

## Pharmacovigilance System Audit Provides Roadmap for Growth

### Overview

Compliance Implementation Services (CIS) was retained in 2009 by a specialty pharmaceutical company to conduct an audit of its Pharmacovigilance (PV) Systems to ensure that key PV Systems remain fully compliant with relevant ICH and U.S. regulatory requirements and guidance. The Audit was prompted by organizational changes within the company over the past 18 months, and by the company's intent to expand clinical development activities in the near future. The PV System Audit is one of several projects that CIS has conducted for this company to ensure its business processes are aligned with relevant and current government regulations and with the company's current strategic intent.

### Scope

CIS concentrated its PV System Audit activity on review of procedural documents from the company and its vendors, as well as interviews with selected company and PV vendor managers. The Audit included one visit to the company's designated PV vendor and one visit to the client offices.

### Methodology

During the PV Audit, CIS performed the following activities:

#### *Documentation Review*

CIS reviewed a total of 123 client documents. The review consisted of existing Safety/PV documentation, including the following items:

- Charter of the client's Global Pharmacovigilance and Labeling Committee
- Policies, SOPs, and other controlled documents governing management of drug safety and Pharmacovigilance at the client site
- Selected PV Vendor SOPs and work practice documents

### 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)

- 2008 Audit Report of PV Vendor
- PV Vendor Work Orders
- MedWatch Forms
- Product Complaints
- Sales Representative Safety Training PowerPoint Presentation
- Two Post-Marketing Periodic Reports
- 14 client Company's Standard Operating Procedures (SOPs)
- Description of the Pharmacovigilance System Approved for Marketed Product

#### *Interviews*

CIS conducted interviews with the following company managers: Chief Medical Officer; Head, Pharmacovigilance; VP, Global Regulatory Affairs & Compliance; Sr. Manager, Medical Affairs. At the Vendor site, CIS interviewed a Sr. Systems Safety Analyst.

## Vendor On-Site Visit

CIS conducted a limited on-site Vendor audit, which included:

- A demo and discussion about the Safety Database with a Sr. Systems Safety Analyst
- Review of six SOPs and four Work Practices
- Review of PV Vendor Company's Client Guide

## Deliverables

CIS provided a comprehensive audit report that detailed, for all documents reviewed, and by PV system, all compliance gaps, findings and recommendations to improve/maintain PV compliance.

## Benefits

The client has benefited from the PV System Audit conducted by CIS in the following ways:

1. The client company has external confirmation of gaps that may exist within their PV systems.
2. The client company is aware of specific documentation that either needs to be developed or revised in order to comply with current ICH/FDA regulations.
3. The client company has in hand recommendations and action plans to remediate compliance gaps or vulnerable areas of drug safety/Pharmacovigilance prior to its planned expansion of clinical research activity.



CIS can help you identify compliance issues that are relevant to your organization, assess their significance and relationship to other potential issues, develop a strategic compliance management plan and ensure its implementation.

Our solutions are centered on your needs and aligned to the size and resources of your company.

### Core Global Clinical Services:

- GMP and GCP Compliance
- Business Process Analysis
- Policies, Procedures and Work Practice Documents
- Drug Safety/PV Strategy and Implementation
- Inspection Readiness
- Sponsor Audit
- PV Audit
- Vendor Audit
- Custom Training

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