

Promotional Speaker Program Implementation

Overview

Compliance Implementation Services (CIS) was retained in 2008 by a mid-sized global pharmaceutical company to provide an in-house compliance resource to assist the client's established Promotional Speaker Program team with the following:

- Supervision of the relationship between Sales Management, Marketing Management and the Program Vendor
- Management of multiple reports over various Business Units (BU) for management's use in evaluating the program
- Ongoing updates of Speaker Program training materials
- Assessments of critical situations and providing timely responses with effective compliance solutions
- Managed Vendor project timelines and budgets
- Facilitation of special program request approvals to ensure compliance
- Management of speaker list maintenance and Program Vendor data feeds

Scope

Promotional Speaker Program support required an understanding of the client's policies and procedures as well as current state and federal regulations. CIS support involved direct communication with several internal key stakeholders and executive level decision makers.

Methodology

CIS provided effective, efficient support to the Promotional Speaker Program team by taking the following proactive steps:

- Reviewed existing client authored policies and procedures

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.

Our Areas of Expertise:

- OIG Compliance Guidance
- False Claims Act
- Anti-Kickback Statute
- HIPAA
- PhRMA Code
- Prescription Drug Marketing Act (PDMA)

- Reviewed Program Vendor policies as they pertained to client specific functions
- Understood and applied current state and federal regulations

Deliverables

During the project, CIS performed the following key activities for Promotional Speaker Program maintenance, refinement and enhancement:

- Managed and maintained active speakers' lists for all BUs
- Provided ongoing QC review of bi-monthly Speaker Feed from IT to Program Vendor

- Generated and reviewed monthly Speaker Utilization Reports
- Executed monthly and quarterly Program Vendor audits
- Maintained active sales representative and Medical Science Liaison (MSL) rosters
- Worked with Sales Training department to coordinate training sessions and maintain training records
- Evaluated post-engagement feedback to identify and evaluate potential compliance issues

Benefits

- CIS provided 'value-added' perspective by identifying areas of risks on an on-going basis and providing remediation recommendations to support an effective, compliant Promotional Speaker Program.
- CIS effectively updated internal client and program vendor policies, procedures and training based on current state and federal regulations and identified risks.

Our deep understanding of industry laws and regulations, innovative and practical applications and custom solutions help our clients establish a 'Culture of Compliance' that is both meaningful and practical.

Our Areas of Expertise:

- Assessments
- Audits
- Policy & Procedure Development & Implementation
- Training Development & Implementation
- State Compliance and Reporting
- System Evaluations and System Validations



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