

“Risk-Based” Approach to Compliance

Overview

Compliance Implementation Services (CIS) has been retained by numerous pharmaceutical companies to facilitate the creation, implementation, and/or maintenance of compliance programs. CIS works with clients to establish a meaningful and effective Compliance Program by applying our “Risk-Based” approach and tailoring this approach to be practical and operational within each organization. Once the foundation of a Compliance Program is in place, the objective of our approach is to proactively identify and mitigate risks through the effective planning and execution of risk evaluation and mitigation programs.

Scope

As a result of changes to business models, business processes, or federal and state regulatory changes, our clients are constantly challenged to refine and integrate compliance into business operations. CIS partners with our clients through the evolution of a Compliance Program to ensure that it remains evergreen and operational over time.

CIS has collaborated with clients throughout the development, implementation and maintenance of the following phases in establishing a risk-based approach to compliance:

- Phase I: Risk Planning and Identification
- Phase II: Risk Evaluation
- Phase III: Risk Mitigation Programs

Methodology

Phase I: Risk Planning and Identification

CIS has worked with clients to identify risk areas that apply to their current business models or processes by conducting a Business Risk Assessment. This Assessment includes the probability and severity of the organization’s exposure to each risk. Other considerations that CIS has integrated into a Business Risk Assessment are risks identified through previous

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:

- Policy & SOP Development, Review and Harmonization
- Risk Management Processes, Assessments and Audits
- System Evaluation, Implementation and Validation
- Training Development and Delivery
- Strategic Outsourcing

Our Areas of Knowledge:

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

Assessments and Audits, Monitoring, changes to federal and state legislations, Corporate Integrity Agreements (CIA) requirements, and/ or investigations. Subsequently, CIS has identified and prioritized the activities that expose the organization to these risks. Once CIS has completed the identification of these activities and prioritization of the risk areas, CIS has built Assessment, Audit and Monitoring plans to proactively evaluate these risks.

Phase II: Risk Evaluation

CIS has implemented a number of techniques to evaluate risk, including: Assessment, Audits and Monitoring.

1. Assessments: CIS has conducted Assessments to provide a high level review of processes within an operational area to determine if the appropriate procedures are in place and in alignment with policy requirements.
2. Audits: Depending on the agreed upon audit scope and methodology, CIS has conducted a comprehensive evaluation of the following:
 - Policy/Procedure Documentation
 - Process (through observation or interviews)
 - Transaction Review (i.e. call notes, contracts, receipts)
 - Systems
3. Monitoring: CIS has reviewed and implemented ongoing Monitoring Processes within a business practice. CIS has helped to execute Monitoring Programs through observing the activity or assessing the monitoring controls within an operational process.

Phase III: Risk Mitigation/Corrective Action

CIS has worked with clients in establishing a mechanism for tracking mitigating actions.

The tracking of the Mitigation Process has included:

- Documenting the findings and mitigating/corrective actions
- Assignment of accountability, roles and responsibility for Mitigation
- Status of Mitigation Progress

CIS has developed Risk Mitigation/Corrective Action Plans and has collaborated with business areas to integrate proper controls and corrective actions.



Deliverables

- Phase I: Risk Planning and Identification - Business Risk Assessment, Corporate Compliance Assessment and Assessment, Audit and Monitoring Plans.
- Phase II: Risk Evaluation - Assessment, Audit and Monitoring Reports.
- Phase III: Risk Mitigation and Corrective Action: Policy/Procedure Documentation, Training and Updates to Audit and Monitoring Plan.

Benefits

- CIS has benefited clients in the effective maintenance of Compliance Programs through our Risk Planning Strategies and execution of Risk Evaluation and Mitigation Programs.
- CIS has implemented independent Risk Evaluation techniques to provide our clients with comprehensive and concise recommendations to support an effective Compliance Program.
- CIS effectively integrates compliance into business operations through the development, implementation and/or updating of Policies, Procedures, Training and ongoing Audit and Monitoring Programs.

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