Practical Considerations for Developing an Effective Compliance Program

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Why is a Compliance Program Essential?

"All companies struggle with a fundamental challenge: the vast array of financial and legal rules that apply to their every activity. These rules are **voluminous**, **multifaceted**, **ambiguous in interpretation and uncertain in application**. I was frankly stunned when I began my tenure at GE in 1987 and began to get a sense of the complexity the company faced… The problems of complexity, ambiguity, uncertainty and mutual inconsistency are multiplied a hundredfold in a multinational company like GE, which is subject not only to international law, but also to the laws of more than one hundred nations."*

- Ben W. Heineman, former General Counsel of GE and author of
    "High Performance with High Integrity" *pp.37-38*

Seven Elements of a Compliance Program
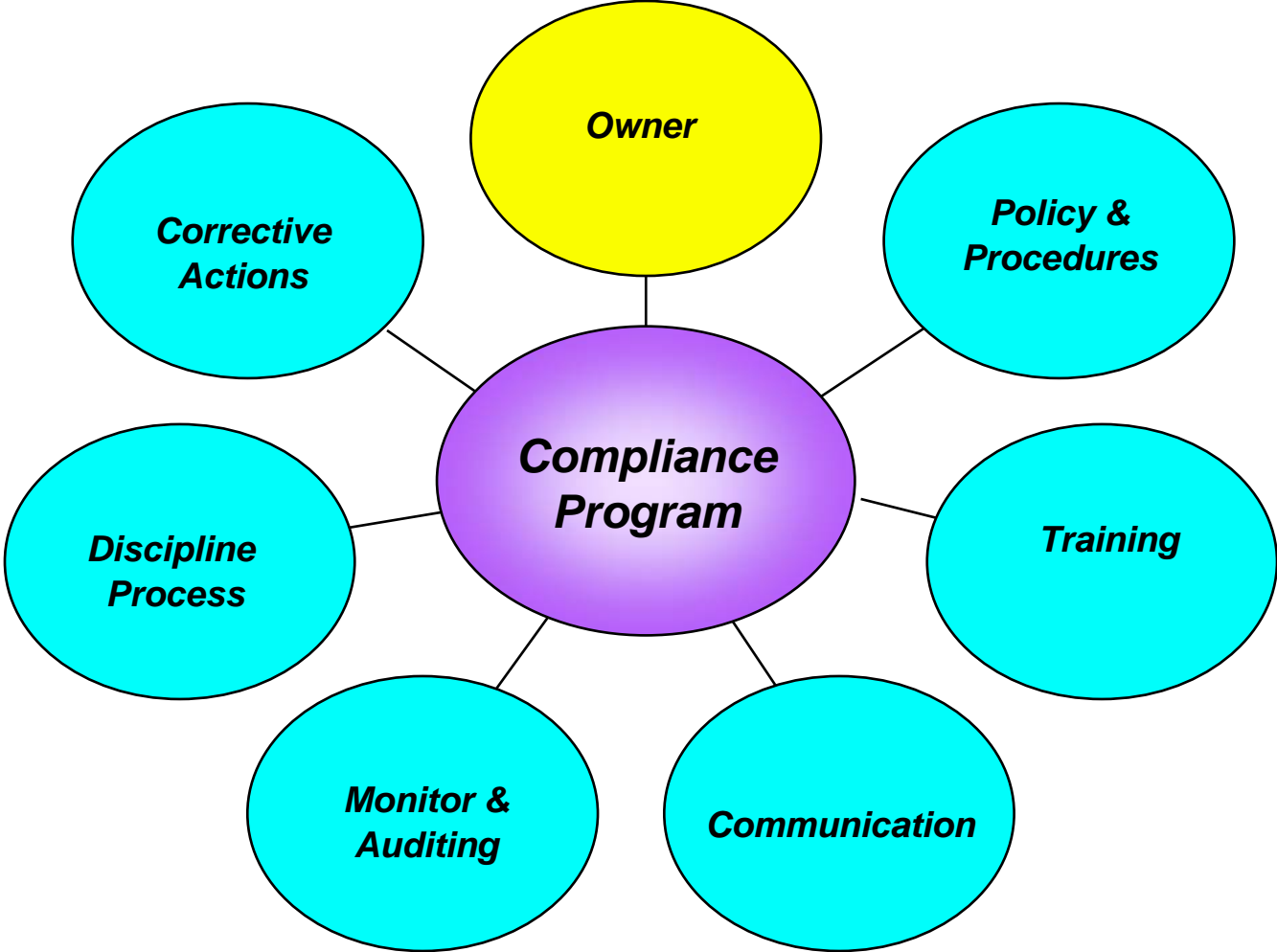
Owner

Compliance Officer

- Senior leader reporting to President or CEO and Board with access to Legal Counsel

Compliance Committee

- Support the Compliance Officer
- Senior Leaders
- Set the tone and guide the program

Success of the program depends on the "Tone at the Top"

- Consistent, Frequent Demonstration of Senior Leadership Commitment
  - Personal Integrity that Walks the Talk
- CIA requirements
  - Board of Directors resolution
  - Compliance Officer and Management Certifications

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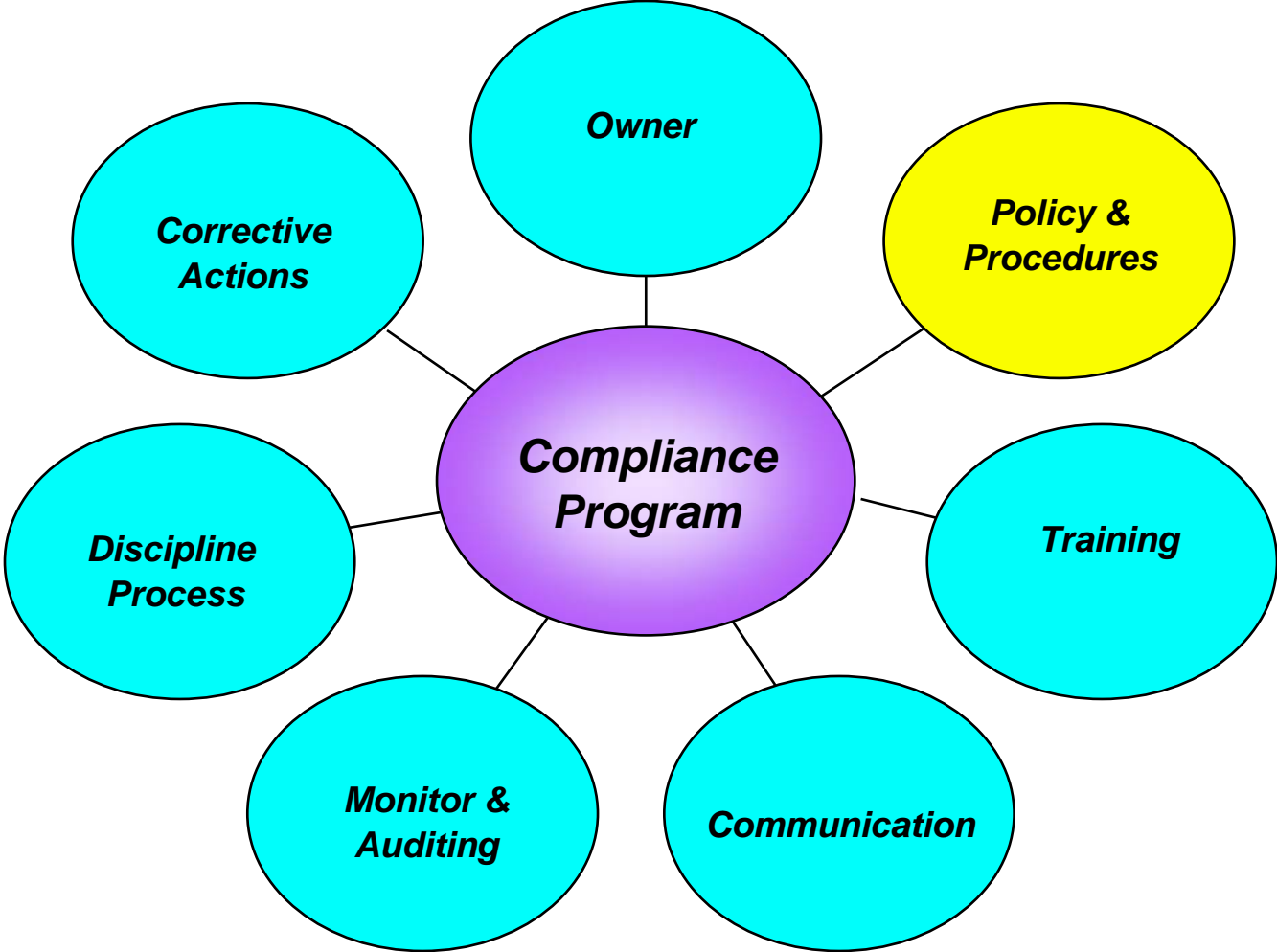
Identify the RISK AREAS

- Promotional Materials
- Sales Personnel
- Medical Information
- Medical Science Liaisons
- Publications
- Press Releases
- Educational Grants/CME
- Charitable Contributions
- Clnical Trial Services
- Clinical Research Grants and Activities
- Product Support Services
- Preceptorships
- Advisory Boards, Consulting
- Speaker Programs and Speaker Training
- Formulary Committees
- PBMs, GPOs, Payers
- Pricing and Discounts
- Coupons
- Exhibit Booths
- Symposia
- Honoraria and Expense Reimbursement
- Call Plans
- Disciplinary actions
- Ineligible Persons

- Off-label Promotion
- False or Misleading Statements Re Efficacy or Safety of Products
- Kickbacks
- Switching
- Unsolicited Questions
- Access Fees
- Value-added Services
- Contracts and Rebates
- Integrity of Price Reporting Data
- Samples and Sample plans
- Sales Force compensation
- Educational Items
- Business Meals
- Nominally Priced Drugs
- Patient Privacy
- Adverse Event Reporting
- Ghost-writing
- Conflicts of Interest
- Compendia
- Patient Advocacy Organizations
- Vendors acting on your behalf
- Market Research
- Fee-for-Service Arrangements
- Post-marketing Research and Investigator-sponsored studies

WORDS MONEY PRIVACY

Policies and Procedures

Company Code of Conduct

- Many companies are posted on the web
- Cover key business areas and legal/ regulatory risks
- Keep it Principle-based

• Departmental Policies and Procedures

- Policies are the What's and Procedures are the How's
- Wherever possible, translate legalese into everyday language
- Order procedural steps in sequence
- Controlled process for managing exceptions

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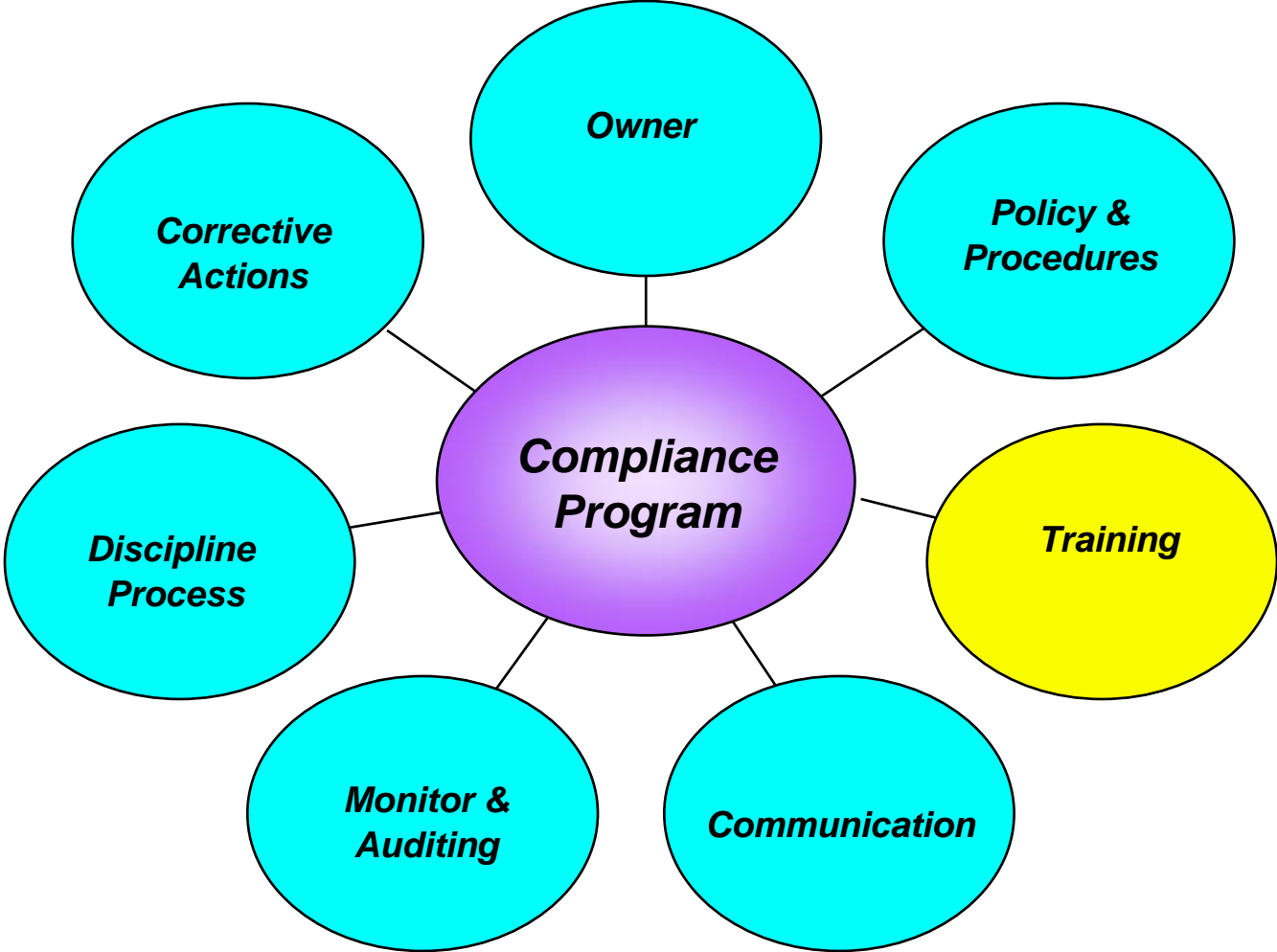
Training

It has to be documented but it needs
    to be more than just "checking the box"

- Impact and Retention
- Behaviors

It's about the Learner's needs

- Learning styles
- Engaging
- Management training

Reinforcing good behaviors or implementing new ones

Explain the "whys" behind the rules

- Understanding "Why" fosters compliance in new situations
- Explain where policies come from (laws, regulations, codes)

Give a man a fish; you have fed him for today.
Teach a man to fish; and you have fed him for a lifetime.

Compliance Training Development

It needs to be a partnership between Compliance and the Training Dept.

- Compliance personnel are the Subject Matter Experts
- Training Personnel are the Experts on Training

Use adult learning principles

- Tell them, and tell them the WIFM (What's in it for me?)
- Develop Practical Scenarios and Case Studies
- Use a range of training formats
  - Self-study
    - Read the local Policies and Procedures
    - Computer-Based courses
  - Group sessions
    - Live sessions with a trainer
    - Video or DVD presentation with group discussion

Self Study Training Development

Computer Based Training

- Works well for administrative topics
    - Expense Reporting
    - Adverse Event / Product Complaint Reporting
    - Sample Accountability
- Introduction by Senior Leader
    - Tone from the Top
    - Reinforces importance of training
- Quick Checks and Scenario Challenges
    - Knowledge of policies
    - Application of policies

Individualized Training

- Situations not applicable to entire audience (e.g., state requirements)
- Situations occurring rarely ("On time" training)

Show CBT example
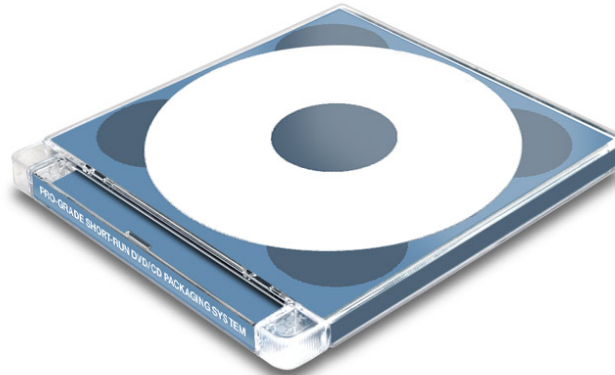
Group Training Delivery

Presented by Management or Trainers

- Creating a culture of compliance
- Holds management accountable for thorough understanding of topics
- Allows for discussion
- Enables management to set clear expectations

Incorporate into existing training processes

- New employee orientation and new rep sales schools
- Ongoing training
  - Live training at planned meetings such as brand team or sales meetings
- Incorporate Compliance into other trainings to reinforce learning

Model appropriate responses to tough situations

- Practice- just like message practice
- Create realistic scenarios to assist with understanding
- Cater training to audience background

Example of Sales Force Training
Inappropriate attendees

Spouses, family, or friends not practicing medicine in a field **relevant** to the information presented

Inappropriate guests must not attend business meals or
FDA – Regulated programs

- Rep can prevent a situation before it happens by:
  - Discuss with HCP in advance
  - Refer to statement on invitation
  - Plan alternatives to evening programs (breakfast, lunch, immediately after office hours)
  - Confirm attendees with a phone call the day before the program
- Or you will have to ask inappropriate attendees to leave

PhRMA Code:
Q: "Under the code, may HCP's spouse or other guest be included in a meal…if the HCP pays for the spouse or guest?"
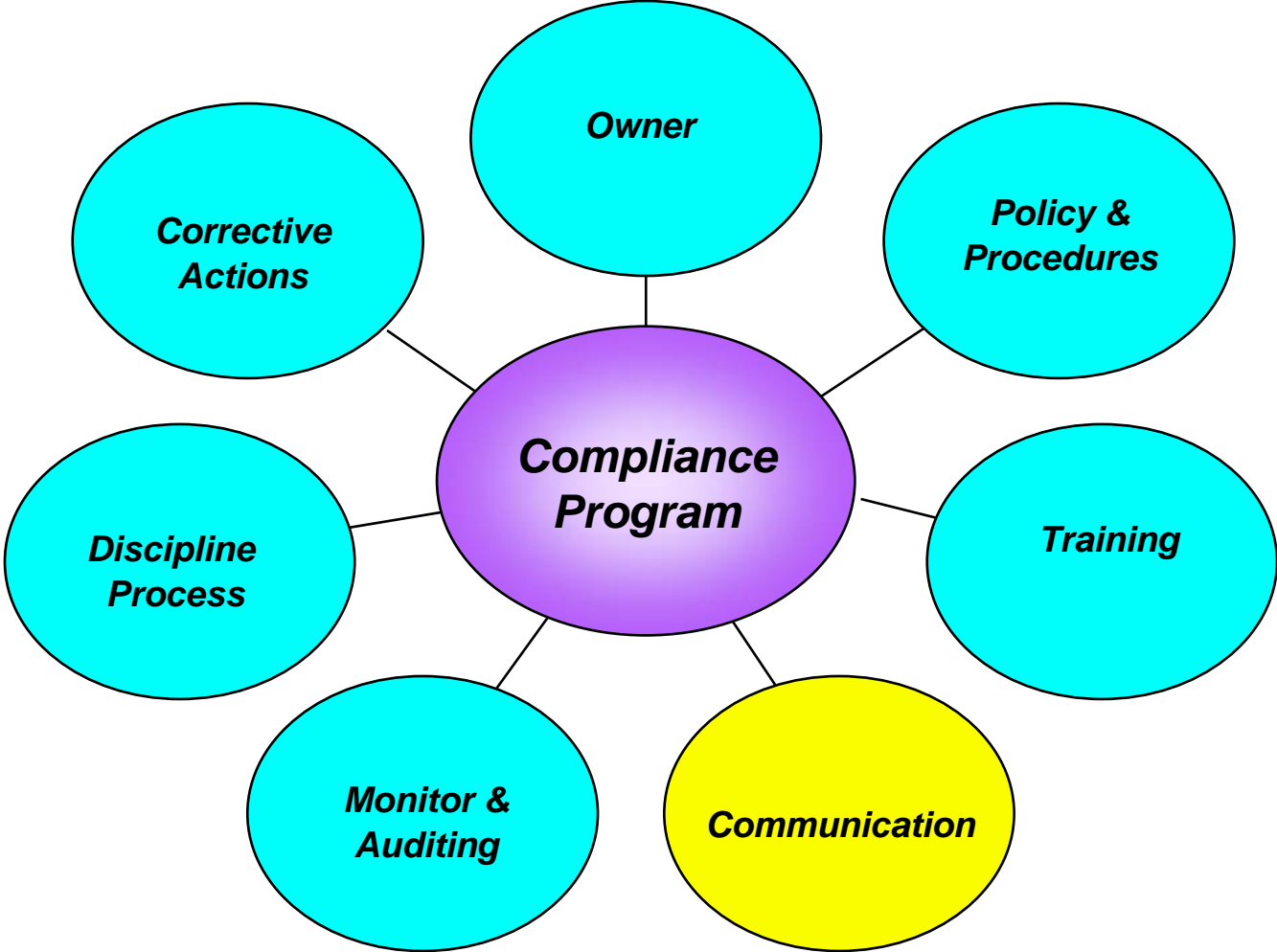**A:** "No. The code provides that it is not appropriate to include a spouse or guest at a meal…regardless of who pays for the meal, unless the spouse or guest would independently qualify as a HCP for whom the informational presentation is appropriate."

Play DVD

Seven Elements of a Compliance Program

Communications

Vehicles to identify risks or potential violations

- Hotline or other mechanism
  - For reporting of potential violations
  - Assure broad awareness (newsletters, posters, wallet cards)
  - Allow option of anonymous reporting
  - Non-retaliation policy for good-faith reporting
  - Use by International employees – Understand local law considerations
  - Use by External parties (HCPs, consumers)
- Surveys
- Exit Interviews

Communications

Provide resources for questions, guidance, best practices

- 1-800 number to reach compliance team
- Intranet Website
- E-mail
- Conference calls
- Compliance Liaisons – local department experts

Create opportunities for dialogue

- Attend meetings
  - Stay for breaks and meals
- Attend trainings
- Routinely scheduled interactions
  - Coffee or Lunch with business partners
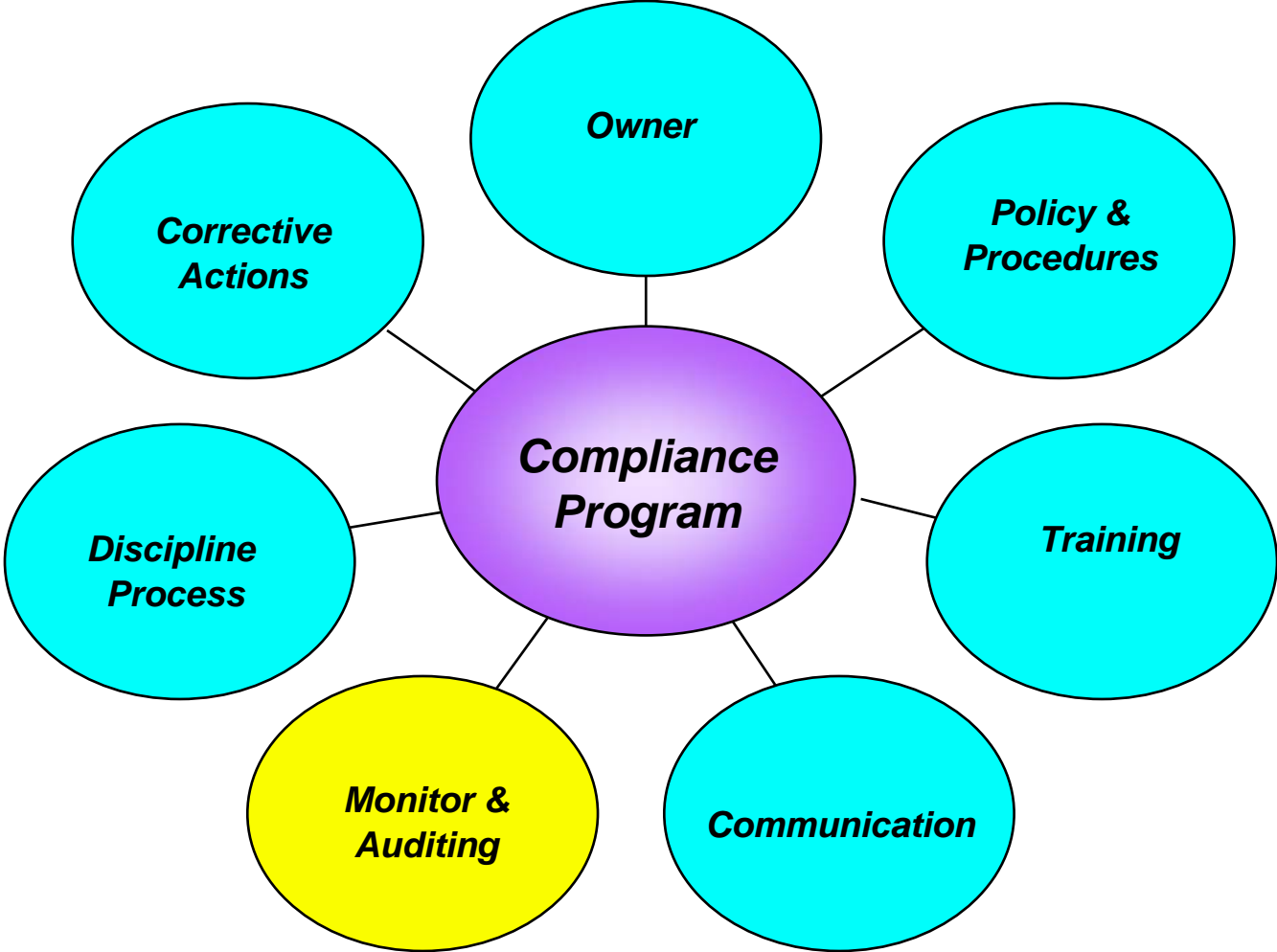 - Rides with Reps, MSLs

Consultations

A major part of your role

Be the **Advisor**, not the **Approver**

- They know their business
- They might not give you all the facts
- The business must retain accountability

Help them understand **WHY**, so they can apply to new but similar situations without your assistance

Seven Elements of a Compliance Program

Monitoring vs. Auditing

Monitoring

- **Conducted by personnel affiliated with Compliance Program**
- **Broad sample of activities**
- **Part of on-going, continuous improvement process**

Auditing

- **Independent personnel - whether internal or external**
- **Focused engagements**
- **Report findings for management action plans**

Different but Complementary Processes

Benefits of Monitoring and Auditing

Assure compliance with policies

- Document that policies are being followed
- If they aren't, you want to find it and fix it yourself

Feedback loop on effectiveness of other program elements

- Policy Language
- Training
- Communication programs

Foster relationships with business partners

- Putting a face with the compliance program
- Opportunities to coach and share the learning
- Opportunities to understand business challenges
- It's not an "ivory tower"compliance program
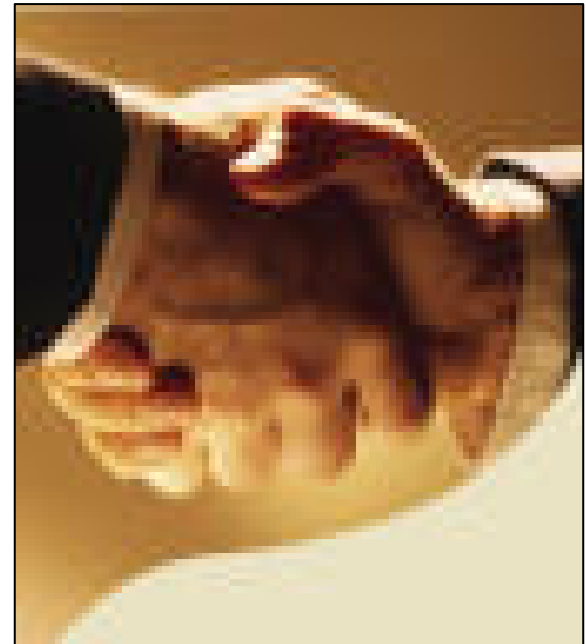
Considerations for Designing A Monitoring Program

Voluntary or mandatory?

-   -Corporate integrity agreements

Internal or external?

-   -Resources to execute it (people/money)
-   -Independence

Direct observations or indirect?

-   -Complementary reviews for certain activities

Scope: Promotional or beyond?

-   -Sales, Marketing, R&D, Medical, Corporate Affairs, etc.

Coordination with Audit activities

Monitoring Plans

Live Event Monitoring and Record Reviews

- Number should reflect volume of business activities
- Assure coverage across risk areas, business units, and brands
- Use Risk-based approach to sampling for selection of events

Non-promotional Activities included in CIAs

- Consultant arrangements
- Post-marketing research including Investigator-sponsored studies
- Publications
- Medical Education Grants

Monitoring Plans

Field Force Monitoring included in CIAs

- Rep Ride-alongs
- Speaker Programs
- Record Reviews
  - Expense reports
  - Sample records
  - Medical Information requests
  - Preceptorships/Tutorials
  - Promotional Materials
  - Call notes
  - E-mail
  - Manager coaching notes
  - Message recall studies

Monitoring Process

Protocols and checklists directly from policies
- "Open book" test

Unpredictable notification for live events

Compliance reviews are unique from traditional financial or GXP auditing
- Intent, content, and context are as important as following procedures

Document what is going well

Investigate any findings and do a root cause analysis
- An isolated finding or an indicator of broader issues?

Take corrective actions as appropriate
- Disciplinary action
- Adjust policy and/or training to provide clarity and consistency
- Document corrective action

Sales Rep Ride-along

Selected by Compliance Department

Observations

- Current promotional materials and package inserts
- Interactions with customers
- Adverse event and product complaint reporting
- Sampling
- State requirements, e.g. Vermont price disclosure, CA expenses

Assess rep's knowledge of policies

- Opportunity to answer their questions
- Feedback loop for improving training program

Opportunity to Explain the Benefits of the Compliance Program

Speaker Programs

Observations

- Invitations
- Venue
- Business Meal policies
- Appropriate Attendees
- Presentation
    - Speaker statements
    - Were all mandatory slides used?
    - Proactive presentation was on-label
    - Fair balance safety information was presented
    - Proper handling of unsolicited questions
- Current package insert and promotional materials
- Educational or Practice-related Items
- Honoraria and expenses
- Sales rep activities and certification

Payment Reviews

Observations:

- Ability to locate records
- Financial transactions
- Business case for services
- Selection criteria for the service provider
- Approvals
- OUS – Anti-corruption due diligence
- Fair market value
- Contracts executed before work begins
- Documentation of services received
- Payment matches services provided

Monitoring Results

Integrate Partnership with the Business
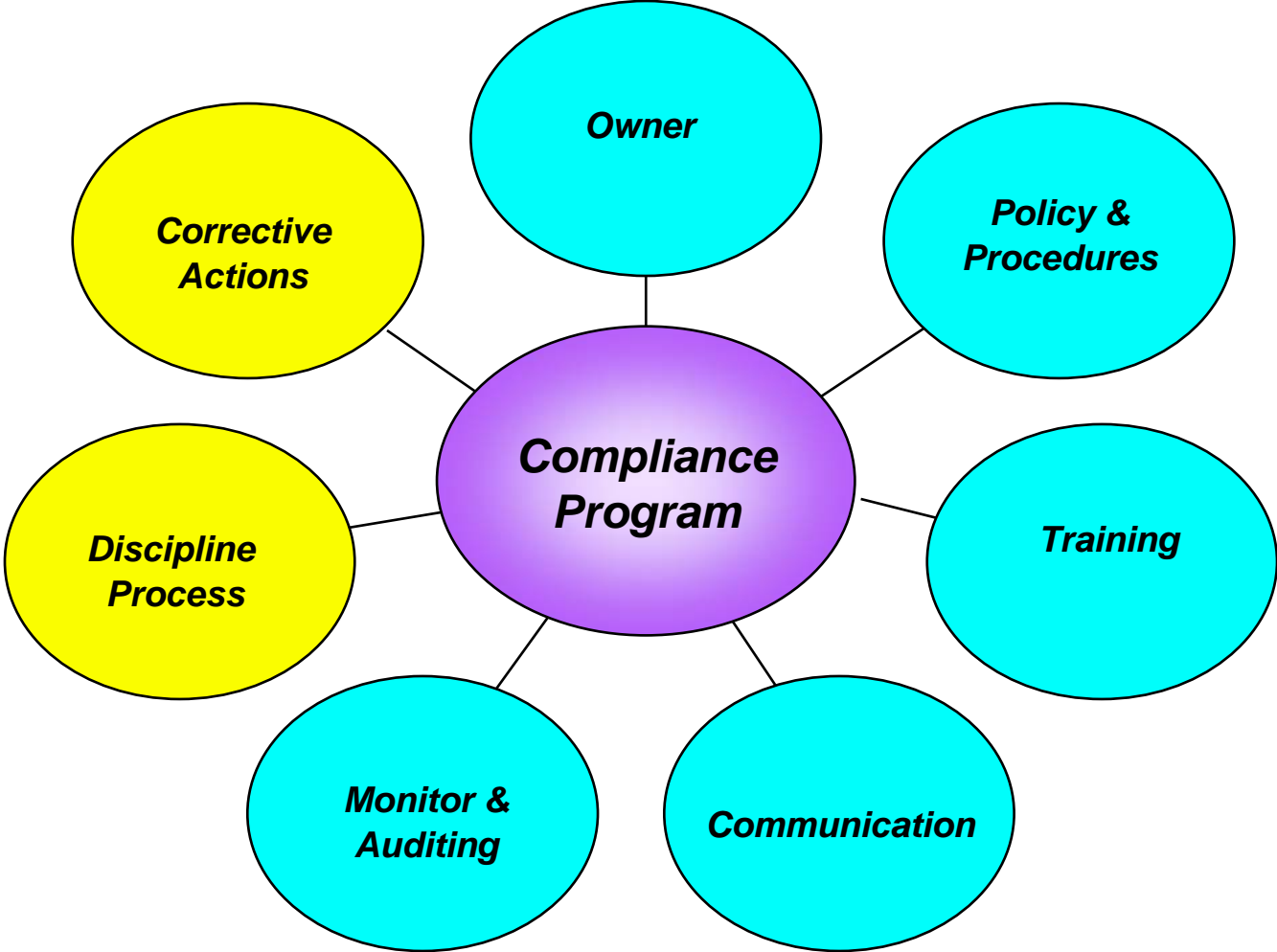
- Provide on-going Dashboard metrics for Business units

Compile quarterly and annual monitoring results for Senior Management Reviews

Look for trends and patterns

- Use as feedback loop for training and policy adjustment
- Findings may identify need for in-depth audit

Seven Elements of a Compliance Program

Discipline Process

- OIG Guidance for Pharmaceutical Manufacturers

  - " A pharmaceutical manufacturer should consistently undertake appropriate disciplinary action across the company in order for the disciplinary policy to have the required deterrent effect. Intentional and material noncompliance should subject transgressors to significant sanctions."

  - " Disciplinary action also may be appropriate where a reasonable employee's failure to detect a violation is attributable to his or her negligence or reckless conduct."

  - " Each situation must be considered on a case-by-case basis, taking into account all relevant factors, to determine the appropriate response."

Disciplinary Process

Clear disciplinary policies setting out consequences of violating the law, regulations, or company policies

Consequences for management failure to detect

Roles of Human Resources and Line Management

Each situation must be considered on a case-by-case basis with all relevant facts

Corrective Actions

OIG Guidance for Pharmaceutical Manufacturers

- Expectation for "responding promptly to detected problems and undertaking corrective actions."

- "Upon receipt of reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred, and, if so, take decisive steps to correct the problem."

- "Detected but uncorrected misconduct can endanger the reputation and legal status of the company."

- **It's not "bad" to find issues; it's bad to find an issue and not correct it**

- **Corrective actions are intended to prevent future issues**
  - **Even if discipline was deemed necessary**
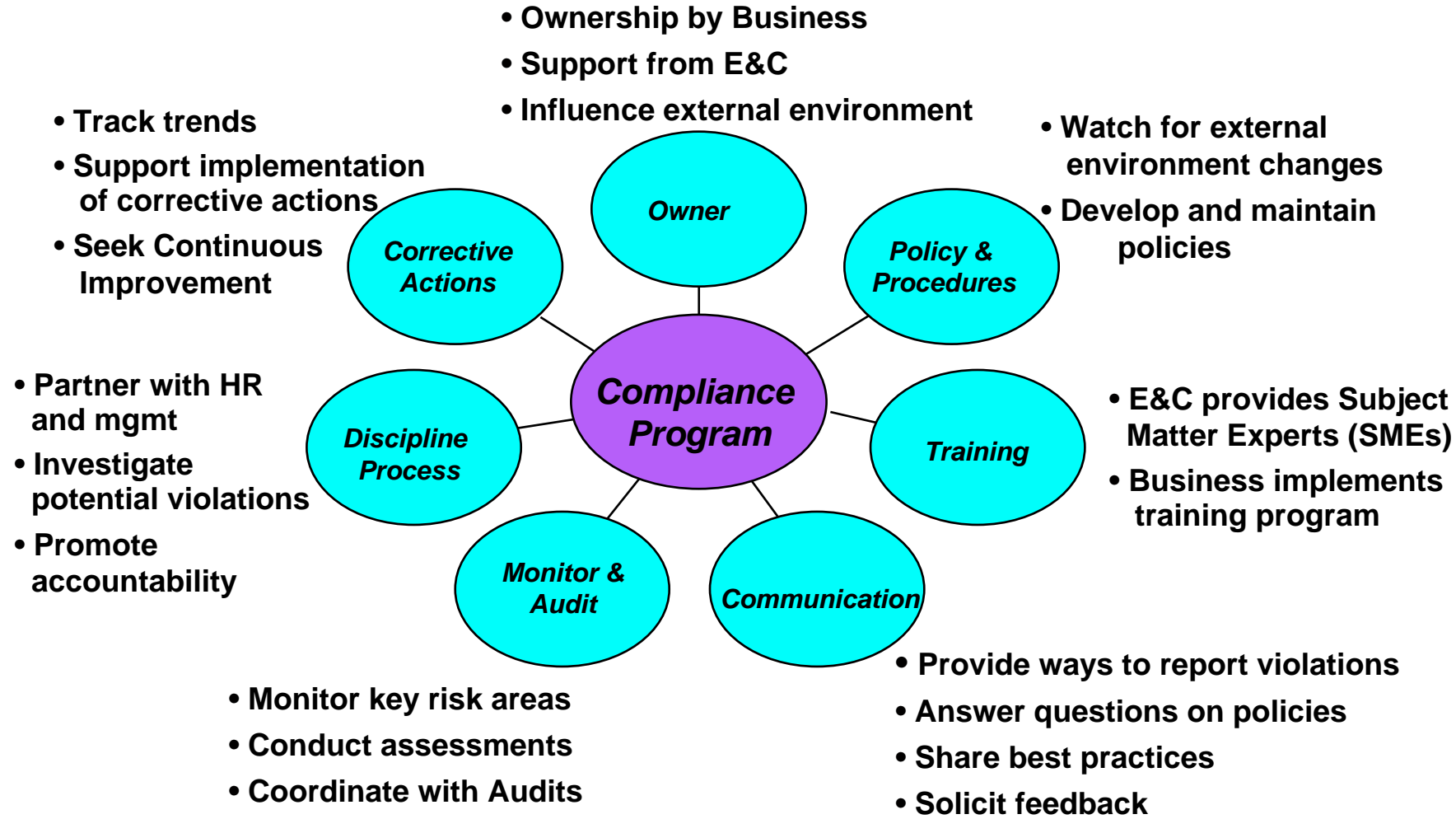
Corrective Action

"Learn and Grow"

Does it require reporting to the government or law enforcement?

- CIA Reportable Events

Do you understand the root cause?

How do you make sure it doesn't happen again?

Seven Elements of a Compliance Program

- **Ownership by Business**
- **Support from E&C**
- **Influence external environment**

- **Track trends**
- **Support implementation of corrective actions**
- **Seek Continuous Improvement**

- **Watch for external environment changes**
- **Develop and maintain policies**

- **Partner with HR and mgmt**
- **Investigate potential violations**
- **Promote accountability**

- **E&C provides Subject Matter Experts (SMEs)**
- **Business implements training program**

Owner

Corrective Actions

Policy & Procedures

Compliance Program

Discipline Process

Training

Monitor & Audit

Communication

- **Monitor key risk areas**
- **Conduct assessments**
- **Coordinate with Audits**

- **Provide ways to report violations**
- **Answer questions on policies**
- **Share best practices**
- **Solicit feedback**

Other things you need to consider:

How do you apply your Compliance Program:

- To Third Parties who are acting on your behalf
  - Vendors
  - Contract Sales Forces
  - Contracted HCPs – Speakers

- To Joint Ventures

- To Mergers and Acquisitions
  - Due Diligence
  - Integration

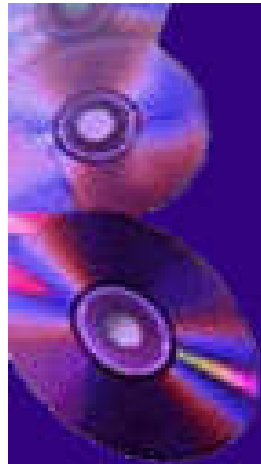- In a Global Multi-National Company
  - International Laws

CONCLUDING THOUGHTS

Compliance Program can't be a paper program,
but it must be a program on paper

Compliance is everyone's responsibility,
not just the Compliance Department's

Play DVD

Questions

Case Study

Sofia, a sales rep in Fargo, has heard that her company is working on a Fair Market Value analysis for physician speaker payments. She wants to be sure that the new rates won't put her at a disadvantage as compared to her competitors. The sales reps in the area have created a group page on Facebook where they share information about things like the doctors' office hours, rep rules, etc. She posts a message asking everyone to share how much each company pays physicians to do a speaker program. Since it's supposed to be fair market value, she thinks this is a great way to be sure the rates really are fair.

What considerations does this situation raise for you as a Compliance Officer?

Case Study

Do you have a policy on Social Media?

Do you have a policy on Interacting with Competitors?

Do you have a policy on Confidential Company Information?

Is there an appropriate way to do benchmarking?

Would you provide Training on these topics?

Are you able to do Monitoring to detect this activity?

If you discovered this situation, what would you consider for corrective action?

    A. What if Sofia "self-reported" because she called to share the rates she got with you to "help with the company's FMV analysis" ?

    B. What if it was reported to you anonymously through your hotline?

What do you think about the role of Sofia's management?