How to Design and Conduct an Effective Compliance Auditing & Monitoring Program

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Disclaimer

- *The opinions expressed herein are our own, are based on our research and experience in the industry, and do not necessarily represent the views or practices of our current employers.*

Auditing vs. Monitoring

- Definitions:
  - Audit – a retrospective examination verifying existence of objective evidence to assess the implementation, performance, and controls of a process against pre-defined criteria
    - Assures a system is in place
  - Monitoring – a review of select data to assure ongoing conformance to standards
    - Checks for ongoing compliance

When to Audit

- Initial assessment of a system to determine gaps against current policies/procedures or best practices
- Ongoing review to assure current practices comply with policies and procedures
- To identify best practices
- To measure the effectiveness of changes

When to Monitor

- Systems that have controls in place to detect non-compliance
- When “real-time” review of data is possible

Developing an Audit Program

- Plan
  - Assess external environment
  - Identify nature and scope of activity
  - Analyze the spend
  - Balance risk and resource
  - Develop and communicate plan
- Methodology
  - Policy, OIG Guidance, P*hRMA Code*
  - Develop audit toolkits for each policy area
  - Plan realistic timeline
  - Conduct activity Reviews

Audit Toolkits

- Requirements
  - Policies, procedures, regulations
- Sampling Tools
- Interview Guides & Questionnaires
- List of Required Documents
- Reporting Tools

Steps of Auditing

- Plan
- Perform
- Report
- Follow-up
- Verify

Monitoring Programs

- Specific/focused
- Limited in scope
- Well defined criteria
- Typically ongoing part of a process

Typical Compliance Monitoring Programs

- Expense Reporting
- Promotion Monitoring
- Product Inquiries
- Speaker programs
- Promotional Material Review
- Educational Grants