

## GCP/GMP Quality Management System (QMS) Assessment

### BACKGROUND

Compliance Implementation Services (CIS) was retained in 2010 by the Clinical Compliance Department of a growing biologics company to conduct an independent assessment of the existing Quality Management System (QMS) structure and process for development and maintenance of controlled procedural documentation (i.e. Policies, SOPs, Guidance Documents). The goal was to identify potential compliance and business risks and to develop a plan to address them.

The client company had experienced unprecedented growth over the previous five years and operated a QMS that developed and maintained both Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) procedural documents. During 2010, the client company wanted to determine whether such a QMS model was sustainable in anticipation of continued growth.

### SCOPE

The assessment required an understanding of the regulations governing procedural document requirements as well as the differences between GCP and GMP compliance requirements. The project included review of the following QMS structural components and related management processes:

- QMS processes, including development, review, approval and maintenance of procedural documents
- Electronic Document Management System (EDMS) used to develop and house controlled documents
- Learning Management System (LMS) used to access and deliver Read, Understand & Sign (RUS) training.

### METHODOLOGY

During the QMS assessment, CIS performed the following key activities:

1. End-to-end evaluation of the QMS process for the development and maintenance of procedural documents, including the following:
  - QMS user-training requirements for new employees
  - Document development/revision/maintenance activities
  - Quality assurance activities
  - Document issuance and staff training activities



### PROVEN EXPERTISE

Compliance Implementation Services (CIS) is a consulting firm specializing in compliance strategies for pharmaceutical companies. Our experts can quickly identify your exposure to compliance risks, help you develop a strategic plan and ensure its implementation, and assist you in on-going adherence to legal and regulatory requirements.

CIS' experts have a deep understanding of the following Clinical areas:

- FDA Regulations
- EMEA Guidance
- International Committee on Harmonization (ICH)
- EU Clinical Trial Directive
- Good Clinical Practice (GCP)
- Drug Safety
- Current Good Manufacturing Practice (cGMP)

2. Document Review – CIS review of existing QMS QA, Clinical and Medical Affairs procedural documents.
3. Interviews – CIS conducted interviews with personnel in the following departments and roles to identify compliance and business risks:

- Biostatistics and Programming
- Clinical Compliance
- Clinical Data Management
- Clinical and Medical Affairs Operations
- Clinical Programs
- Medical Writing
- Quality Systems Documentation

### **DELIVERABLES**

CIS provided assessment findings and observations during a review meeting with the client company’s key project stakeholders. After the review meeting, CIS provided a final assessment report and Strategic Action Plan (SAP) containing the following:

- An Executive Summary of the assessment activities and high-level recommendations.
- A detailed, report of assessment findings and observations including:
  - A comprehensive assessment of each phase of the QMS process identifying compliance and business risks
  - Tactical and strategic recommendations for immediate improvement and long-term improvement of the QMS process.
- A Strategic Action Plan (SAP) detailing recommended activities and path forward to remediate potential compliance concerns and streamline QMS processes. The phases of the SAP were flexible enough to allow Clinical Compliance to implement early phases of the plan while waiting for more strategic technology decisions to be made by the company.
- A Clinical Procedural Document Tracking Grid detailing documents that require immediate update per the company’s biennial review compliance requirements.



*The client company received tactical solutions that could be implemented immediately and strategic solutions that could be developed in anticipation of a replacement EDMS.*

### **BENEFITS**

The client company has benefited from the CIS assessment in the following ways:

- The company has an external, independent assessment outlining areas for improvement to minimize business and compliance risks that may exist when combining GMP and GCP procedural documents within a unified QMS.
- The client company received tactical solutions that could be implemented immediately and strategic solutions that could be developed in anticipation of a replacement EDMS.
- The company has a phased Strategic Action Plan with accompanying cost and resourcing estimates.