

# Quality and Regulatory Compliance Support



## Fostering product quality and safety and reducing regulatory risk

### WHY LEIDOS LIFE SCIENCES?

- ▶ Deep knowledge of vaccine, drug, biotherapeutic, and medical device manufacturing and testing requirements and standards
- ▶ Experienced team that includes former FDA scientists and inspectors who understand how requirements and standards are applied

Leidos Life Sciences' quality and regulatory compliance experts assist customers to help ensure their production facilities apply industry best practices and are in compliance with stringent U.S. Food and Drug Administration (FDA) and international regulatory requirements.

Supporting customers globally, Leidos performs comprehensive pharmaceutical manufacturing and testing facility audits and assessments to help identify potential process deficiencies and take corrective action prior to regulatory agency inspections. To help ensure the proper procedures are in place, we develop, implement, and manage compliance strategies for pharmaceutical, biologic, and medical device manufacturers.

Leidos Life Sciences advises and trains customers on current Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and Good Clinical Laboratory Practice (GCLP); we write and review vendor qualifications and process equipment validation protocols for completeness to help ensure they are in compliance with regulatory guidelines; and we perform mock inspections and assess facility qualifications worldwide to facilitate manufacturing and product quality.

The following are examples of the types of services that Leidos Life Sciences provides to its clients:

## Auditing, Validations, and Qualifications Support

The Leidos Life Sciences team provided global regulatory compliance support for a government medical research laboratory that produces biologics, drugs, and medical devices in facilities located in the United States, United Kingdom, France, Singapore, North Africa, and Central and South America. We assessed equipment qualifications, clinical laboratory readiness, contract manufacturing organization qualifications, and early- and late-phase clinical site and laboratory readiness. We conducted GMP and GLP audits and provided GMP person-in-the-plant (PIP) support. We also validated assays, provided cold-chain management for multiple products, and designed and managed stability programs. Our support helped ensure that quality systems were in compliance with regulatory requirements, and facilitated the timely completion of development activities.

## Quality System Auditing

On behalf of a renowned infectious diseases research institute, Leidos delivered quality audit support services. We conducted GMP and GLP compliance audits and provided PIP services to support the critical phases of a vaccine production process. Our Life Sciences team determined the cause of an out-of-specification result, which occurred during the aseptic filling of the vaccine, and recommended corrective action that mitigated the issue for subsequent lots of vaccine. Our audit helped ensure that quality systems were in place following industry best practices, and that product quality and safety were in compliance with applicable standards.

## Mock Inspection Audits and Remedial Action Planning

Leidos Life Sciences conducted a mock preapproval inspection (PAI) for a major pharmaceutical manufacturer in the People's Republic of China to determine whether the client's facility was in compliance with FDA current GMP requirements and to assess their readiness for an FDA PAI. This audit assessed the aseptic production of sterile injectable drugs and evaluated the manufacturing process, including the client's quality system, quality control operations, facilities and equipment, manufacturing processes, materials system, packaging and labeling, standard operating procedures, and training. The audit team identified potential deficiencies and recommended remedial actions to prevent delays in the approval process. Through our proactive involvement, Leidos helped reduce regulatory risk and improve time-to-market.

## Services

### Quality Systems Auditing

- ▶ GMP, GLP, GCP, GCLP, and mock preapproval audits
- ▶ PIP visits
- ▶ External quality operation reviews

### Regulatory Gap and Risk Analyses

- ▶ Manufacturing and testing facility readiness
- ▶ Risk identification
- ▶ Remediation plan development

### Validations and Qualifications

- ▶ Standard operating procedure, protocol, and final study report design and preparation
- ▶ Process design and validation
- ▶ Vendor and utility qualification
- ▶ Aseptic processing suites and equipment design and qualification
- ▶ Computerized systems validation

### Quality Program Development

- ▶ Assay development
- ▶ Cold-chain management
- ▶ Deviations and corrective and preventive action systems
- ▶ Pharmacovigilance and complaint-handling systems
- ▶ Out-of-specification investigation and remediation
- ▶ Receipt, handling, and storage of materials

### Training

- ▶ GMP, GLP, GCP, GCLP, and International Conference on Harmonisation training

## FOR MORE INFORMATION

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