

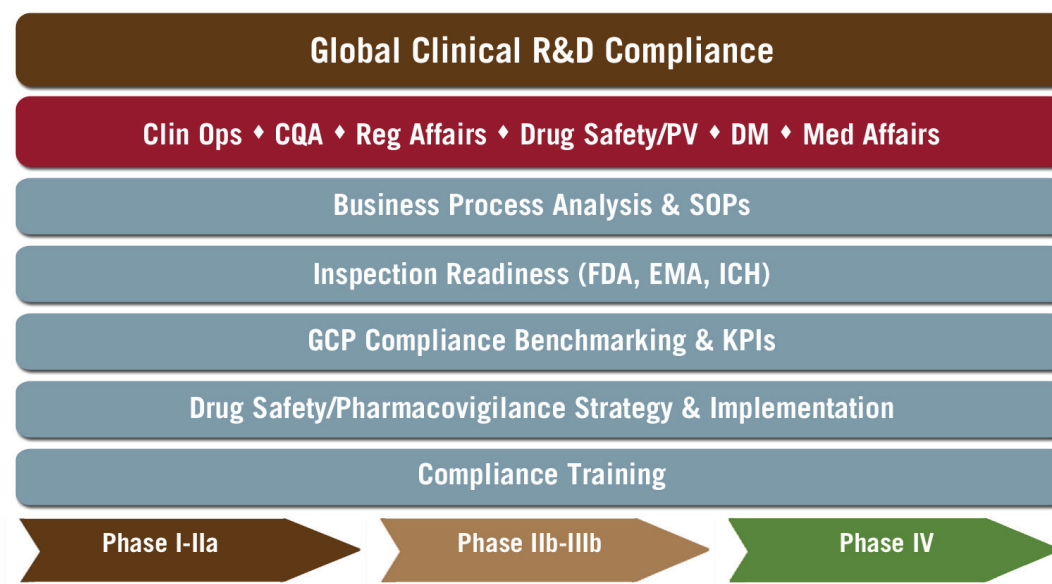
## ABOUT CIS

Compliance Implementation Services (CIS) is a consulting firm specializing in compliance strategies for pharmaceutical companies, from Global Clinical Research and Development, through Manufacturing, U.S. Commercial Compliance, and Government Programs. Founded in 2004, our clients rely on our 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.

## CIS CLINICAL COMPLIANCE

We can help you identify compliance issues that are relevant to your organization, assess their significance and relationship to other potential issues, develop a strategic compliance management plan and ensure its implementation. Our solutions are centered on your needs and aligned to the size and resources of your company.



## BUSINESS PROCESS ANALYSIS AND STANDARD OPERATING PROCEDURES

Ensuring compliance across an organization is often a difficult task and a challenge to manage. With a focus on roles, responsibilities and streamlined business processes, CIS will help you address compliance issues by developing high-quality, user-friendly policies, procedures (SOPs) and work practice documents. CIS offers custom solutions for:

- Assessing controlled documents
- Auditing SOPs
- Developing a controlled document strategy
- Developing business process flow diagrams
- Creating and harmonizing SOPs
- Implementing new/harmonized business processes
- Designing, developing, delivering user training
- Creating an ongoing SOP maintenance process

## **INSPECTION READINESS (FDA REGULATIONS, EMA GUIDANCE, ICH)**

CIS will identify potential compliance issues and provide realistic feedback on regulated processes before health authority inspections occur. Our clinical experts work with the following methods: SOP Assessment/Audit, Mock Audit, Sponsor Audit, PV System Audit, Trial Master File (TMF) Audit, Investigator Site/Clinical Audit and Vendor Audit. CIS offers custom solutions for:

- Designing and developing an audit strategy
- Planning, managing, and performing audits
- Designing and developing CQA function
- Establishing a quality issue reporting process
- Implementing solutions to audit findings
- Designing, developing, and delivering compliance training
- Validating systems

## **GCP COMPLIANCE BENCHMARKING & KPIS**

CIS uses its proprietary inspection-readiness profiles and its GCP regulatory requirements inventory to internally benchmark the as-is state of a sponsor's GCP quality assurance and quality control systems, as well as its supporting controlled documents. Internal benchmarking identifies compliance risks, provides a data-driven list of areas for improvement, facilitates rapid improvements in many areas, and enables the application of root cause analysis and corrective and preventative action planning (CAPA) for more complex compliance issues.

## **DRUG SAFETY/PHARMACOVIGILANCE STRATEGY AND IMPLEMENTATION**

CIS will create and implement a customized Safety and Pharmacovigilance Strategy for your company or for a designated product/product family. Our clinical experts will help with benefit/risk assessment, signal detection processes, Risk Evaluation and Mitigation Strategies (REMS), Risk Management Programs (RMPs) and outsourcing strategies. CIS offers custom solutions for:

- Analyzing product safety profiles
- Designing and implementing safety systems
- Recommending levels of outsourcing
- Managing vendor selection
- Performing PV system audits
- Evaluating REMS effectiveness

## **CUSTOMIZED TRAINING**

Having multi-faceted education and training programs across the organization is integral to compliance accountability. CIS will evaluate, develop or improve your compliance training programs in accordance with industry best practices. And, we can provide workshops and educational programs tailored to your needs. CIS offers custom solutions for:

- Analyzing clients' current training approach and needs
- Developing a training strategy and curriculum
- Reviewing and/or developing a training SOP
- Incorporating SOPs into training modules
- Delivering training to any clinical R&D/GCP audience

For assistance with your clinical research and development compliance needs, please contact CIS.