

Current Good Manufacturing Practice (cGMP) regulations require a quality approach to manufacturing so that companies can minimize the instances of errors. Pharmaceutical companies are keenly aware that they must ensure ongoing compliance with the regulations and be “inspection ready” in the event of an inspection by a regulatory body.

MAINTAINING CGMP COMPLIANCE

Compliance Implementation Services (CIS) offers services that provide a high-level evaluation to ascertain your company’s current level of cGMP compliance and develop a CIS Compliance Roadmap to help guide efforts to maintain and enhance cGMP compliance. Our subject matter experts have a deep understanding of managing global regulatory inspections, including by the U.S. Food & Drug Administration (FDA) and the European Union.

To effectively implement and meet cGMP requirements, CIS offers consulting services in the following areas:

PROGRAM	DESCRIPTION
Document Control System	Policy and SOP development, review and harmonization. Evaluate procedures in place and develop a strategic plan to global procedures. Implement the globalization plan by developing the procedures. Batch record development and review. Change control review and action item closures.
Inspection Readiness	Design and implement a CIS Inspection Readiness program. Provide training to employees on inspection readiness, as well as train employees on effectively handling inspections. Provide support in response to the FDA on 483 observations.
Internal System Audits	Support the client’s quality department and its internal audit program by executing internal audits that are defined within the program.
Development of Key Performance Indicators (KPIs)	Evaluate current systems and work with the client to develop metrics to monitor the systems. Will use statistical analysis to define targets and will implement corrective actions to address non-compliance issues.
cGMP Training	Provide cGMP and regulatory training to required personnel. Develop and implement training materials and tools. Develop and deliver “Train the Trainer” program.
Pharmaceutical Stability Programs	Evaluate program against current regulations to develop or enhance a stability program for final product, API, intermediates and raw materials.
Development and Enhancement of Quality Systems	Evaluate current systems related to the six (6) FDA Inspection System. Will develop or enhance the quality system, facilities and equipment systems, materials system, production system, packaging and labeling system, and the laboratory control system from a quality assurance perspective. Development of a quality system based on ICH Q10. Provide support to the client’s quality assurance team in performing quality activities.

PROGRAM	DESCRIPTION
Quality Control Programs	Evaluate quality control programs in the laboratory to assure compliance. Develop and implement robust programs.
Global Quality Process Harmonization	Develop and execute strategic plans to harmonize the quality system throughout the organization.
Root Cause Analysis and Corrective and Preventive Actions (CAPAs) Effectiveness	Perform a review of investigations/deviations and CAPAs. Provide training on root cause analysis. Provide resourcing to close investigations and CAPAs. Develop and implement strong investigation and CAPA program.
System Validation Documentation Review	Review and develop validation documents.
Supplier/Vendor Audits	Perform supplier/vendor audits to support supplier program. Develop a supplier/vendor qualification program.
Regulatory Filings	Review and write regulatory filings. Train employees on electronic filing with the FDA.
Training	Provide training on regulatory guidance documents.
Risk Assessment	Develop a risk management program based on ICH Q9.
Start-up Activities	Review/support of design review documents and commissioning test plans.

ABOUT CIS

Compliance Implementation Services (CIS) is a global life sciences consulting firm specializing in compliance strategies for pharmaceutical, biotech and medical device companies, from clinical research and development, through manufacturing, commercial compliance, and government programs. CIS provides its clients with a deep understanding of industry laws and regulations, innovative and practical applications, and custom solutions to establish a “Culture of Compliance” that is both meaningful and sustainable.

Our experts identify, assess and prioritize your organization’s exposure to compliance risks, subsequently developing and implementing risk evaluation and mitigation techniques to ensure adherence to legal and regulatory requirements.

For assistance with manufacturing compliance, please contact CIS.