

“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



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Compliance Programs How Comprehensive Should They Be?

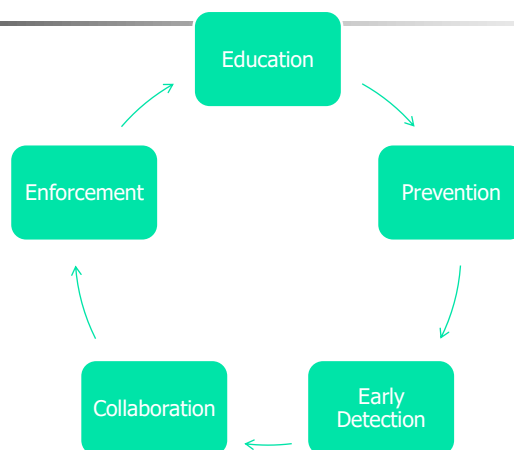
- Price fixing by suppliers
- Anti-Trust
- Anti-Corruption / Bribery
- Pharma
- Research
- Applicable Contract Laws
- Tax Law
- Others



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A Compliance Program Provides:



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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

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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

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Organizational Steps to an Effective Compliance Program



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Gain Support/Commitment

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



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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

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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)

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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



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Standards and Procedures

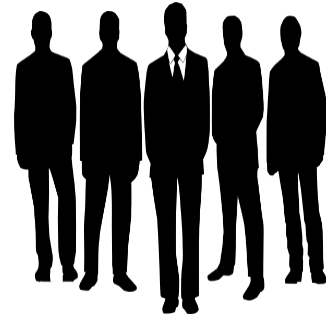
- Code of Conduct
 - Keep It Simple
 - Tailored to the organization's culture, ethical attitude, business, and corporate identity
 - Annual Attestation
 - Scenarios
 - Letter of endorsement by President, CEO, Board Chairman
- Policies and Procedures
 - Accountability
 - Assure affected persons are involved in policy development
 - Conduct policy review according to "Policies on Policies"
 - Collaborate with those affected by the policies

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Compliance Oversight

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



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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



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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

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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.

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Enforcement and Discipline

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



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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



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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?

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QUESTIONS???

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