Auditing:
A Panel Discussion of Evolving Compliance Strategies

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Disclaimer

- The opinions expressed herein are the panelists' own, are based on their experience and knowledge in the industry, and do not necessarily represent the opinions of their current or any former employer.

Compliance Auditing: A Relatively New Development

- Scope of our discussion: Compliance Auditing in sales, marketing and medical affairs
- Historically, areas addressed by legal direction, high level policy, and legal training
- Violations of policy were addressed on a one-off basis through investigations
- Contrast to well established financial, gmp and glp auditing practices designed to prevent violations

OIG Guidance

- Use of audits and risk evaluation techniques to
  - Monitor compliance
  - Identify problem areas
  - Assist in the reduction of identified problems
- Nature of reviews
  - Prospective systemic review of processes, protocols, and practices
  - Retrospective review of actual practices
- Also evaluate whether
  - Policies cover identified risk areas
  - Policies were implemented and communicated
  - Polices were followed

Sentencing Guidelines

The organization shall take reasonable steps

- To ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct
- To evaluate periodically the effectiveness of the organization's compliance and ethics program

A survey of Five CIAs : the government's areas of concern for external review and internal audit

- Serono
- Schering-Plough
- Astra Zeneca
- TAP
- Pfizer

IRO Responsibilities

- **Promotional and Product Services Engagement**
- **Educational Sponsorship Arrangements Review**
- **Government Pricing and Medicaid Drug Rebate Related Functions**
- **Managed Care Expenditures Engagement**

IRO Systems Reviews (follow the policies)

- **Field Activities:**
  - ✓ MSL's and Off-label requests
  - ✓ MSL interactions with field reps
  - ✓ MSL compensation
  - ✓ Call plan development
  - ✓ Samples Procedures

- **Speaker Programs/ Marketing**
  - ✓ Business need for HCP engagements as speakers; no tracking of speaker prescribing habits
  - ✓ FMV and speaker tier criteria
  - ✓ Verification of work product before payment
  - ✓ Reimbursement services
  - ✓ Document controls and promotional program approval processes

IRO Systems Reviews Cont'd

- **Grant Process and Research Activities**
  - ✓ Grant funding criteria, including procedures for request
  - ✓ Disclosure of support
  - ✓ Independence of programs funded by company

IRO Transactions Review ("follow the documents")

- Retention of HCPs, purchasers and/or prescribers of company's products for speaking or consulting arrangements and review of related agreements
- Awarding or payment of research grants or other participation in research activities and review of related agreements
- Awarding or payment of charitable contributions or sponsorships and review of related agreements
- Provision of gifts, meals, entertainment or other items of value to HCPs and review of related field and marketing expense reports

Company (internal) audit requirements under CIAs

Serono

- Serostim Inquiry Report- quarterly report provided to compliance officer regarding all off-label inquiries for Serostim
- Review of Detailing Sessions – verbatim/records obtained from outside, independent entity reflecting the content of detailing interactions between sales reps and HCPs for two covered products (annually selected by the OIG)
- Internal audit option (upon request and approval from OIG) available for Education Sponsorship and Promotional and Product Services Review for the fourth and fifth annual reporting periods

Company (internal) audit requirements under CIAs (cont'd)

Schering

- Specialty Field Sales Force Promotion Monitoring Program – program to identify off-label promotion by specialty field sales teams through Global Compliance & Business Practice Group observation of field activities
- Monitoring and Review of Off-Label Information – off-label inquiry analysis of requests for medical information.
- Message Recall Monitoring Program – analysis of commercially available studies generated by an independent outside company regarding physician recall of marketing messages delivered by specialty field sales teams

Company (internal) audit requirements under CIAs (cont'd)

AstraZeneca

- Medicaid Rebate Review – internal audit group to assist company in ensuring accuracy of Best Price reporting (subject to IRO verification and review)
- Sales and Marketing Review - internal audit group to conduct annual review for three (3) business centers including interviews of employees and sales and marketing documents relating to Promotional and Product Services (subject to IRO verification and review)

TAP

- Internal audit option (upon request and approval from OIG) available for *Drug Price Reporting Engagement* and *Sales and Marketing Engagement* after the fourth annual reporting period

Factors Driving Compliance Auditing – Why We Audit

- OIG Guidance and other government direction
- Compliance with the proliferation of state laws, and federal laws (anti kickback, FDCA, PDMA, other federal healthcare program laws)
- Compliance with the PhRMA Code, ACCME and other voluntary guidelines
- Internal Policies
- Perception auditing – the NY Times test (like modest meals)
- Consent Decrees, DPAs, CIAs
- Culture change: assuring people understand the organization's values

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
- Ascertain 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

Risk areas by Function not by Department

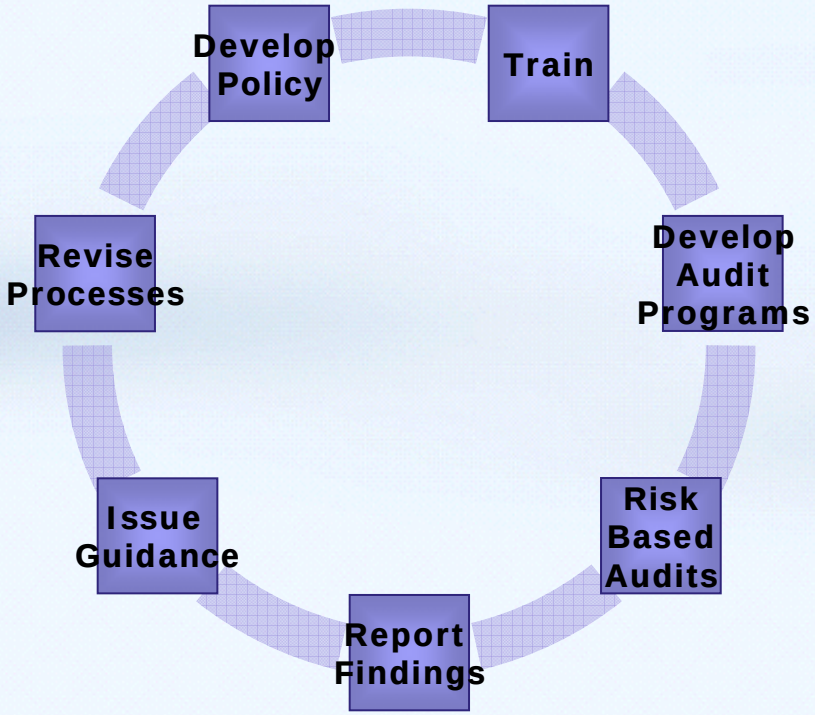
4 P's +

- **Product** …quality, safety, functionality
- **Price** … retail price, discounts, rebates
- **Place** … distribution channel, market coverage
- **Promotion** … advertising, sales promotion, personal selling, publicity
- People … trained, motivated, skill set
- Process … practices and behaviors

Comparing Financial Auditing & Compliance Auditing

	Financial Auditing	Compliance Auditing
Purpose	•Provide assurance that data presented in financial statements presented in accordance with GAAP	•Provide assurance that activities are conducted in accordance with compliance standards
Objectives	•Transactions are complete, accurate, valid and have occurred; access is restricted	•Intent, content, and context of activities are as important as following standard procedures
Characteristics	•Past records only •Financial focus	•Past and Live Components •Activity focus
Outcomes	•Adjustments, Corrections, Restatements	•Process Improvements, Training, Disciplinary Actions

Continuous Improvement



Develop Audit Toolkit

- Conduct Audit
- Present specific findings to management
- Share findings with process improvement workstream
- Issue Audit Report
- Develop and issue guidance based on audit findings

Auditing - Monitoring

	Auditing	Monitoring
Purpose	•Provide assurance that processes and activities comply with laws, regulations and policies	•Measure activities to assure achievement of operational & compliance objectives
Scope/Focus	•Internal controls and processes related to stated business standards and policies	•Activities and transactions related to a specific function or department
Characteristics	•Systematic and structured review conducted by independent staff	•Ongoing process of checking and measuring performance conducted by operations & compliance
Frequency	•Schedule determined by risk based audit plan	•Schedule determined by frequency of transaction
Outcomes	•Formal audit report with findings and recommendations	•Variance analyses, exception reports, metrics

How do you determine areas that require audit?

- Changes in Policy or Process
- Areas of high legal risk (payments to HCPs, grants)
- Areas of organizational change
- Areas where stretch financial targets have been set
- Risks uncovered through monitoring; Compliance review of audit plan

Auditing Structures: Where Do Companies' Compliance Audit Functions Sit?

- One model has Compliance Audit within an OIG (seven elements) comprehensive compliance program; facilitates integration with policy and process development
- Another model: auditing is independent; reports up through Internal Audit
- Where does internal audit sit within Corporate structure?

How do you interact with the Businesses?

- When do you need to advise the business of an audit- and when do you not?
  - Consider whether discussion will prospectively affect behavior (e.g. notification of an audit of off-label requests to Medical Affairs)
  - Understanding of the purpose of audits encourages cooperation (change in culture; recognition that audit identifies problems before the regulators come in)

- How do you stay in touch with evolving business strategies?
  - Where are your touch points-e.g Compliance integration in business councils, decision making fora

Does the Imposition of a CIA or Consent Decree Change Your Audit Approach?

- Government may be focused on different risks (consistency across CIAs)
- Mandatory reporting of “reportable events” may affect the continuous improvement focus
- IRO evaluation of systems and transactions may enhance or redirect auditing efforts

Role of the Legal Department in Auditing

- When do you want your lawyers involved? Expertise in subject matter (for example, current off-label issues that should be spotted in a speaker program or field force audit)
- When is it appropriate to conduct an audit under privilege?
- Can there be a privileged audit when operating under a CIA or Consent Decree?
- What other expertise is appropriate to enlist?

Specific Risk Area Issues in Compliance Auditing & Monitoring: Field Force

- Communications and interactions at training identify areas of risk or concern
- Hotline calls and investigations
- Documents: expense reports, sample accountability, performance management documents (e.g. Manager documentation of field observation), call notes, action plans, district expenses, compliance training records
- Monitoring through rep rides: direct field force observation
  - who does the observation (separation of those who monitor from those who provide advice and assistance)
  - length of observation: spending more than one day with a single representative may be a “best practice” (viewing rep conduct and customer expectations)

Specific Risk Area Issues In Compliance Auditing and Monitoring: Speaker Programs

	Retrospective: Past Programs	Prospective: Live Programs
Attributes	– Ensure compliance with company' policy	
	Documentation – Program Content • Agenda • Slide deck • Approval • Attendance – Speakers • Selection criteria • Contracts • Training • Compensation – Reconciliation • Budget versus actual	**Observation** – Content • Presentation v. Social • Approved slide deck • Fair balance and safety data • Unsolicited questions – Audience • Physicians or other HCP • Others - no spouse or guests – Venue • Following policy • Modest
Challenges	– Sample size – Multiple stakeholders	– Schedules – Interactions with attendees

Metrics and Data Sources

- How is compliance measured?
- What constitutes a comprehensive audit?
- How do you track trends and issues?
- Adequacy of data bases: what spend is captured in your data bases, and how does that affect your auditing practices?

When do you turn compliance over to the business?

- Field monitoring of programs: Representatives have responsibility for monitoring speaker adherence to policy
- Modest meals and sample reconciliation: Performance issue; sales management, business operations report and monitor
- But, we have a long way to go before the audit/monitoring function is obsolete!