

## Consistent Medical Review of Promotional Materials

### Overview

Compliance Implementation Services (CIS) was retained by a mid-sized global pharmaceutical company to assess their current process for medical review of promotional materials and to recommend best practices for efficient, streamlined process improvement for subsequent reviews. Once the foundation of a revised medical review process was in place, CIS proactively identified potential areas for compliance and business risks and managed the execution of a risk mitigation program.

### Scope

As a result of rapid growth combined with an ever-changing regulatory landscape, the client company was challenged to identify best practices, refine the existing medical review process and integrate compliance into the Global Medical Affairs (GMA) and Marketing Operations departments. CIS partnered with the client company to assess and refine the process to ensure that it met updated corporate standards as well as federal and state regulations.

### Methodology

Using CIS' Business Risk Assessment, CIS provided a high level review of the existing processes within GMA to determine if the appropriate procedures were in place and in alignment with policy requirements. CIS then completed a thorough evaluation of the client company's policy and procedure documentation. CIS also developed and executed a Metrics Tracking process which measured the consistency in data collection.

During the detailed assessment, CIS interviewed several key stakeholders and reviewed existing procedural documents to identify potential risk areas that applied to GMA's current process for the medical review of promotional materials. CIS prioritized the activities that exposed GMA to these risks. To mitigate risk, CIS

### 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

partnered with the client to develop new process flows, work instructions and monitoring plans.

### Deliverables

CIS presented the resulting assessment observations to the client company's key stakeholders. With key

stakeholder feedback, CIS provided and executed a client-approved action plan including:

- New policy and procedure documentation and Work Instructions
- Revised Vendor Training
- Metrics Tracking Spreadsheet

CIS delivered ongoing project updates to the key stakeholders within GMA. CIS also presented a quarterly, high level overview to GMA executives, which included all metrics and targets.

### Benefits

The client company benefited from the assessment conducted by CIS in the following ways:

- The client company has external, independent confirmation outlining areas of improvement to minimize business and compliance risks.
- The client company integrated compliance into the GMA promotional review process through the updating of policies, procedures, training and ongoing metrics tracking.

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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