

Building A Pharmaceutical Compliance Program

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Background

- Industry in the Spotlight
- Prosecutions, Settlements and CIAs
- PhRMA Code
- OIG Proposed Guidance (October 2002)
 - Identified Risk Areas:
 - Government Reimbursement
 - Kickbacks
 - Samples

Foundation

- Compliance Assessment
 - *What and how is our company doing?*
- Benchmarking
 - *What and how are other companies doing?*
- Senior Management Support
 - *What channels exist for gaining management support?*

Structure

- Compliance Officer and Committee
- Written Policies and Procedures
- Education and Training
- Internal Communication
- Auditing and Monitoring
- Enforcement of Policies and Procedures
- Responding to Detected Offenses

Compliance Officer and Committee

- Placement of Officer within company
- Funding, resources, staff
- Compliance Committee membership
 - *Legal, Sales & Marketing, HR, Regulatory, Finance, R&D, Business Development, other*

Written Policies and Procedures

- Identify and prioritize gaps
 - *Consider OIG risk areas*
- Code of Conduct
- Standardize decentralized and/or informal policies and procedures

Education and Training

- General or focused?
- Centralized or dispersed?
- Choosing among options
 - *Online vs. face-to-face*
- Tracking and documenting

Internal Communication

- Fashioning a basic compliance message
 - *Link to business goals*
- Compliance Committee as prime communicators
- Identifying communication opportunities
 - *Manager and sales force meetings, all-employee meetings, newsletters, etc.*
- Senior management and the Board
- “Hotline” vs. “helpline”

Auditing and Monitoring

- Need for a formal system
- Prioritizing areas in need of monitoring
 - *E.g., Sales & Marketing: do consultants deliver value?*
- Relationship to other company auditing functions

Enforcement of Policies and Procedures

- Do clear and specific policies exist?
- Are infractions of marketing code treated in a consistent manner?
- Training managers on enforcement expectations

Responding to Detected Offenses

- Establishing a formal system
- Use of corrective action plans
- Identifying and implementing triggers for heightened scrutiny

Challenges

- New vs. established programs
- Scope and “turf”
- Establishing realistic priorities and timelines
- Dealing with a far-flung sales force
- Foreign parents and subsidiaries
- Vendors and other agents