



**Compliance Reporting and
Auditing:
Best Practice Exchange**

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Concurrent Session Agenda

- **Compliance Auditing: Why it's critical now**
- **Approaching Compliance Auditing**
- **Areas of Focus**
- **Staffing Considerations**
- **Getting Started**
- **Discussion**

Why it's critical now:

An aggressive government

- Aggressive investigations...rising drug costs are driving intense government scrutiny.
- OIG workplan concentrating on illegal schemes to market, obtain, use or distribute prescription drugs to stop drug price inflation and improper payments by Medicare/Medicaid.
- Federal budget expects \$20 billion in recoveries from pharmaceutical companies over five years.
- Recent Corporate Integrity Agreements have been extensive, expensive and disruptive.

Why It's Critical Now: *Industry Response*

- The industry is actively responding to the risks arising from the government investigations by:
 - Adopting PhRMA guidelines on interactions with physicians
 - Adopting defensive strategies, such as implementing or upgrading compliance programs and
 - upgrading the effectiveness of processes and controls in risk areas.
- Most companies either have a compliance program or are actively adopting a program that conforms with guidance provided by US Sentencing Guidelines.

Why It's Critical Now: *Effective Compliance Programs*

- Implementing written policies and procedures
- Designating a compliance officer & compliance committee
- Conducting effective training and education
- Developing effective lines of communication
- **Conducting internal monitoring and auditing**
- Enforcing standards through well-publicized disciplinary guidelines and
- Responding promptly to detected problems and undertaking corrective action.

Why It's Critical Now: *Monitoring and Auditing*

- Companies are recognizing that day-to-day responsibility for ensuring compliance - “monitoring” - lies with operating management.
- Auditing is by nature one of the last elements of an effective compliance program that companies adopt.
- Auditing represents evidence that a company is making a good faith effort to use “internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements.”

Why It's Critical Now: *Government Emphasis on Auditing*

- “Perhaps the best evidence that a provider's compliance program is operating effectively occurs when the provider, through its compliance program, identifies problematic conduct, takes appropriate steps to remedy the conduct and prevent it from recurring, and makes a full and timely disclosure of the misconduct to appropriate authorities.” – IG Brown, March 2000
- “...one of the precepts of an effective compliance program is the early detection of billing errors and other problems through a system of internal audits and by empowering employees to do the right thing.” – AIG Morris, July 2001
- The government's emphasis on auditing carries over to CIAs, which require extensive transaction-based auditing.

Why It's Critical Now: *Draft OIG Compliance Guidance*

“An effective compliance program should incorporate thorough monitoring of its implementation and an ongoing evaluation process”

- Draft OIG Compliance Guidance

Why It's Critical Now: *Industry Practices*

- General trend towards increased compliance auditing
- Many pharmaceutical companies are moving towards developing capabilities to perform periodic audits of:
 - Proper functioning of the elements of compliance program
 - Key monitoring controls in key risk areas,
 - Sales and marketing
 - Clinical compliance
- Audit approach varies depending on maturity of controls.

Approaching Compliance Auditing: *Different from testing mandated by a CIA*

Compliance Auditing

- Flexibility of approach
- Risk based
- Is the control process effective?
- How can process be improved?

CIA Audits

- Directed approach
- Specified scope
- Is the company complying with the CIA?
- Monitoring mechanism for OIG
- Statistical sampling of a large number of transactions

Approaching Compliance Auditing:

Key components of approach

- Inventory the risk areas and the audit universe
 - What is the pool of possible controls/processes that should be audited?
- Identify and understand the compliance controls
 - How is the process controlled?
 - What are the key controls?
 - What is the maturity of those controls?
- Identify and assess auditing already performed outside of compliance department (e.g. samples)
- Establish the objectives of the audits
 - What is the audit trying to accomplish?

Approaching Compliance Auditing:

Key components of approach

- Establish the terms of reference
 - Against which laws, regulations or policies are you auditing?
- Coordination with Compliance Officer/Committee and Legal Department
 - Setting of scope
 - Documenting, addressing and following-up on findings
 - Agree on a reporting mechanism
 - Privilege considerations
- Establish timeline and set priorities
 - Which audits should be performed first, second, thereafter?
 - Rotation schedule warranted?
 - How often should areas be audited

Approaching Compliance Auditing:

Key components of approach

- Design procedures
 - Will vary depending on maturity of controls
 - Controls process review vs transaction testing
 - Number of selections, how tested.
- Execute
- Report on results
- Perform follow-on work on findings
- Refine approach
- Reassess priorities, rotation, and timetable

Areas of Focus:

Partial list of possible audit areas

- Discretionary Spending
- Speaker programs
- Other local events
- Preceptorships
- Consulting agreements and advisory boards
- Grants
- Phase IV studies
- Contracting
- PBM/GPO relationships
- Government pricing
- CME/ME
- Samples
- Value-added services
- Advertising/professional communication agencies
- Third party sales forces
- Off-label “promotion”
- Executive education
- Off-contract discounts and concessions
- Training/Education
- Exception reporting
- Disciplinary action
- Privacy
- Human Subject Protection
- Clinical trials (GCP)
- CFR Part 11
- Animal rights
- Relationships with clinical investigators

Approaching Compliance Auditing:

Example of approach

Priority	Audit Area and Brief Description	Audit Objective	Nature of Audit Procedures	Timing Factors
Priority 1	Discretionary Spending – spending by field representatives and marketing personnel on building relationships with physicians that is processed principally through expense reports.	Audit would seek to test whether the controls in place over discretionary spending are appropriately identifying and addressing exceptions to policy/operating guidelines.	<ul style="list-style-type: none"> • Review the policies in effect for controlling discretionary spending through the T&E process. • Walkthrough the review process performed by corporate expense reporting (CER) of field and marketing expense reports to verify that review process is functioning. • Walkthrough the process by which CER brings exceptions to the attention of the company, and the process by which the company tracks and addresses those exceptions. • Select a sample of expense reports using objective criteria and test District Manager's and CER's review by performing a review of those expense reports for compliance with policy. 	

Approaching Compliance Auditing:

Example of approach

Priority	Audit Area and Brief Description	Audit Objective	Nature of Audit Procedures	Timing Factors
Priority 1	Initiation, approval and monitoring of studies with Phase IV clinical investigators.	Audit would evaluate study approval procedures and documentation requirements designed to demonstrate that the study is a bona fide study with a valid business and medical purpose. Also, audit would seek to test if approved studies are monitored for compliance with policies and procedures.	<ul style="list-style-type: none"> • Review the policies and standard operating procedures in effect over clinical trials. • Walkthrough the study approval and monitoring processes to determine whether the related procedures are being followed. • Select a sample of approved studies and test for compliance with policy: <ul style="list-style-type: none"> ◦ Documentation supporting clinical need for study ◦ Acceptability of proposed clinical investigators ◦ Review/approval by medical affairs ◦ Ongoing management of study including payment only against milestones. ◦ Receipt and review of deliverable for value-for-money criteria ◦ If study is managed externally, test bidding and contracting process for compliance with policies. 	.

Approaching Compliance Auditing:

Example of template

Priority	Audit Area and Brief Description	Audit Objective	Nature of Audit Procedures	Timing Factors
Priority 2	Professional education (ME/CME) and use of advertising agencies or other third parties to plan and execute promotional activities.	Audit would seek to test that promotional or educational activities sponsored through third parties are controlled in accordance with the guidelines.	<ul style="list-style-type: none"> Review the policies in place over professional education and the use of advertising and other agencies for promotional activities. Walkthrough the process of engaging and contracting with third parties, and monitoring their activities. Select a sample of vendors to ensure that (a) contracts contain language required under guidelines (b) the activity is consistent with the guidelines, (c) advisory board agenda and budgets are approved by legal and (d) invoices from vendors and nature of spending incurred are reviewed and approved for compliance with the policies prior to payment. 	

Staffing Considerations:

Necessary Skill-set and Mind-set

- Competency in processes and controls
- Competency in auditing
- Competency in laws and regulations
- Knowledge of industry
 - Knowledge of sales and marketing or applicable practices
 - Knowledge of clinical trials processes and GCP
- Creativity, judgment, teamwork
- Independence, Skepticism, Maturity

Staffing Considerations:

Staffing alternatives

- In-sourcing
 - Cost effective,
 - Knowledgeable about company/industry and audit practices
 - *May not be knowledgeable about compliance laws and regulations*
 - *Reduced access to industry best practices*
- Out-sourcing
 - Independence
 - Knowledge of industry, laws/regulations and audit techniques
 - Budgetary control without increased infrastructure
 - Brings insight into industry best practices
 - *Inability to develop internal expertise*

Staffing Considerations:

Staffing alternatives

- Co-sourcing
 - Benefits of out-sourcing at reduced cost
 - Knowledge transfer from co-sourcing partner
 - Access to resources as needed, including highly specialized resources for niche audits
 - Control over auditing activities by co-sourcing partner without infrastructure build-up.

Getting Started

- Inventory audit areas and assess risk of areas
- Assess status/maturity of controls and policies
- Assemble audit universe
- Discuss scope with compliance officer and legal
- Evaluate auditing already being performed and incorporate above into an audit plan

Getting Started

- Develop initial audit priorities and timeline including agreement on audit objectives for each area
- Determine staffing and agree on budget
- Develop reporting process and formats

Benefits:

The OIG is not the only reason

- Stronger controls embedded in operations which improves responsiveness and risk profile.
- Evidence of a good-faith and meaningful commitment by management to reduce the risk of unlawful conduct
- Demonstration of effective operation of a compliance program
- Helps toward Sarbanes-Oxley risk disclosure system requirements
- Improved control over significant components of sales and marketing spending
- Reduction in surprises



Your worlds



Our people