

## GLOBAL QUALITY ASSURANCE SOP HARMONIZATION

### OVERVIEW

Compliance Implementation Services (CIS) was retained in 2009 by a mid-sized global pharmaceutical company to assess their Global Quality Assurance (GQA) procedural documentation. The purpose of the assessment was to evaluate all existing GQA standard operating procedures (SOPs) and associated policies to assist the company in developing a global strategy that would harmonize the SOPs to reflect the company's current GQA global operations.

### SCOPE

The assessment required an understanding of the company's entire process for SOP development and approval, including related templates and document control procedures. The SOP for the control of SOPs and quality manual were reviewed, evaluated, and cross-referenced with the company's research and development SOP system to identify best practices across the organization.

### METHODOLOGY

The assessment entailed identifying the current procedural activities, areas or activities that were redundant, SOPs that should become obsolete, as well as prioritizing SOPs within a document development strategy. To ensure the development of a solid strategy, CIS employed the following approach for gathering information:

#### Documentation Review:

- Compiled a master list of procedures
- Categorized 714 SOPs across multiple functional areas into one of nine policies
- Further prioritized 224 GQA-related SOPs into levels based on risk to QA/QC regulatory compliance, quality compliance, and business operations
- Reviewed content of the SOPs and their compliance to the GQA Control of Standard Operating Procedures SOP
- Identified policies that should be obsolete as they fall outside of the company's quality manual



### 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 areas:

- Supplier and Vendor Audits
- Inspection Readiness
- Key Performance Indicators (KPIs) Development
- Quality Systems Development and Enhancement
- Global Quality Process Harmonization
- Root Cause Analysis and CAPA Effectiveness
- Document Control System Development and Enhancement

## **DELIVERABLES**

CIS provided a report to the client containing the observations made as a result of the assessment. After review, the client enlisted CIS to pioneer the harmonization of the GQA-related documents.

CIS provided the support staff to fulfill the roles of SOP facilitator and technical writer for the project. Brainstorming sessions were facilitated with subject matter experts identified by the company to obtain the best practice information required for the harmonization of the documents. CIS provided industry-standard expertise on quality-related issues to ensure compliance throughout the project. The documents were effectively revised and approved according to the process outlined in the company’s control of documents procedure.

## **BENEFITS**

The client has benefited from the CIS assessment and harmonization process in the following ways:

- The assessment identified areas for SOP harmonization, which enables the client company to work more efficiently.
- Redundancies and opportunities for SOP reductions were identified for functional areas outside of GQA.
- The harmonization process resulted in a 40% reduction in GQA SOPs and a 27% reduction in associated forms.
- There were enhancements and language clarifications made to multiple identified gaps within the GQA SOPs.
- The reduction in GQA documentation has resulted in a reduction of non-value-added document management and training time.
- The client now has a strategic action plan for harmonizing their SOPs across the organization.



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