# Promotional Speaker Program Audit

## Overview

Compliance Implementation Services (CIS) was retained by a large public pharmaceutical manufacturer to conduct an internal audit of their Speaker Program, including audits of the program records and receipts generated by field based employees. The manufacturer had established policies and procedures for maintaining records of their Speaker Program as well as developed an electronic system for tracking programs. CIS undertook the following strategy to meet the project goals and objectives:

- Reviewed the client's current policies and procedures to gain an understanding of the internal Speaker Program process
- Reviewed the client's internal electronic Speaker Program data capture and approval system
- Through sample testing, performed an evaluation of the current activities against the client's policies and procedures
- Identified and prioritized observations and recommendations based on actual and potential compliance and business risks as well as suggested process improvements

## Scope

CIS concentrated on the review of the client's policies, procedures, systems and activities, as they pertained to the management of the Speaker Program. In performing the Audit, CIS tested activities against the requirements of the policies, procedures and business rules by randomly selecting Speaker Program transaction records for accuracy and compliance.

## 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 Audit Expertise:**

- Sales & Marketing, Medical Affairs, R&D Consultant & Ad Board Meetings
- Promotional Speaker Programs
- Sampling
- State Reporting
- Patient Assistance Programs & Reimbursement Services
- Federal Lobbying Disclosure
- Territory, Call Planning and Call Notes
- Promotion Review Committee Process
- Grants CME, Non-CME & Sponsorships
- Sponsorship, Exhibits & Displays
- Meals & Entertainment
- HR Discipline & Corrective Actions

## Methodology

In order to effectively evaluate compliance to the Speaker Program, CIS performed the following functions:

- Document Collection and Review: Client's Speaker Program policies, and procedures, including contractual process, speaker training and program approval process

- CIS consultants conducted the on-site audit of the identified Speaker Program records concentrating on the following:
    - Interviews with the client's key Speaker Program stakeholders
    - Review of data captured and internal document management, identifying compliance risk to the client including: Speaker contracts, Speaker training, program location, appropriate attendee compliance, program compliance to meals and entertainment policy, Healthcare Practitioner (HCP) capture for state reporting purposes, employee compliance and management oversight

## Deliverables

CIS provided the Corporate Compliance Office with the following deliverables to describe the results of the audit and suggested ways to make improvements based on the audit observations:

Speaker Program Audit Report:

- A Summary Report of the audit including the background, scope and methodology of the audit as well as a high level summary of the comprehensive observations and recommendations
- A Risk Matrix providing the detailed observations and recommendations, prioritizing each as one of the following: Compliance Risk, Business Risk or Process Improvement
- A Compliance Roadmap outlining the logical workflow and timeline for corrective and preventive actions in implementing each recommendation
- Identified areas within the tested documents that posed a concern with the field based employees such as questionable documents or activities

## Benefits

The client has benefited from the Speaker Program Audit conducted by CIS in the following ways:

- A Gap Analysis of the current program as it pertains to regulatory requirements, with in hand recommendations and action plans to remediate compliance gaps or vulnerable areas of compliance with program requirements
- Observations made of the overall program as a result of the audit of program documentation
- Identification of key areas that require alignment between client expectations and actual activities as well as potential concerns with field based activities

Additionally, based on the experiences of the auditors, CIS was able to provide the clients with unexpected project benefits:

- Recommendations for process improvements that would allow for a more streamlined and cost effective program
- Recommendations for revision of existing documentation to address state reporting and compliance requirements
- Identification of gap in approval process for Speaker contracts

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