Quality Assurance Services

DSI has managed operational Quality Assurance functions for biopharmaceutical companies in all stages of development, as well as commercial operations. We have provided management of quality investigations, deviations, out-of-specification testing, change control, commercial complaints, and batch record review and release. In addition, we have facilitated QA review of CMC documentation including manufacturing process development protocols and validation reports, product specifications, manufacturing master records, and test methods.

The DSI Quality Team is focused on providing the highest level of cGMP Quality Assurance for all stages of development and manufacturing. Our quality team is made of pharmaceutical industry professionals with years of industry experience. Our team is experienced in API and Drug Product cGMP compliance for both small and large molecules, and also medical device cGMP. We have strong technical skills in aseptic processing and sterile products manufacturing, and we bring you extensive experience in analytical chemistry and microbiology laboratory operations.

QA Services

- Prepare and manage required SOPs for cGMP compliance
- Train staff in cGMP policies and compliance
- Prepare and execute Quality Agreements with contract manufacturers (CMOs/CDMOs)
- Serve as the Release Authority on behalf of the client

cGMP Auditing

- Assess and consult on the level of compliance of manufacturers
- Provide written gap analysis
- Propose compliance improvement opportunities

cGMP Remediation & Compliance Improvement DSI works directly with the manufacturer's quality unit to implement improvement programs:

- Define required CAPA
- Establish missing or incomplete quality systems
- Prepare needed SOPs
- Train both manufacturing and quality unit staff

Manufacturing Operations

- Review and recommend opportunities for improvement of batch records and other operations documentation to improve shop floor and QA release efficiency
- Advice on the suitability of facilities for API, large molecule, and sterile product manufacturing to ensure GMP compliance
- Advice on design and operation of environmental monitoring systems for "clean rooms" and other controlled manufacturing facilities
- Provide an organizational strategy for conducting and reporting sterility failure investigations to assess root cause and define corrective action and preventative actions

Validation

- Help create the critical process parameter analysis experimental plan to be consistent with Quality Design (QbD) concepts
- Draft the process validation protocol to be consistent with QbD concepts
- Help organize the process validation plan or validation data

Preparation for Agency Inspection (FDA PAI) Train Quality staff to manage a regulatory authority inspection, including:

- Assist in the selection of subject matter experts (SME)
- Train SMEs on proper procedures for responding to investigator questions
- Set up documentation "war room"
- Ensure all previously identified CAPA are complete
- Perform final housekeeping inspection to ensure a facility is fully prepared
- Organize daily de-briefing and assignment of follow-up duties
- Advice on response to all inspection observations

Benefits

- Prevention of Compliance issues
- Maintain GMP Compliance
- Cost-Effectiveness
- Efficient preparation for regulatory agency inspection
- Post-inspection Rapid Response and Remediation

Good Manufacturing Practices (GMP) Services
DSI provides comprehensive, hands-on GMP Quality Compliance services to the pharmaceutical, medical device, and biotechnology industries. We have been providing GMP consulting services to clients worldwide for the past 15 years.

Our GMP consulting services are characterized by:

- Knowledge: We know what is important to FDA.
- Experience: Seasoned GMP consultants, each with at least ten years in GMP.
- Holistic Approach: In addition to process and procedures, we review the organization, employee engagement, systems, training, etc.
- Root Cause Analysis: We focus our resources on determining and rectifying the root cause.
- Strong Project Management: Regardless of project size, each engagement is assigned a project manager with responsibility for project success, acting as a single point of contact for you and your team.
- Value: Our consultants are competent and efficient, producing results as quickly as possible. We do not believe, as some of our competitors do, that the best results are obtained by engaging legions of consultants to rewrite SOPs.
- Speed: Time is critical when manufacturing issues arise. We mobilize quickly to assist our GMP clients worldwide.

Benefits of Having a GMP Consultant

GMP Consultants can bring expertise and experience that your business does not have. They can help manage and complete a compliance project that requires specialized skills or help get work done efficiently.

DSI: GMP Compliance Experts

As our client, you can expect a partner that will not only be hands-on but will also work alongside you to provide quality compliance services as well as the strategy and training to help you improve your quality systems, thus mitigating future risk.

We will work with you to identify the appropriate GMP Consultant based on your organizational requirements and needs. We will then work with you to define, draft, and execute a plan to optimize your GMP quality and compliance programs.

DSI has provided biotech, and pharmaceutical consulting services to companies worldwide. We have consulted with companies of every size on every continent supplying them with viable and efficient GMP Compliance solutions. DSI takes a proven, active approach to listening and addressing our clients' specific needs to ensure their quality and regulatory operations are in compliance with current industry standards, as well as FDA and international regulations. DSI is the GMP Services company of choice for the pharmaceutical, medical device, and biotechnology industries.

GMP Service Offerings

By utilizing our consulting services, you can address the following:
Design of Quality Systems for:

- Production
- Facilities and Equipment
- Laboratory controls
- Materials
- Packaging

Within the Quality System, we can provide the following services:

- Policies, Standards, SOP Preparation, and/or Optimization
- Batch Record Review
- Remediation Project Management
- Quality Systems Development, Assessment, Remediation
- Root Cause Investigations and Corrective Action/Preventive Action (CAPA) Remediation
- Third-party GMP and GLP Compliance Auditing
- Mock FDA/International Regulatory Agency Inspections & PAI Readiness
- Due Diligence Compliance Inspections, Audits, and Assistance
- FDA Actions (483 Observations, Warning Letters, Consent Decrees) Remediation
- Data Integrity Compliance
- Mergers & Acquisitions (M&A) regulatory integration

DSI Solutions

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