

CLINICAL QMS EXPERIENCE

- » QMS Framework Strategy
- » Global Clinical and Medical Affairs QMS Assessment and Strategic Action Plan
- » QMS Framework for expanding Clinical R&D Activity
- » PV Compliance Audit
- » Quality Manual Development
- » GCP Compliance Benchmarking/Risk Assessment and Process Improvement
- » Clinical Development Medical Affairs (CDMA) Compliance Risk Assessment
- » GCP Compliance Policy Development
- » GCP SOP Compliance Gap Analysis and Remediation

CIS experts are knowledgeable about the following regulatory standards:

- » FDA, ICH, EMA
- » FDA: Title 21-Parts 11, 50, 54, 56, 312, 314
- » FDAAA 2007: clinicaltrials.gov and REMS
- » ICH: E6, E2A, E8, E9
- » EMA: EU Clinical Trials Directive, EU Good Clinical Practice Directive

Quality Management System (QMS) refers to the collection of processes, procedures, tools and technologies that a biopharmaceutical company uses to foster quality and ensure regulatory compliance. While a clinical QMS is not currently mandated by Good Clinical Practice (GCP), many clinical groups are addressing the growing need for complex compliance management by borrowing from practices that closely align with recent International Conference on Harmonization guidelines on quality risk management and the pharmaceutical quality system.

CIS can help you develop a Clinical Quality Management System (QMS) that meets relevant GCP regulatory standards and addresses the business need for ongoing process improvement, compliance management and the ability to track GCP processes to monitor quality and reduce costs.

OUR SERVICES

QMS Assessment and End-to-End Evaluation of QMS Processes. The CIS team will identify QMS elements, goals and objectives. It will also evaluate key QMS elements, documents and systems including: user-training requirements for new employees; controlled document development, revision and maintenance; quality assurance activities; document issuance and ongoing staff training activities; existing Clinical R&D and Med Affairs procedural documents; electronic document management system (EDMS); learning management system (LMS), and other IT systems supporting the QMS.

We also assess each element relative to regulatory requirements and industry best practices, identify gaps and related compliance

risks, and conduct detailed document review and interviews with personnel in functional areas related to GCP.

QMS Assessment Report. CIS can summarize potential risks, recommendations/remediation and provide an assessment roadmap for corrective actions.

Standard Operating Procedure (SOP) Development. CIS can assess controlled documents; audit SOPs; create, revise, and harmonize SOPs; as well as create an ongoing SOP quality management process.

Vendor QMS Assessment and Audit. CIS can plan and conduct vendor QMS assessments and/or audits, examining how the vendor manages quality for its clinical trial services. Staff can also provide recommendations for vendor qualification and selection.

Corrective Action/Preventive Action (CAPA) Program Development. CIS works with your team to develop a clinical CAPA program to do the following: identify problems, perform assessment to determine root cause, develop CAPA action plan that identifies roles and responsibilities, provide ongoing compliance monitoring and support.

Key Performance Indicators (KPIs) Program. CIS collaborates with your team to identify key metrics related to compliance effectiveness: develop and implement a KPI program for routinely collecting and reporting performance data; use data to define targets for improvement; and implement corrective actions to address non-compliance issues.

Our deep experience across the compliance spectrum, and our industry relationships, gives us a unique perspective.

ABOUT CIS

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

Remediation Services. We offer remediation services in response to communications received from the U.S. FDA (e.g., Form 483 observations, warning letters), or in response to inspection findings from other health authorities.

Custom QMS Training. The CIS team can analyze your current GCP/SOP training approach and needs; develop a GCP/SOP training strategy and curriculum; review and/or develop a training SOP; incorporate SOPs into training modules; and deliver training to an R&D/GCP audience.

BENEFITS OF A CLINICAL QUALITY MANAGEMENT SYSTEM



Improved processes & SOPs



Ability to monitor/assess trends & complete ongoing assessments



Better audit outcomes (TMF, Site, Database, FDA)



Centralized tracking & accurate AE reporting



Better monitoring of clinical site & personnel performance



Reduced operational costs & better management of CROs/vendors



BALANCING DEMANDS. BUILDING COMPLIANCE.

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