

Potential Risk of Off-Label Promotion

Overview

Compliance Implementation Services (CIS) was retained in 2009 by the Compliance Department of a small specialty pharmaceutical company to review existing programs in order to assess the efforts in place to prevent product promotion for use in a manner that is outside of or otherwise inconsistent with the product labeling (off-label promotion), including an evaluation of employee understanding and conformity to the Company's off-label policies and procedures

The client company was recently acquired by an overseas pharmaceutical company and public reports of civil and criminal actions against pharmaceutical companies for off-label promotional activities were a concern for the parent company. The client company wanted to ensure all of the necessary precautions for preventing off-label promotions were not only in place, but met or surpassed current industry standards. The client company was also in the process of restructuring its sales operations and wanted to evaluate the program in order to implement any changes during the restructuring process.

Consequently, the client company proactively retained CIS to conduct an independent assessment of the structure, components and effectiveness of the promotional compliance program.

Additionally, the Compliance department was interested in publicly certifying compliance to the Pharmaceutical Research and Manufacturers of America's Code of Conduct for Interactions with Healthcare Professionals (PhRMA Code). The client company asked CIS to be mindful of the requirements of the PhRMA Code when conducting the assessment and evaluate any areas governed by the Code that were within the scope of the assessment.

Scope

The assessment required an understanding of the regulations in place governing off-label promotions as well as the PhRMA Code.

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 is committed to providing an efficient and affordable means of compliance that is scalable to the needs and priorities of an organization.

The project included a review of the client company's Compliance Program, Compliance Training, Compliance Guidance Manuals, Corporate Compliance Policies and Corresponding Standard Operating Procedures. The Assessment also included ride-along assessments with field-sales force personnel and interviews with selected company personnel.

Methodology

During the assessment, CIS performed the following key activities:

1. On-site Assessment – CIS met with key personnel who presented an overview of the following:
 - Off-label Risk Analysis conducted by client company
 - Company Compliance Guidance
 - Training
 - Surveillance and Audit Process and Disciplinary Actions
2. Documentation Review – CIS review existing program documents, Corporate Policies, Procedures and supporting documentation and conducted a gap analysis to the regulatory requirements.

3. Interviews - CIS conducted interviews with personnel in the following departments and roles to determine compliance to the existing program:

- Corporate Compliance
- Sales Operations
- Marketing
- Promotional Review Board
- Event Review Committee
- Internal Audits
- Quality and Compliance
- Medical Affairs
- Finance
- District Manager, Sales
- Sales Representative – conducted as a Ride-Along in the field

Deliverables

CIS provided the observations made as a result of the assessment activities during a review with the client company's key stake holders in the project. After the review, CIS provided a final assessment report containing the following:

- Comprehensive observations of the programs to prevent off-label promotions.
- General compliance-related observations noted during the assessment activities.
- Recommendations for mitigating any identified compliance or business risks as well as recommendations for process improvements. Recommendations included references to specific Regulatory requirements and Industry Guidance, and CIS' experiences and knowledge of industry best practices.

In addition, CIS provided the client company with the following:

- A separate document outlining observations with regard to compliance to the requirements of the PhRMA Code.
- A slide deck of the assessment project for use during a presentation to the parent company.

Benefits

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

1. The client company has external, independent confirmation outlining areas for improvement to minimize business and compliance risks that may exist within the program to prevent off-label promotions.
2. The client company received additional observations and recommendations outside the scope of off-label promotional activities as a result of CIS' experience in corporate compliance.
3. The client company has references to the specific documentation governing any recommended program revisions or enhancements.
4. The client company has recommendations and action plans to remediate identified compliance gaps or vulnerable areas in the promotional compliance program prior to its planned restructuring of sales operations.
5. The client company has the independent review needed in order to publicly certify its adoption to and compliance with the PhRMA Code.
6. The foreign-based parent company has the reassurance it needed that the new acquisition is operating under the highest standards.



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