

Process Development, Optimization and Validation

Experienced management of these activities ensures the quality of the materials being produced and the reliability of the clinical and commercial supply chain as it moves from bench-top through scale-up. We have experience with small molecule and biotechnology processes.

A Deeper Department

A Regulatory Drug Development consulting business that (works exclusively with) serves the needs of small emerging biotechs, 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.



Chemical Development

The DSI team of development experts has unparalleled process chemistry and bioprocess expertise. We assist early stage companies manufacturing early phase clinical supplies to setting commercial scale processes and operations for late stage or commercial products. Our team has developed chemistry and launched multiple pharmaceutical products. We work on technical transfers, DoE, validation, and manufacturing oversight.

Services

- Synthetic Route Selection
- Regulatory Starting Material Definition
- Method Development Strategy
- pGTI (Potential Genotoxic Impurities) review
- Analytical Strategy Development
- Report Documentation

Benefits

- Chemistry appropriate for your stage of development
- Access to our highly experienced industry team

Drug Product Development

Our drug product team has wide experience in formulation process development, scale up, and commercialization of sterile, oral solid, ophthalmic, topical and veterinary products.

Services

- Formulation Development
- Excipients/Ingredient Selection
- Drug Product Analytical Methods Development
- Analytical Strategy Development
- Report Documentation

Benefits

- Solutions for all aspects of your drug product development needs
- Access to our highly experienced industry team

Process Research & Development

DSI is your drug development consulting resource. We are dedicated to helping you advancing your drug from clinical candidate selection through commercial success, and help you work with your CMOs identified as best fit for your specific project needs. CMOs we recommend are organized and managed by experienced analytical and process development chemists and pharmacists to tackle questions that can only be answered by experiment. Moreover, drawing on the experience of our project managers and the consulting expertise at DSI, we'll make sure the right experiments are done and the correct conclusions drawn from the results.

Your project will follow a well-defined and effective road map, with emphasis on open and consistent communication. Our structured approach to project management delivers efficient and timely monitoring of scientific progress, coupled with tight tracking of both project cost and scope. DSI subject matter experts can supplement the experience and efforts of your own development group or fulfill all the roles of a complete process and analytical development group many of today's emerging companies require.

Services

API Process Research and Development

- Route evaluation and selection and expert review of existing routes
- Novel routes suggested by process experts
- Rigorous evaluation of cost of goods
- Devise novel synthetic and fermentation technologies to achieve your manufacturing goals and build IP
- Develop processes that operate robustly and safely at scale, ensuring security of supply
- Develop robust and appropriate analytical methods to minimize scale-up and quality issues
- Identify, develop and implement cost reduction strategies for existing API syntheses
- Rapid resolution of scale up issues to avoid costly delays in compound supply

Drug Product Research & Development

- Evaluation of formulation options
- Determination of goals of drug product form
- Formulation options suggested by pharmacy experts
- Experimental evaluation of strongest options
- Solve formulation problems with a designed experimental program created by our experts
- Work out placebo and comparator issues

Quality by Design (QbD)

- Expertise in design and execution of critical process parameter analysis and experimental plans consistent with Quality by Design concepts
- Establish proven acceptable ranges of operation
- Statistical experimental design (DoE) and focused stress tests to improve weaker synthetic steps

Method Development

- Support development of robust analytical methods for API, drug product, stability analysis, in-process controls, and impurities

Benefits

- Identify and select project-appropriate CMOs to conduct experiments
- Select scientists and teams fit-to-purpose and based on experience and expertise
- All intellectual property (IP) belongs to the client

Bio & Fermentation Development

The DSI team of development experts has experience in every aspect of the industry. In addition to small molecule drug substance development, DSI has extensive experience in biological and cell culture technologies, including cell line engineering and recombinant protein expression and biotransformation. Our analytical development team has comprehensive methods development and validation experience.

Services

- Bioprocess Strategy Development
- Regulatory Master and Working Cell Bank Development
- Strain Selection
- Protein Fermentation & Purification
- Analytical Strategy Development
- Analytical Testing/Validation
- Formulation Development
- Excipients/Ingredient Selection
- Report Documentation

Benefits

- Solutions for all aspects of your bioprocess development needs
- Access to our highly experienced industry team

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