

Globalization Requires Harmonization

Overview

Compliance Implementation Services (CIS) was retained in 2006 by a leading specialty biopharmaceutical company to assess existing Clinical and Regulatory Standard Operating Procedures (SOPs) and to design and implement a path toward harmonizing global SOPs. The company, originally headquartered in Europe, relocated its headquarters to the US and needed to standardize its procedures across all regulatory and clinical departments. Because maintaining SOPs across company functions and departments is vital to ensuring compliance with regulatory requirements and guidelines, and the company had no Process and Compliance function in place, CIS undertook several initiatives to address immediate needs:

- Performed a gap analysis to determine the state of the current procedural documentation
- Standardized procedures and work flows across functional areas worldwide to ensure consistency among the global organizations
- Ensured standard processes included adaptation to US regulatory requirements
- Centralized and globalized document management processes for clinical and regulatory SOPs and accompanying forms

Scope

CIS concentrated its assessment and subsequent initiatives on the review and re-design of all existing clinical and regulatory procedural documentation (approximately 80 SOPs); CIS also evaluated the need for additional SOPs. Keeping in mind the company's recent move from Europe to the US, CIS harmonized the new and existing SOPs while focusing on compliance within global and local regulations and guidelines.

Proven Expertise

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 ongoing adherence to regulatory requirements.

CIS has a deep understanding in the following Clinical areas:

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

Methodology

To effectively harmonize the company's SOPs, CIS performed the following steps:

1. Reviewed existing SOPs for alignment with company policies and global requirements
2. Assessed and streamlined existing procedures relative to current FDA, ICH and EMEA regulations and guidelines
3. Worked collaboratively with key stakeholders throughout the company to draft work flows and develop SOPs
4. Created new procedural documents where none existed previously
5. Provided recommendations for implementation and ongoing maintenance of the global SOP documents

Maintenance of the R&D SOP System

Once new or revised SOPs were approved and implemented, CIS continued to monitor the library of documents by providing the following services:

1. Tracking review cycle dates and ensuring documents are reviewed within agreed upon timeframes
2. Reviewing and updating SOPs, as appropriate
3. Facilitating meetings with key stakeholders to gather feedback and information regarding processes occurring within the company to ensure SOPs operationally reflect the current procedures
4. Coordinating information, drafting new/revised documents based on information provided by company personnel and current regulations, and forwarding to Subject Matter Experts within the company for review and approval
5. Ensuring SOPs are aligned with current global regulations and guidelines
6. Managing the review and approval process of updated SOP documents

Deliverables

CIS provided the following deliverables to harmonize the complete set of global SOPs:

1. 133 process work flows, created as needed to standardize work process and reach consensus among stakeholders across functional areas and geographic regions
2. 80 SOPs updated/revised
3. 53 New SOPs developed

Benefits

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

1. The Process & Compliance Department now maintains a library of 70 cross-functional & 63 departmental (e.g. clinical development, pharmaceutical development, medical affairs, quality assurance) SOPs, all on a regular review and update rotation.
2. The company was able to standardize and streamline procedures across functional areas and geographic regions in alignment with global regulations and guidelines.
3. The company does not need to spend full-time resources on the management of their SOPs on an ongoing basis because CIS has the knowledge and expertise to continually monitor and appropriately revise and update procedures on a timely basis.
4. The company is assured that its Clinical and Regulatory Affairs SOPs reflect current company practices and are compliant with relevant regulatory requirements.



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