# Vendor Qualification, Inspections and Mock Pre-approval Audits

Proactive initial and routine evaluation of vendor cGMP compliance minimizes the risks of quality issues and supply chain disruptions. It also reduces the potential for health authority actions such as 483s, compliance observations, warning letters, market restrictions, consent decrees, etc. Preparing in advance for preapproval inspections demonstratively assists in the avoidance of surprises during the approval and launch process. We identify, remediate, and help to minimize the impact of compliance issues, which can cause costly stock out or delays in commercial approval.

## Benefits of Having a GMP Consultant

Our compliance experts conduct audits worldwide and have extensive experience auditing in the United States, Canada, Europe and in countries in Asia. In addition to conducting audits, our compliance team can act as a remote quality unit and provide on-site training programs to help you ensure continued compliance with regulatory agency requirements. Our auditors are specialists who understand the regulatory impact of compliance activities. They do not simply take a check-list approach.

DSI has audit expertise in every domain (e.g., nonclinical, clinical, CMC, other regulated activities). Whether you need to proactively review and refine operational processes or need to implement an audit program in response to prior regulatory contention, DSI is your partner.

DSI's comprehensive audits of bioequivalence studies and bioanalytical analyses reinforce the accuracy of data submissions to the FDA and help expedite drug approval and market launch. When sponsors of pending or approved ANDAs encounter FDA challenges to their studies, they turn to DSI for professional validation of findings. DSI meets or exceeds all FDA criteria for "audits conducted by a qualified independent expert." DSI's panel of scientific and regulatory experts provides impeccable audits that meet and exceed the highest professional and FDA scrutiny.

### Audit Services

- Solutions to address regulatory/compliance challenges and requirements
- Services customized to your study/program needs
- Comprehensive expertise that meets or exceeds all qualification criteria
- CMO evaluation, selection and contracting

# COMPLIANCE SERVICE OFFERINGS
# GMP SERVICES

## Staff Augmentation

For many biotechnology companies, maintaining a full complement of product development experts, from nonclinical researchers to clinical trial experts, medical writers and regulatory professionals is not possible. However, lacking access to these experts hinders the progress product development.

DSI has designed a unique solution to address this issue with our Staff Augmentation offerings. Our team is comprised of former industry scientists and subject matter experts who adhere to the highest standards of professional conduct. We:

- Employ a full roster of consultants in every area of pharmaceutical, biologic/biosimilar, medical device, and therapeutic product development,
- Offer our clients the opportunity to make our team yours, on-demand,
- Provide a team able to step in to augment your current team, providing you with the benefits of a world-class staff at a fraction of the cost,
- Work with firms of all sizes on projects of all magnitudes,
- Bring a unique insider perspective to each engagement, allowing you to maximize the value of every dollar spent while accelerating your development timeline.

## Due Diligence

Information is the key to managing risk. DSI's Due Diligence services draw on deep experience and understanding of the regulatory and product development requirements for success, to:

- Help our clients make informed business decisions,
- Provide professionals to perform comprehensive due diligence on the strategic and operational realities of the target,
- Serve: Venture Capitalists, M&A Parties and their Advisors, Industry Venture Groups, Business Development Departments, Alliances and Co-Development Partnerships.

## 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