

Materials Characterization and Formulation Development

DSI guides sponsors in the critical exercise of materials characterization and the establishment of reference standards for NCEs as well as in the formulation of drug products from the IND-enabling stages of development through postapproval evergreening changes. We have experience with small molecule and biotechnology products and the full range of dosage forms used in solid oral, inhalation, intranasal, topical, and parenteral administration.

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.



We help make it right the first time

DSI gives you a complete range of support. Start with us and we'll help you identify a synthetic route suitable for early phase API supply. Join us in later phases and get the insight and quality that leads to success faster.

Materials Selection and Characterization expertise includes:

- Route scouting
- Process development
- Clinical supply manufacturing
- Technology transfer, development and scale up of established processes
- Expertise with structurally complex and difficult to manufacture APIs
- Ability to safely handle high potency compounds and controlled substances
- Process validation
- Comprehensive analytical services
- Commercial supply manufacturing
- Supply chain management
- Spray drying
- Particle Size Reduction
- Physical characterization

DSI's early involvement in the drug development process saves you substantial time and money. From API and formulation sourcing, to manufacturing, scale-up and packaging, we provide invaluable strategic guidance and CMC development services.

Our Oral Solid Dose (OSD) development expertise includes:

- cGMP manufacturing advice at all scales (Phase I, II and III)
- Quick options for first-in-human studies
- A range of powders, granulates, tablet, capsule and softgel dosage experience in a variety of formats to meet drug delivery needs
- Advanced formulation experience such as controlled release, abuse deterrent, bilayer and trilayer tablets, and multicomponent capsules
- Various pediatric formulation experiences
- Quality by Design (QbD) process development
- Full analytical support and stability testing
- Experience with blinded dosage forms such as over-encapsulation and matching placebos
- Registration batches
- CMC documentation for regulatory submissions
- Confidence & reliability from our strong regulatory track record

Our Sterile development expertise includes:

- A wide range of dose forms, including large and small-volume parenterals, liquid and lyophilized vials, pre-filled syringes, and cartridges
- Formulation and process development
- Lyophilization cycle development and optimization
- Batch sizes to meet your clinical trial demands
- Appropriate handling of sensitive and precious drug substance
- Clinical trial services, including pre-filled syringe and auto-injector assembly
- Aseptic filling and terminal sterilization
- Let us help you transform your discovery into a drug product with the best possible chance for approval.

Our network of contract manufacturing organizations (CMOs) allows us to identify the most suitable service providers for your compound and dosage form and ensure optimal performance within your time and budget parameters. Throughout the process, DSI experts advise on formulation and design, handle site inspection/monitoring, design/review protocols and identify the best method validation strategy to ensure compliance with FDA and ICH guidelines — a critical step for first-cycle review.

The CMC (quality) modules of a regulatory application often are written as stand-alone components of the file.

However, if a common thread connects the CMC modules to the nonclinical and clinical modules, the regulatory application becomes a coherent story. It's not unusual for development programs to undergo a formulation or specification change along the path of preparing a regulatory submission. This can all be managed provided the changes are documented and the impact of the change is evaluated and supported by data. Providing a connection from the old to the new with a data trail is the best way to assure the FDA that the development history of the product is in the application.



The connection from the drug product (all CMC components) to the clinical trial data and the supportive nonclinical data is the heart of the application to the FDA. DSI ensures this connection is clear and seamless so that the data will speak for your application.

At DSI, our people pride themselves on solving your pharmaceutical drug development challenges. Whether you have a small molecule API or large molecule biologics project, our objective is to help speed your molecule through early phase trials and prepare you for commercial success, faster. When you start working with us, your project will immediately benefit from our years of experience and deep expertise. Whether you need small quantities of small molecule API (active pharmaceutical ingredient) for initial development work or many kilograms for a late phase trial, you can reduce the risk and raise the bar on quality with a partner whose reputation is built on both quality and excellence in experience.

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