“Introduction to Compliance”

Chile Regional

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Why Do Organizations Need a Compliance Program?

- Communicate Organization’s Commitment
- Provides “safe” mechanisms for reporting suspected wrong doing
- Creates a process for early detection
- Raises Awareness
- Makes Good Business Sense
- Public Image
Compliance Programs
How Comprehensive Should They Be?

- Price fixing by suppliers
- Anti-Trust
- Anti-Corruption / Bribery
- Pharma
- Research
- Applicable Contract Laws
- Tax Law
- Others

A Compliance Program Provides:

- Education
- Prevention
- Enforcement
- Collaboration
- Early Detection
Benefits of an Effective Compliance Program

- Demonstrates organization’s commitment to good corporate conduct
- Identify and prevent criminal and unethical conduct
- Facilitates a centralized source of information on industry regulations
- Provides a methodology that encourages employees to report potential problems

Benefits (con’t.)

- Develops procedures that allow the prompt, thorough investigation of alleged misconduct
- Initiate immediate and appropriate corrective action
- Reduce the organization’s exposure
Organizational Steps to an Effective Compliance Program

Gain Support/Commitment

- Board
- Management/Supervisors
- Key Professionals
- Staff
- Shareholders
- Investors
Support Needed

- Structure First
- Development/Start-up
  - Resources (people, financial)
  - Materials, ie: education/communications/reporting mechanism advertising/code of conduct, etc.
  - Electronic or manual capabilities for data management related to program; tracking/trending; inter/intra connectivity
  - Auditing and monitoring
- Ongoing Operations

Compliance Program Staffing Needs

- Appoint compliance officer
  - High level individual
  - Appropriate authority, adequate resources
  - Reporting structure defined (“to the top”)
- Develop job functions/job descriptions for staff, ie: Education/training, auditors, communications, background checks, reporting, policy and procedure development
- Counsel (internal or external)
Seven Essential Elements of a Compliance Plan

1. Standards and Procedures
2. Compliance Oversight
3. Education and Training
4. Monitoring and Auditing
5. Reporting, Investigation, Background Checks
6. Enforcement and Discipline
7. Response and Prevention
   - Risk Assessment
   - Effectiveness Assessment

Standards and Procedures

- Code of Conduct
  - Keep It Simple
  - Tailored to the organization’s culture, ethical attitude, business, and corporate identity
  - Annual Attestation
  - Scenarios
  - Letter of endorsement by President, CEO, Board Chairman

- Policies and Procedures
  - Accountability
  - Assure affected persons are involved in policy development
  - Conduct policy review according to "Policies on Policies"
  - Collaborate with those affected by the policies
Compliance Oversight

- Compliance Officer
  - Appropriate authority
  - Reporting structure clearly defined
    - “to the top”, no buffers, independent
- Oversight Committee
- Other Committees, Task Forces
- Board

Education and Training

- Develop annual education and training plan
- Internal Vs. External
- Mandatory Vs. Voluntary
- General Vs. Specific
- Training Method
- Sanctions for non-compliance
- Attestations
Monitoring and Auditing

- Audits – independent/objective
- Monitoring – usually not independent but can be/perceived or real subjective
- Audit and Monitoring plan
  - Prioritize actions
  - Scalable to risks and resources
- Communicate findings to management

Reporting, Investigation and Background Checks

- Reporting System
  - Anonymous (Hotline, etc.)
  - Timeliness
  - Internal vs. External
- Triaging and handling investigations from concerns
  - Reports – to whom, how, what?
  - Decision making on outcomes of concerns
- Encourage Reporting
  - Strong non-retaliation policy
- Assure appropriate background checks are conducted.
Enforcement and Discipline

- Sanctions for non-compliant behavior
  - Incentives aligned
  - Policy communicated
- Fair and Consistent enforcement
  - Support from Leadership
- Stand firm
- Critical to effectiveness

Response and Prevention

- Timely response
- Action is comprehensive related to the potential/real concern
  - Is it really a problem?
  - How serious is it?
  - Are there enough facts to investigate?
- Counsel considered
- Create Policy
- Preventative measures
  - Resolution of issues
  - Education and Awareness
  - Development of Policies and Procedures
Is Your Compliance Program Effective?

- Are all seven elements in place?
- Is the culture right?
- Is the structure right?
- Is there awareness?
- Are you continually assessing your compliance program?

QUESTIONS???