

Design, Implementation and Remediation of Quality Systems

Efficient and well-designed quality systems and appropriate development-stage implementation ensure that the expectations of regulators, sponsors, and investors are met. Many companies have unique needs that are best managed using customized quality systems and standard operating procedures. We develop or review Quality Management Systems to ensure compliance for a company's current stage of operation.

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.



What is Pharmaceutical Quality Management?

Compliance to current Good Manufacturing Practices (cGMPs) is critical to your business, your patients, and an expectation of the Food and Drug Administration. Today's pharmaceutical and medical device manufacturing is complex and requires significant experience in GMPs to ensure compliance. Ensuring your Contract Manufacturing Organization (CMO) or Contract Laboratory Organization (CLO) meets or exceeds FDA regulations is a must in today's highly regulated environment. To comply with the FDA's requirements under 21 CFR parts 210, 211, 820, and 11, you must have robust quality systems and processes, and a well-defined supplier qualification process. DSI has the expertise and industry experience to perform and manage these processes for your organization.

DSI: Your Trusted Partner for Pharmaceutical Quality Systems

DSI will work with you to make sure all processes are compliant by conducting a Quality Gap Analysis or performing independent GMP audits. Whether your challenge is with manufacturing, packaging, aseptic processing, laboratory investigations, labeling, validation, Standard Operating Procedures (SOPs), training, corrective and preventive actions, product adulteration, raw materials storage, risk management, or other quality issues, our GMP services will provide the quality operations, quality systems, and manufacturing expertise required to help you prevail.

Our Quality Gap Analysis experts will spend significant time on-site at your facility examining all aspects of your quality systems and manufacturing operations.

We will work with your organization and review the following:

- Personnel Qualification and Staffing
- Quality Manual
- Change Control
- Deviations
- Investigations
- CAPA
- Document Management
- Electronic Quality Management Systems
- Process Validation
- Cleaning Validation
- Equipment Qualification and Validation
- Manufacturing Batch Records
- Packaging Batch Records
- Part 11 Compliance
- Analytical Method Validation
- Supplier Qualification Program
- Internal Audit Program
- Raw Material Testing and Controls
- Environmental Monitoring
- Inventory Management

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