
The Most Important Element to Assure That Your Sales and Marketing Compliance Program is Working Effectively: Monitoring and Auditing

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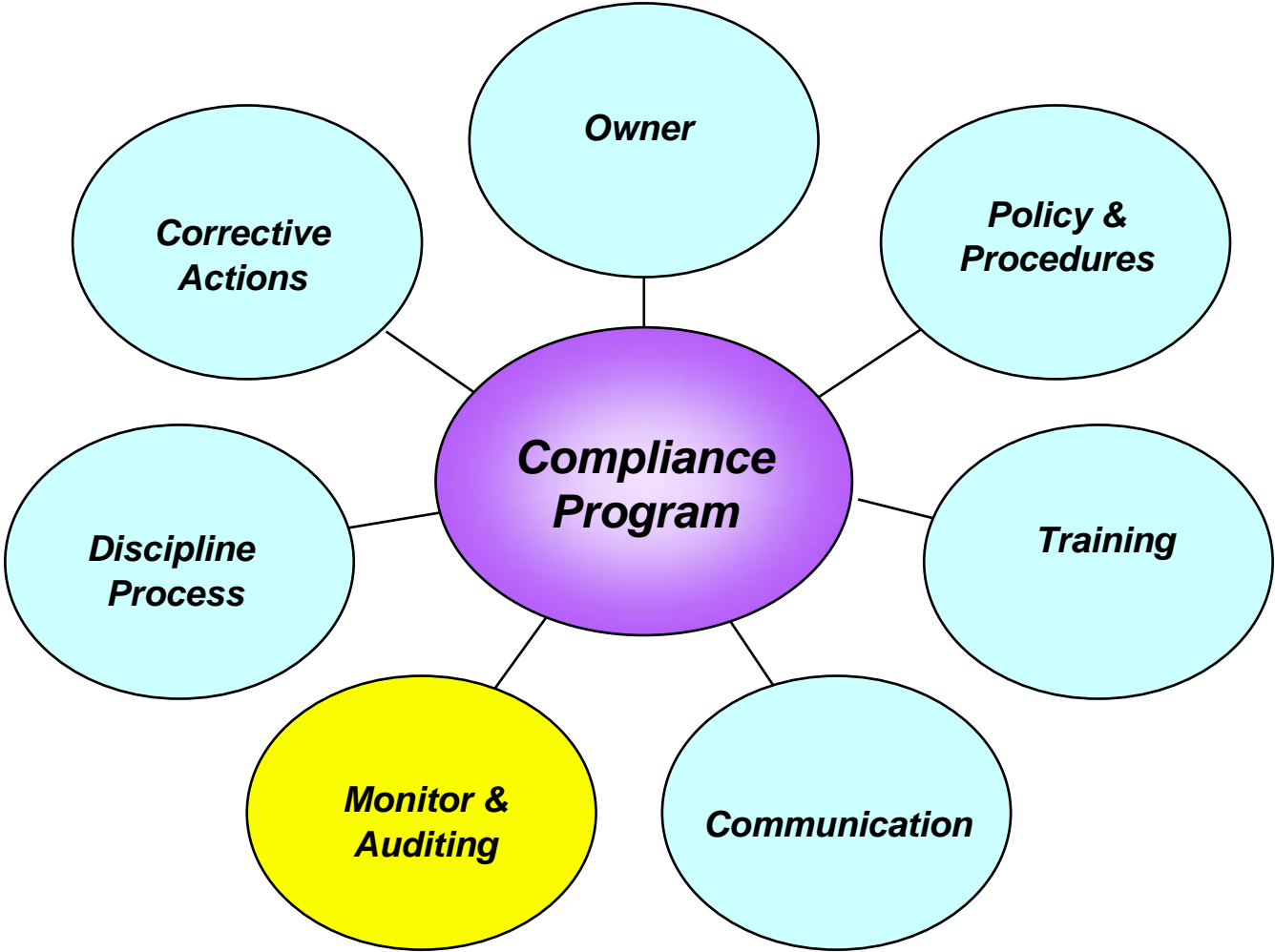


Answers That Matter.

Pharmaceutical Sales and Marketing Compliance

- Federal Food Drug and Cosmetic Act
- Federal Healthcare Program Laws
- Anti-Kickback Laws
- Prescription Drug Marketing Act
- FDA Regulations
- State Laws and Regulations
- PhRMA and IFPMA Codes
- Consent Decrees and Corporate Integrity Agreements

Seven Elements of a Compliance Program



Monitoring vs. Auditing

Monitoring

- Conducted by personnel affiliated with Compliance Program
- Broad sample of activities
- Part of on-going, continuous improvement process

Auditing

- Independent personnel - whether internal or external
- Focused engagements
- Report findings for management action plans

Different but Complementary Processes

Sales and Marketing Monitoring Plan

Areas covered

- Sales school programs
- Rep ride-alongs
- Speaker Training
- Speaker Programs
- Sales/Brand Meetings
- District reviews (GBPs)
- Exhibits
- Advisory Boards



Sample size determined by statistical analysis

- Annual target based on volume of business activities
- Weighting across areas based upon perceived risk
- Assure coverage across business units and brands

Monitoring Process

Protocols and checklists directly from policies

- “Open book” test

Random selection of events and unpredictable notification

Document what is going well

Investigate any findings and do a root cause analysis

- An isolated finding or an indicator of broader issues?
- **Take corrective actions as appropriate**
 - Disciplinary action
 - Adjust policy and/or training to provide clarity and consistency
 - Document corrective action

Sales Rep Ride-along

Randomly selected by Compliance Department

Observations

- Current promotional materials and package inserts
- Interactions with customers
- Adverse event and product complaint reporting
- Sampling
- State requirements, e.g. Vermont price disclosure, CA expenses

Assess rep's knowledge of policies

- Opportunity to answer their questions
- Feedback loop for improving training program

Opportunity to Explain the Benefits of the Compliance Program

Good Business Practice Review (GBP)

In-depth review of a sales district's adherence to policies

Pre-work Review

Expense reports, sample accountability, performance management documents, field visit or call notes, action plans, district expenses, speaker program database, compliance training records, violation log

On-site

Ride with one representative

Meet with district manager and review information

Post-work

DM investigation and corrective action on any findings

Final report issued to Area Director and Business Unit Leader

Speaker Training

Attended by supporting Compliance Associate or Mgmt

Observations

- Venue
- EPRI's
- Business Meal policies
- Appropriate Attendees
- Coaching on handling unsolicited questions
- Presentation
 - Were all mandatory slides presented
 - Were Compliance slides presented

Opportunity to Explain the Benefits of the Compliance Program

Speaker Programs

Observations

- Invitations
- Venue
- Business Meal policies
- Appropriate Attendees
- Presentation
 - Were all mandatory slides used?
 - Proactive presentation was on-label
 - Fair balance safety information was presented
- Proper handling of unsolicited questions
- Current package insert and any other promotional materials
- EPRI's

Monitoring Results

Provide on-going Dashboard metrics for Business units

Integrate Partnership with the Business

Compile annual monitoring results for Senior Management Reviews

Look for trends and patterns and use as feedback loop for training and policy adjustment

Findings may identify need for in-depth audit



Auditing Program

Annual plan

- By geography, business unit, and/or functional area
- Define the population and sampling approach

For-cause audits

- Need could be identified from monitoring results, hotline report, or management request

Sales and Marketing audits have some aspects unique from traditional financial auditing

- Intent, content, and context of activities are as important as following standard procedures

Benefits of Monitoring and Auditing

Assure compliance with policies

- Document that policies are being followed
- If they aren't, you want to find it and fix it yourself

Feedback loop on effectiveness of other program elements

- Policy Language
- Training
- Communication programs

Foster relationships with business partners

- Putting a face with the compliance program
- Opportunities to coach and share the learning
- Opportunities to understand business challenges
- It's not an "ivory tower" compliance program



Questions

