



# How to Operationalize the Guidance In A Pharmaceutical Company

OIG Guidance Pharma Audioconference

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# Presentation Overview

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- The Basics
- Beyond the Basics
- Implementation
- What Happens When You Still Have a Problem?

# The Basics

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- Written standards
- Corporate Compliance Officer
- Corporate Compliance Committee
- Training
- Lines of communication to the CCO (hotlines, etc.)
- Audits
- Procedures addressing the non-employment of “excludes”
- Enforcement of discipline
- Procedures for investigations
- Corrective action where necessary

# Beyond the Basics: Stated Purposes of the Guidelines

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- “Guidance is provided to assist companies...in evaluating and...refining compliance programs.” (p.2)
- “This guide is not a compliance program. Rather, it is a set of guidelines that ... manufacturers should consider.” (p.2)
- “Benchmark or comparison” (p.2)

# Beyond the Basics

## What Else is Required?

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- Support and commitment of senior management and governing body (p.3)
- Leadership should strive to create culture of compliance (p.3)
- \$\$: May require a “reallocation of existing resources,” but long-term benefits outweigh initial costs (p. 3)
- Begin with a formal commitment by board (p.6)

# Implementation

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- Step One: Formal commitment by senior management, evidenced to the rest of the Company
- Step Two: Compliance Officer and Committee
- Step Three: Code of Conduct
- Step Four: Everything else

# Formal Commitment By Board

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- Allocation of sufficient resources
- Timetable for implementation
- Identification of Compliance Officer
- (pps 6-7)

# Compliance Officer & Committee

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- Officer
  - OIG prefers Officer not report to GC
  - Has to have authority, independence, access
  - Must be able to effectuate change
  - Roles listed on pps. 40-42
- Committee
  - Advise and assist CCO; Provide increased oversight
  - Personality criteria
  - MUST BE TRAINED
  - “Task Forces” for smaller co.s



# Written Standards/Code

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- Provide to all employees
- Provide to contractors and agents (who provide services that impact federal health care programs)
- Provide to co-promoters (p. 9)
- “Brief”
- “Easily readable”
- “Cover general principles”
- Involve senior management, and evidence their involvement
- Policies/Procedures covering the Risk Areas, but more

# Everything Else

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- Training
  - Minimum number of hours (p. 45)
  - Condition of continued employment
  - Discipline to those who do not participate
  - Factor in annual evaluations
- Access to Compliance Officer
  - Open Door as first line (p.46)
  - Confidentiality, non-retaliation
  - CCO should document questions (p.47)
  - Hotlines: Logs and reports to senior management
  - Exit interviews; surveys (p. 47)

# Everything Else (continued)

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- Audits
  - Risk assessments
- Disciplinary Guidelines
- Corrective Action

# Reporting

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- SIXTY (60) Days (p. 51)
- Disclosure demonstrates good faith and will be considered a mitigating factor (p. 51)

# What Happens When You Still Have A Problem?

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- “The OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct ...”
- “...a good faith effort by the company to comply with applicable statutes ...demonstrated by an effective program, significantly reduces the risk of unlawful conduct and any penalties that result from such behavior.”
- Elements listed “provide a comprehensive and firm foundation upon which an effective compliance program may be built.”
- BUT, list starts out with the qualifier: “*At a minimum*, a comprehensive ... program should include the following elements:”

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**END**