

## SOPs FOR A CLINICAL START-UP

Compliance Implementation Services (CIS) was retained by an established global specialty pharmaceutical company to help develop Good Clinical Practice (GCP) Standard Operating Procedures (SOPs) for its start-up clinical organization. The company needed to develop the necessary clinical SOP baseline to document how it would meet FDA, EU and ICH requirements. CIS was chosen for the project due to its GCP knowledge and awareness of related business practices in a range of clinical R&D organizations, as well as business process analysis, project management, and technical writing expertise.

### PROJECT SCOPE AND DELIVERABLES

CIS collaborated with the client's Clinical Operations, Regulatory Affairs, Pharmacovigilance, and Medical Affairs executives to address immediate and long term needs:

- CIS first addressed priority areas that focused on SOP standards, drug safety, and product complaints
- CIS analyzed the client's existing SOPs, re-purposed some content, identified unnecessary redundancies, and recommended de-commission of some documents
- CIS also identified GCP SOPs that were most critical to the company's current clinical R&D efforts, resulting in development and approval of 30 new SOPs within a 6-month period
- CIS facilitated internal discussion of the business process for each new SOP, using CIS' proprietary generic flowcharts, and other consensus-building approaches to determining procedural steps and responsibilities across functional areas
- For each SOP, CIS developed supporting documentation that referenced relevant Health Authority regulations and guidance, client documents, definitions of key terms and identification of responsible role
- CIS also developed forms, checklists, or other support documents needed to implement an SOP

### METHODOLOGY

CIS performed the following steps to create global SOP documentation:

- Reviewed existing SOP documentation for alignment with company policies and global GCP requirements
- Worked collaboratively with key stakeholders to identify and develop new business processes

- Led interim document review meetings to resolve specific content issues
- Provided a strategy and structure for development, implementation, and ongoing maintenance of global Clinical R&D SOP documents
- Created new SOP documents that clearly express how the client will implement relevant FDA, ICH and EMA regulations and guidelines
- Made an ad hoc recommendation for creating a Clinical Quality Assurance function

### BENEFITS

The client has benefited from the SOP initiative led by CIS in the following ways:

- Key clinical R&D business processes agreed upon and implemented
- Documentation of GCP SOPs to guide clinical research activities
- SOP documentation in user-friendly, electronic format, using standardized templates
- An organizational structure for Clinical Quality Assurance
- Infrastructure in place for a Clinical Quality Management System

### PROVEN EXPERTISE

Compliance Implementation Services (CIS) is a consulting firm specializing in compliance strategies for pharmaceutical companies. 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.

Our service areas of clinical compliance are:

- Business Process Analysis & SOPs
- Inspection Readiness (FDA, EMA, ICH)
- GCP Compliance Benchmarking & KPIs
- Drug Safety/Pharmacovigilance Strategy & Implementation
- Compliance Training