A Deeper Department

A Regulatory Drug Development consulting business that (works exclusively with) serves the needs of small emerging biotech, most of whom do not yet have major products approved and on the market (to improve performance in strategy and leadership). Whether advocating CMC strategy, directing CMC operations or developing CMC submission content that represent the best interests of emerging biotech, we focus on the critical CMC and Regulatory issues and build programs that enhance development.



## Getting It Right, Early

Drug Development requires innovation, creativity, and a multiple disciplinary approach in obtaining a successful path to approval. A successful program can provide a high-value opportunity for a drug development company. Because of the regulatory compliance similarities between both small and large molecules, DSI is ideally positioned to help develop and guide a successful, efficient drug development program and create a high-value opportunity for your company. DSI's multidisciplinary team includes in-house regulatory experts, CMC, and subject matter experts who can improve your chances of avoiding a clinical hold or a complete response letter due to CMC concerns.

### DSI's regulatory strategy team:

- Leads the largest percentage of submissions of any team submitting to the FDA
- Has guided 50+ Marketing Application approvals
- Holds 1 to 3 pre-IND meetings a month
- Upholds a 100%+ FDA concurrence rate for fulfilling Marketing Application approval requirements
- Offers extensive therapeutic expertise: DSI has filed with every division of the FDA's Office of New Drugs numerous times
- Has brought all types of products to market (e.g., drugs with new indications, branded generics, orphan drugs)
- Is experienced across all drug formulation and delivery types (e.g., routes of administration, dosage forms, sterile/non-sterile)

## The DSI Process

DSI's outstanding history of first-cycle FDA approvals is testament to our ability to work as your FDA liaison and ensure regulatory alignment every step of the way from concept to commercialization. We provide regulatory advice and problem-solving as well as advocacy on your behalf. Even in cases where your clinical study or IND program has been put on clinical hold, DSI will step in and work with the FDA to put your drug development program back on track. DSI has a proven process for FDA planning, execution and submissions in order to achieve both development and corporate milestones; this is reflected through our long history of success with the agency and numerous clients that return to us.

- Investigational New Drug preparation and submission
- Pre- and post-Investigational New Drug and New Drug Marketing Application meetings with Agencies
- Preparation and submission of INDs, IMPDs, NDAs, ANDAs, BLAs, CTAs, and DMFs

## Drug Development and Regulatory Approval Strategy

Traditional drug development via the 505(b)(1) approval pathway takes an average of 12 years from end to end. In contrast, a 505(b)(2) development program can be completed in just two to five years. But this shortened development pathway demands expertise — DSI is adept at navigating the regulatory waters surrounding 505(b)(2). Our team specializes in de-risking and shortening development programs. In particular, we design development plans to acquire and present data, study reports and well-reasoned arguments to meet the strategic needs of your company, address regulatory requirements and fulfill the needs of your target markets, often niche markets. Through exacting feasibility assessment, gap analysis and typical work requests (e.g., IND, pre-INDs), every step we take is toward viable product approval, no matter the product form or therapeutic indication at hand.

## Regulatory Strategy

- Advice on developmental, manufacturing, analytical, and supply chain issues, including registered starting material (RSM) selection and change control
- Full identification and documentation on supply chain
- Assembly of CMC sections of INDs and NDAs
- Preparation of DMFs

## Benefits

- Access to top level industry experts
- Efficient resolution to regulatory issues
- Regulatory Strategy for starting material designation (RSM)
- Regulatory Strategy for organization
- Streamline regulatory filings
- Preparation of IND, DMF, NDA documents for regulatory filings

## 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