Implementing a Compliance Monitoring Program

January 29, 2014
Agenda

1. Mission and Purpose
2. Scope
3. Situational Analysis
4. Best Practices
5. Questions
Mission and Purpose
Mission and Purpose

Mission

- To help customers and consumers see our companies’ commitment to integrity in the research, development, sales and marketing of our products.

Purpose

- To prevent, detect or correct violations or law, regulation or company policy or procedures.
The Value of a Monitoring Program
## Monitoring vs. Auditing

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>Auditing</th>
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<tbody>
<tr>
<td>- Real-time</td>
<td>- Retrospective</td>
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<tr>
<td>- Targeted analysis</td>
<td>- End to end process analysis</td>
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<tr>
<td>- Tests if a process is working effectively at present</td>
<td>- Tests if a process was accurately followed</td>
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<tr>
<td>- Early detection to prevent systemic issues</td>
<td>- Identifies past issues to prevent recurrence</td>
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<tr>
<td>- Results provided to functional management</td>
<td>- Results provided to senior management</td>
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<tr>
<td>- Functional area addresses findings</td>
<td>- Requires formal corrective and preventative actions</td>
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The Value of a Monitoring Program

1. Prevention of Legal or Regulatory Enforcement Actions
   a. Rework to correct the concern
   b. Paralysis of work force involved in concern
   c. Opportunity costs for funds diverted for Legal fees and investigation support activities
   d. Costs associated with damaged relationships with:
      - Patients
      - Healthcare Professionals or Institutions
      - Payers
The Value of a Monitoring Program

2. Process Efficiency and Problem-Solving
   a. Early discussion of a tactic or challenge can lead to a solutions discussion instead of a remediation/rework discussion.
   b. Identification of internal support or external vendor processes where the business is not getting the best return on investment.
   c. Real-time feedback or coaching to build trust with key stakeholders, inform future training efforts and keep management aligned with agree upon objectives.

3. Integrity as a Competitive Advantage
Integrity as a Competitive Advantage

CELC research reveals that there is a strong, positive relationship between business performance and corporate integrity.

A CULTURE OF INTEGRITY DRIVES PERFORMANCE

The Relationship Between Business Performance and Integrity

[Graph showing the relationship between business performance and corporate integrity]
Scope
Scope

- Company-wide or Business Unit Specific

- Typical Relevant Functions
  - Sales & Marketing
  - Pricing / Reimbursement
  - R&D
    - Medical Affairs (e.g., MSL Activities)

- Relevant Functions role in Compliance monitoring
  - Commercial or R&D Operations

- Activity Type
  - Live Monitoring
  - Records Review (Promotional & Non-promotional)
Live Monitoring & Records Review

**Live Monitoring**
- Routine Sales Calls
- Promotional Speaker Programs
- Advisory Boards
- National Sales Meetings or Plan of Action Meetings

**Records Review**
- Ad Hoc Consulting Arrangements
Situational Analysis
Situational Analysis - Strategic

- **Start-up**
  - Do you need to build your monitoring program from scratch?

- **Turn-around**
  - Is there a crisis that your monitoring program must address quickly?

- **Realignment**
  - Has there been a change in environment requiring you to convince people that something may go wrong?

- **Sustaining Success**
  - Is your monitoring program at the point where it identifies and fixes small problems before they become big ones?
Situational Analysis - Tactical

■ Start-up
  □ What aspects of the monitoring program should be developed first?
    ■ Activities governed by a regulatory requirement
    ■ High-risk activities
      □ Payments to HCP
      □ Interactions with HCPs

■ Turn-around (Crisis Management)
  □ What corrective actions need to be taken immediately?
  □ What was the root cause of the crisis?
  □ What can be done to prevent a similar crisis in the future?
    ■ Training
    ■ Policy changes
  □ Leverage for greater transparency or oversight?
Situational Analysis - Tactical

- **Realignment**
  - What has changed in the environment that is now presenting a concern?
  - What are the observable behaviors/actions creating the concern?
  - What is the potential tangible impact to the business?

- **Sustaining Success**
  - Are there process improvements that can be made to make the monitoring program more efficient?
  - What industry trends do you need to stay ahead of to prevent the need for a realignment or turnaround?
  - Are there initiatives you should consider to take your program to the next level?
  - Are there other monitoring activities you could undertake to bring more value to the Compliance program?
Best Practices
Best Practices

- Gaining Compliance Management Commitment
- Obtaining buy-in from impacted business functions
- Securing Access to Relevant Information
- Developing Monitoring Plans to Address Highest Risks
- Standard Approach for Monitoring Activities:
  - Transparency
  - Execution
  - Reporting
  - Decision-making
  - Remediation
- Routine Collaboration with Stakeholders
Best Practices

Gaining Management Commitment

1. Business case for monitoring
2. Meaningful objectives
   a. To identify the nature and scope of potential concerns
   b. Collection of information necessary to make proper corrective actions
   c. Minimal disruption to the business
   d. Achieve best possible outcomes
3. Adequate resources
4. Communication of objectives with relevant stakeholders
Resourcing

- Internal vs. External Support

  - **Internal Support Advantages**
    - Depth of knowledge about business and/or function
    - Opportunity to forge relationships with key business partners

  - **Internal Support Disadvantages**
    - Time constraints
    - Inability to provide a completely objective look at a business or function

  - **External Support Advantages**
    - Objectivity about business and/or function
    - Knowledge of industry best practices

  - **External Support Disadvantages**
    - Lack of knowledge depth about your business and/or functions
    - Cost
Best Practices

Obtaining buy-in from the business/impacted functions

1. Convincing impacted functions of the value of monitoring
2. Communicating resources required from impacted function, if any
3. Planned approach and frequency of monitoring activities
4. Establishing trusting relationships by delivering on your agreed upon objectives and approach
Best Practices

Securing Access to Relevant Information

1. Corporate policies and procedures, if available.
2. Review of previous enforcement documents
   a. CIAs, Complaints, Warning Letters, etc.
3. Prior audit, monitoring or investigation reports
4. Strategic business unit or brand plans
5. Business unit organizational charts, materials, activities and tracking data
Best Practices

Monitoring Plans to Address Highest Risks

1. CIA-Directed Activities
2. Activities or initiatives where a potential concern has been identified
3. Activities or initiatives with traditionally high potential for concerns
4. Transactions with healthcare professionals or healthcare organizations ("Follow the Money")
Prioritizing Risks

- Ensure Legal is comfortable with your risk prioritization approach and documentation

- Likelihood and Consequence
  - High
  - Medium
  - Low
Best Practices

Standard Approach to Monitoring

1. Random and risk-based sampling
   a. Leveraging information from previous results or reports
2. Notification of monitoring activity (e.g., timing, frequency)
3. Use of reporting templates and data repository
4. Categorize findings
5. Process for making decisions regarding findings
6. Process for executing and documenting remediation activities, when appropriate
7. Periodically reviewing results in aggregate (e.g., yearly) to identify trends
Categorizing Monitoring Findings

- Context
- Frequency
- Intent
- Severity

Behavioral Context:
- Unforeseen Event
- Mistake
- Carelessness
- Abuse
- Fraud

Intents:
- Coaching
- Corrective Action

Confidential-For Internal Use Only
Best Practices

Routine Collaboration with Stakeholders

1. Legal & Regulatory
   a. Changes in regulatory environment or risk tolerance

2. Business Unit
   a. Product Launch
   b. Change in Sales & Marketing Campaign
   c. Incentive Compensation/Call Plan changes

3. Sales & Marketing / R&D Support Function
   a. Process or system changes
   b. Exceptions or departures from normal process
Questions?
Support Slides
The 7 Elements of an Effective Compliance Program

1. Designating a Compliance Officer or Contact
2. Implementing Written Standards and Procedures
3. Conducting Appropriate Training and Education
4. Developing Open Lines of Communication
5. Conducting Internal Monitoring and Auditing
6. Responding Appropriately to Detected Offenses and Developing Corrective Action
7. Enforcing Disciplinary Standards through Well-Publicized Guidelines
Risk Matrix Example
Managing Field Sales Expectations

Inactivity or Inability?

Corrective Action

Coaching

Good Hiring Practices
Sales Training
Expectation Setting
Incentive Compensation
Encouragement
Support

Effective & Compliant Sales Conduct

Policy Bending or Breaking?

Corrective Action

Coaching

Business Risk

Compliance Risk

Performance