

# What's Next for You and Your Compliance Programs: A Session for Beginners

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## Key Topics for This Session

- Obstacles and keys to success for a compliance & ethics program
- The role of ethics in a compliance & ethics program
- Considerations in planning for a successful career in compliance & ethics



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## Keys to Success for a Compliance & Ethics Program



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## There are Many Benefits of Having an Effective C&E Program

- Compliance with laws and regulations, leading to avoidance of fines, penalties, and other ramifications of noncompliance
- Reduction in fines and penalties when instances of noncompliance occur, if the program demonstrates an intent and good faith effort to avoid violations
- Respect from the business community
  - Improved organizational reputation
- Promotes a positive and ethical workplace/culture for employees
- Meet expectations of other stakeholders
- Creates a proactive and risk-aware environment – avoid problems before they happen
- Gives management a new set of controls for the business



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## But, There are Ongoing Challenges

- Resistance by some
  - Management doesn't think it's necessary; Views it as a cost center
  - Employees think it's all words and no deeds
  - Belief that company and people are so good that nothing will happen
- People hesitant to come forward and report wrongdoing



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## Ongoing Challenges

- Constantly changing laws and regulations
- Not about rules but about corporate culture
  - Also challenge of different cultures across a company, especially when multinational
- Lack of history of enforcement in many countries
- Turf battles
- Belief that all problems will stop, and, if they don't, compliance doesn't work
- Inconsistent enforcement can lead management to "take the chance" the organization will never be investigated



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## Changing Scope of C&E Programs

- The history of C&E programs began with bribery and corruption
- Now, C&E programs may address:
  - Antitrust
  - Contracts and agreements
  - False Claims Act
  - Tax compliance
  - Employment laws
  - Environmental
  - Conflicts of interest, including Stark and Anti-Kickback
  - Product/patient/student safety
  - Privacy
  - Many other laws and regulations



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## Keys to Success

- Securing buy in from the board and direct line to it
- Strong tone at the top
- Ensuring that tone cascades to the middle
- Open lines of communication and acting on it so employees see response
- Consistent discipline
- Willingness to own problems and not hide them



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## Keys to Success

- Understanding how the business works and designing a program that is integrated in it and not bolted on
- Learning best practices and applying them
- Strong but independent relationship with other departments: legal, HR, risk
- Approaching compliance as a way to help the business not as a hindrance



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## Keys to success

- Take a drip, drip, drip approach.
  - Can't just do once and move on.
  - Need to be communicating constantly: Job descriptions, training, email and other reminders, messages within leadership emails, and on and on



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## Bottom Line

- Stronger internal controls
- Avoids cost and reputational harm from violations
- Helps make your business (pharma, medical device) a part of global supply chains if you are a smaller company, and helps bigger organization ensure its suppliers can be trusted
  - Reducing risk to customers
  - Demonstrating commitment to proper behavior
  - Building an ecosystem of how to do business right

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## The Role of Ethics

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# U.S. Federal Sentencing Guidelines

To have an effective compliance and ethics program, an organization shall—

- (1) exercise due diligence to prevent and detect criminal conduct; and
- (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

- Note: 2004 Amendments to the guidelines added the above consideration of ethics
- It's not a question of ethics or compliance. You need both.

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# What is “Culture”?

- “The set of shared attitudes, values, goals, and practices that characterizes an institution or organization”
  - Source: Merriam-Webster
- Let's break this down:
  - Attitude – a mental position, feeling or emotion regarding a fact or state
  - Value – something (such as a principle or quality) intrinsically valuable or desirable
  - Goal – the end towards which effort is directed
  - Practice – the usual way of doing something

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# Characteristics of Corporate Culture

- Culture is:
  - Shared
  - Pervasive
  - Enduring
  - Implicit
    - Source: The Leader's Guide to Corporate Culture, by Boris Groysberg, Jeremiah Lee, Jesse Price, and J. Yo-Jud Cheng, *Harvard Business Review*, January-February 2018

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# Corporate Culture

- Six signs of a poor corporate culture:
  1. Inadequate investment in people
  2. Lack of accountability
  3. Lack of diversity, equity, and inclusion
  4. Poor behavior at the top
  5. High-pressure environments
  6. Unclear ethical standards
    - Source: 6 Signs Your Corporate Culture Is a Liability, by Sarah Clayton, *Harvard Business Review*, December 5, 2019
- Plus one more for compliance: Fear of being able to speak up

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# Ethics

- Two relevant definitions from Merriam-Webster:
  - a set of moral principles : a theory or system of moral values
  - the principles of conduct governing an individual or a group
- Individual ethics is not the same as organizational ethics
- But the line can become blurred, especially:
  - Politics
  - Social causes
- Another concept to consider is “situation ethics”:
  - a system of ethics by which acts are judged within their contexts instead of by categorical principles

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# Applications to C&E Programs

- Focus on attitudes relating to compliance with laws and regulations
- Important considerations
  - Strive for clarity in policies (Code of Conduct, etc)
  - Effective and ongoing training
  - Focus on communications and transparency
    - E.g. Results of investigations
  - Create an environment where people can feel safe and speaking up
  - Encourage management to value those with the courage to do so
    - Perhaps the most difficult part of all

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## Building Your Career as a Compliance & Ethics Professional

- Certification
- Networking
- Additional or specialized training
- Developing a career plan

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## Why Get Certified?

- Credibility
  - Peers in the profession
  - Co-workers
  - Supervisors and senior management
  - Regulators and enforcement officials
- Shows that you did more than sit through a class; Rather, that you have mastered a body of knowledge
- Salary surveys show that professionals with certification average higher compensation than those without
- Puts you on par with other professions: HR, fraud, internal audit

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## Qualifications and Steps for Taking an Exam

- At least one year in a full-time compliance position or 1,500 hours of direct compliance job duties earned in the two years preceding your application date
- Your job duties directly relate to the tasks reflected in the “Detailed Content Outline”
- Earn 20 CCB approved Continuing Education Units (CEUs) within the 12-month period preceding the date of the examination (at least 10 of the CEUs must be from live events, not recordings, on-demand, etc)
  - These do NOT need to be from SCCE or HCCA
- Complete and submit the application
- Schedule and take the examination
  - At a testing center or
  - Online: <https://www.hcca-info.org/certification/become-certified/exam-information>
- See the Certified in Healthcare Compliance (CHC) and all other handbooks at:
  - <https://www.hcca-info.org/candidate-handbooks>

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## Where Next?

- By passing the exam and getting certified, you demonstrate a mastery of some of the most valuable concepts and their application to C&E programs
- But, does certification guarantee success?
  - Of course not
- Other keys to a successful career in compliance and ethics:
  - Communication
  - Relationship-building
  - Persuasion
  - Negotiation
  - Collaboration
  - Networking
  - Business skills
  - Commitment to continued learning

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# Continuing Education

- Specific laws and regulations, for example
  - HIPAA, Stark, Anti-Kickback, False Claims Act
- Deeper dives into specific elements of C&E programs, for example
  - Investigations
  - Risk assessments
  - Training
- Complimentary skills, for example
  - Supervising and developing a staff
  - Budgeting, understanding financial reports
  - Negotiation
- Treat the need for 40 CEUs every two years to maintain certification not as a requirement but an opportunity to stay current or to grow and add new skills



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# Connect Online

- HCCAnet: <https://community.corporatecompliance.org/hcca/home>
- Twitter: @theHCCA
- Facebook: <https://www.facebook.com/HCCA>
- LinkedIn: <https://www.linkedin.com/groups/83345/>



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# Become a Contributor to the Profession

- Our profession grows through the sharing of knowledge
- Don't keep what you have learned to yourself. Let others benefit:
  - Write for the magazine
  - Write for the blog
  - Lead a webconference
  - Speak at a conference
  - Be a guest on a podcast



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# Questions ?

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