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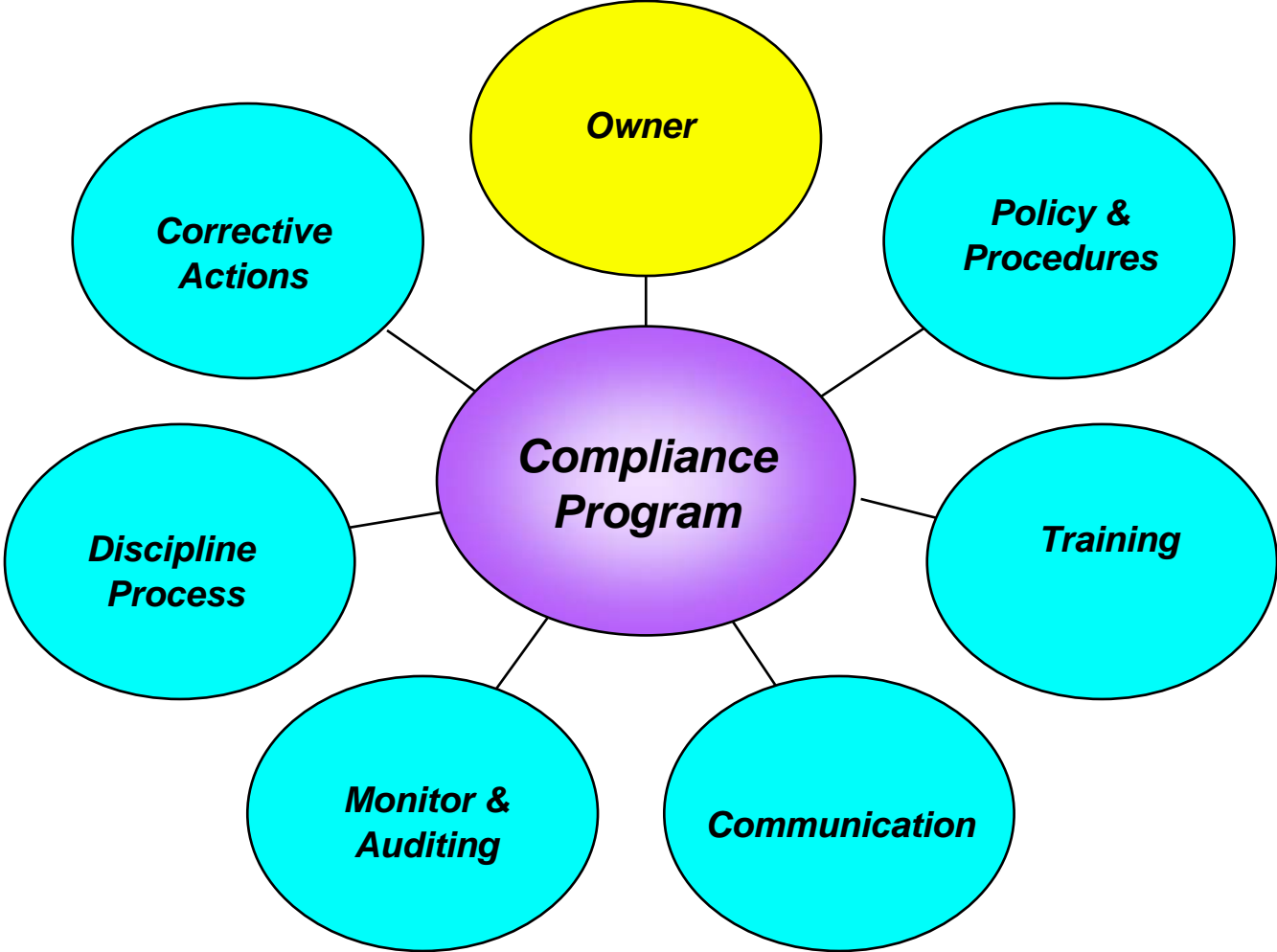
# Practical Considerations for Developing an Effective Compliance Program

**Kelly B. Freeman, Ph.D.**  
**Ethics and Compliance Officer**

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Answers That Matter.

# 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

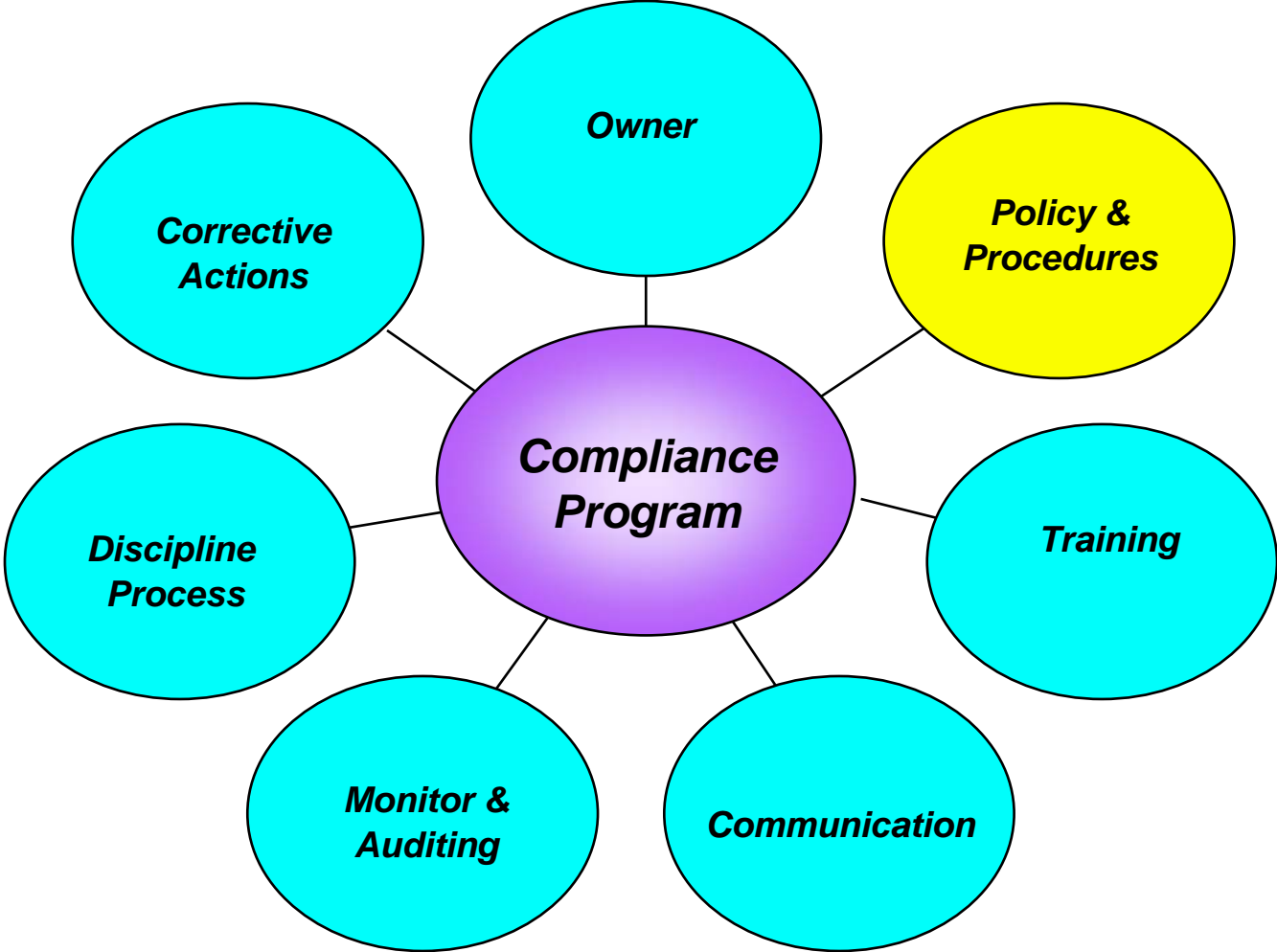
- Support the Compliance Officer
- Senior Leaders
- Set the tone and guide the program



## 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

# Seven Elements of a Compliance Program



# Identify the RISK AREAS

- Promotional Materials
- Sales Personnel
- Medical Information
- Medical Science Liaisons
- Publications
- Press Releases
- Educational Grants/CME
- Charitable Contributions
- Clinical Trial Services
- Clinical Research Grants and Activities
- Product Support Services
- Preceptorship
- 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

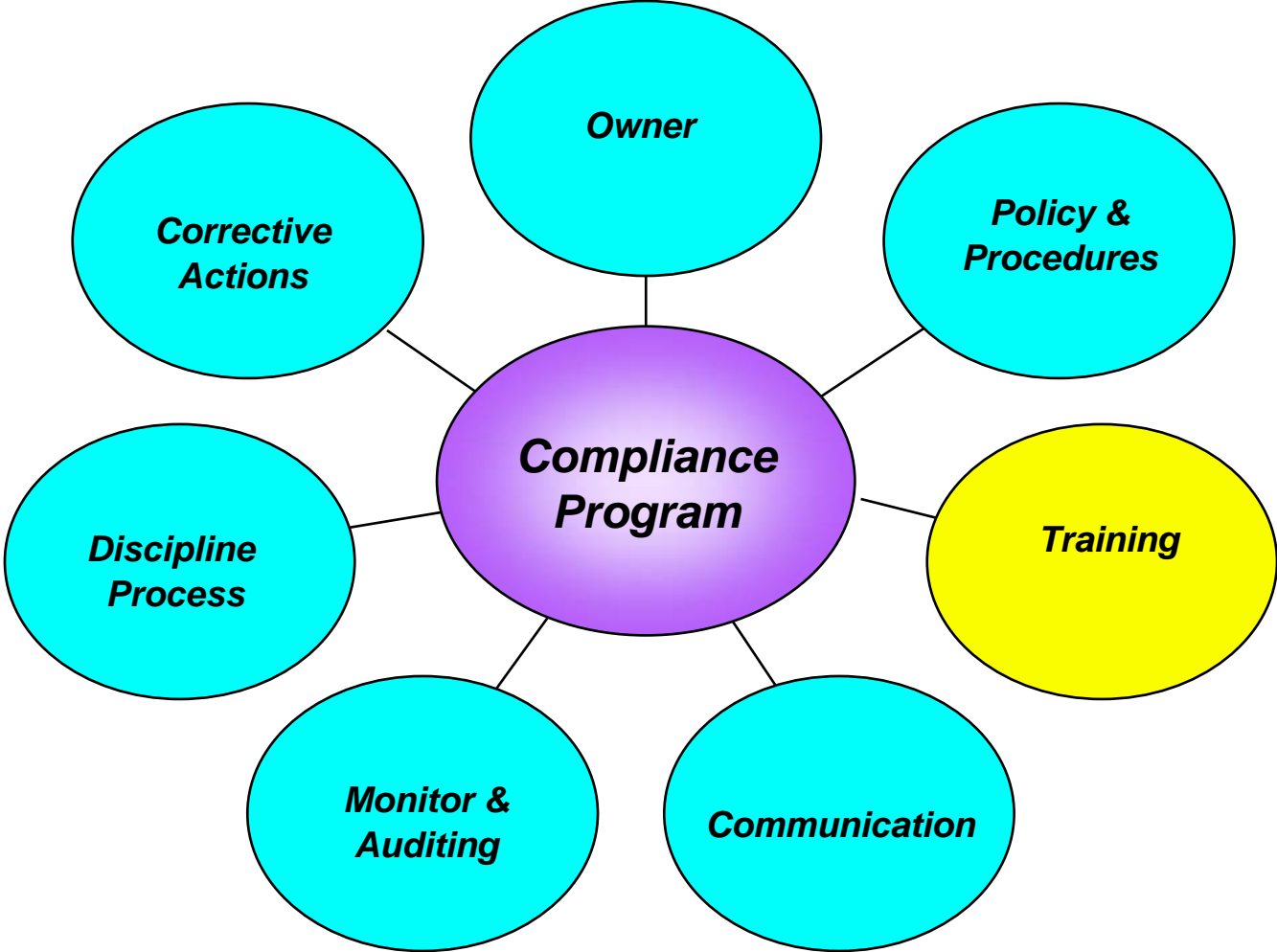
# Policies and Procedures

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## Company Code of Conduct

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

# Seven Elements of a Compliance Program



# Training

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

Typical annual CIA training requirements

- 1 hour of General training
- 3 hours of Specific training

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

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## Use adult learning principles

- Tell them, and tell them the WIFM
- Practical Scenarios
- Use a range of training formats
  - Self-study
    - Read the Policies and Procedures
    - Computer-Based
  - Group
    - Live sessions with a trainer
    - Video or DVD presentation with group discussion

## Explain the “whys” behind the rules

- Understanding “Why” fosters compliance
- Explain where policies come from (laws, regulations, codes)

# Self Study Training Development

## Computer Based Training

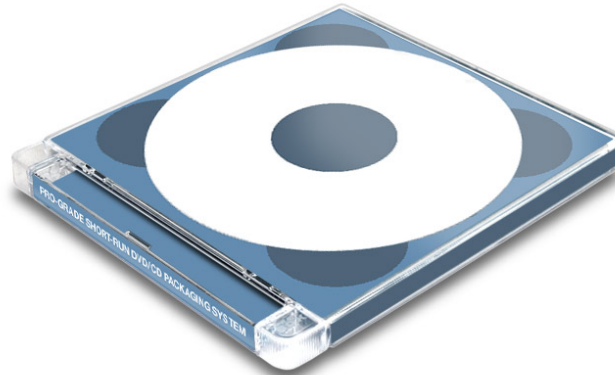
- Works well for administrative topics
  - Expense Reporting
  - Adverse Event / Product Complaint Reporting
  - Sample Accountability
- Introduction by Senior Leader
  - Tone from the Top
  - Reinforces importance of training
- Quick Checks and Scenario Challenges
  - Knowledge of policies
  - Application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

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## 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

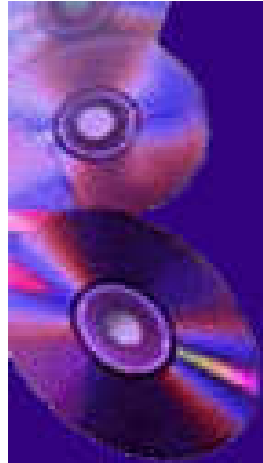
- Rep can prevent a situation before it happens by:
  - Discuss with HCP in advance
  - Refer to statement on invitation
  - Plan alternatives to evening programs (breakfast, lunch, immediately after office hours)
  - Confirm attendees with a phone call the day before the program
- Or you will have to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

### PhRMA Code:

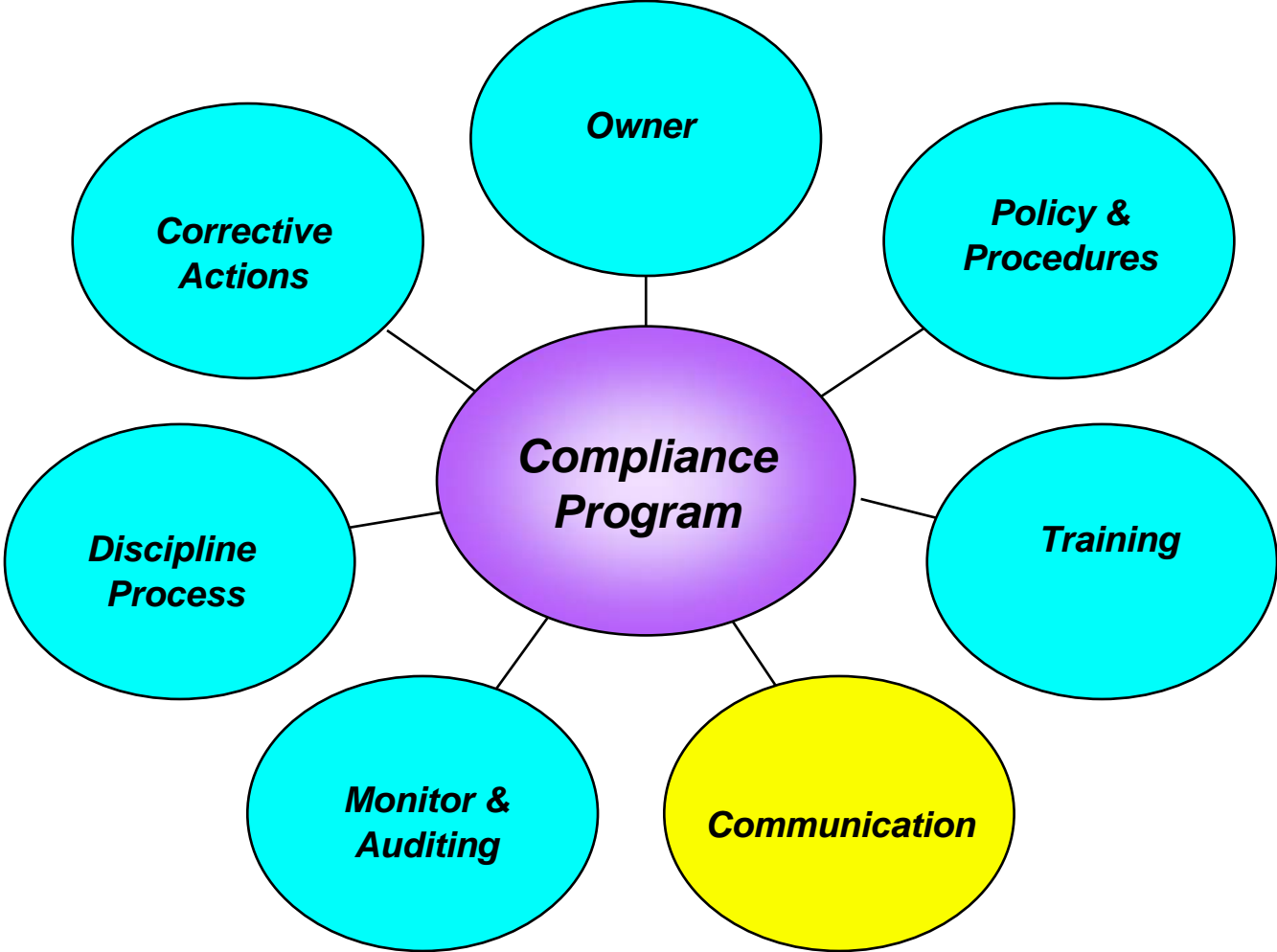
**Q:** “Under the code, may HCP’s spouse or other guest be included in a meal...if the HCP pays for the spouse or guest?”

**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

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## 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
  - Use by External parties (HCPs, consumers)
- Surveys
- Exit Interviews



# Communications

Provide resources for questions, guidance, best practices

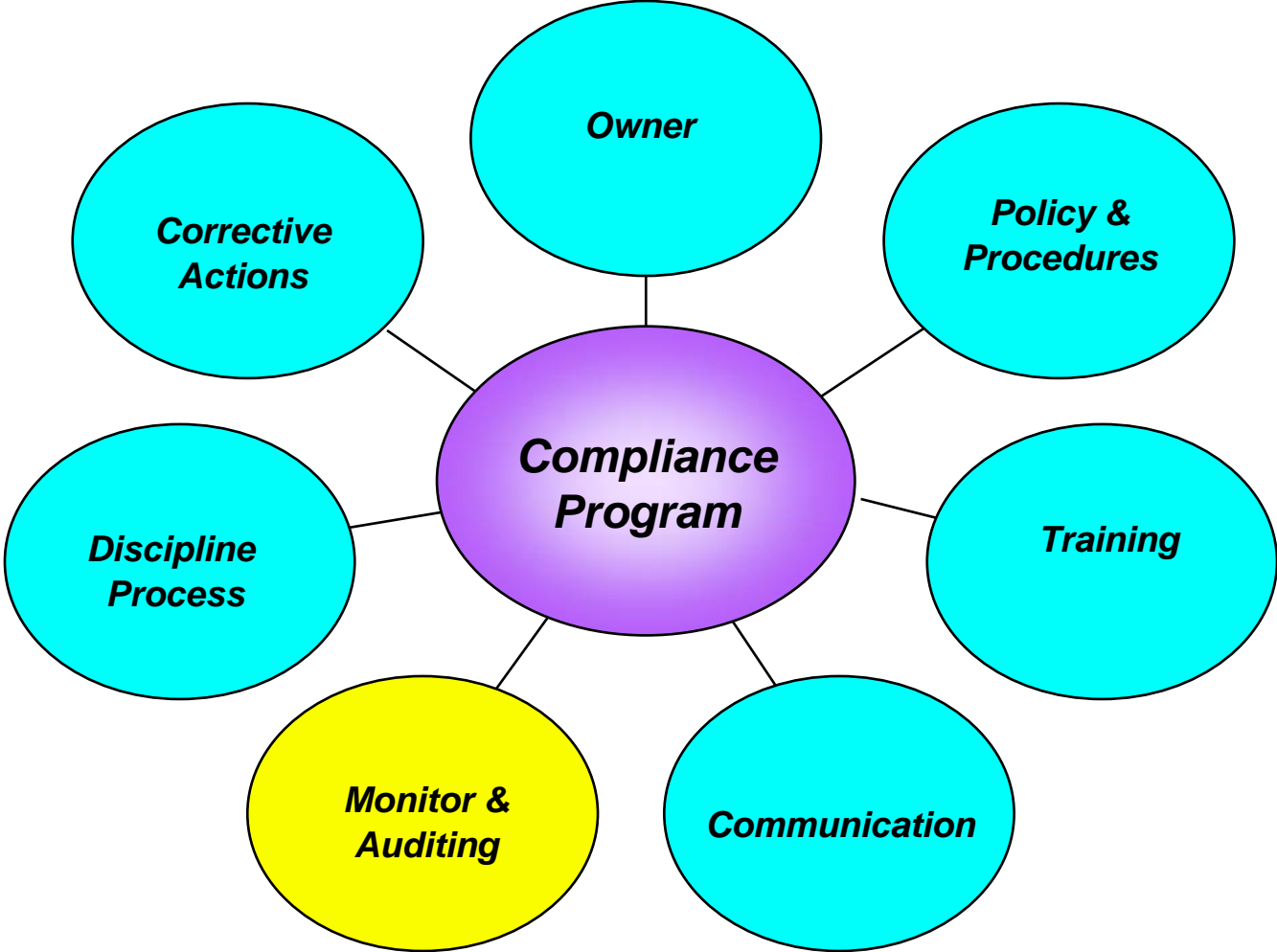
- 1-800 number to reach compliance team
- Intranet Website
- E-mail
- Conference calls
- Compliance Liaisons

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



# Seven Elements of a Compliance Program



# Monitoring vs. Auditing

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## 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**

# 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 and 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

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## 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

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## **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





# 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



# Benefits of Monitoring and Auditing

## Assure compliance with policies

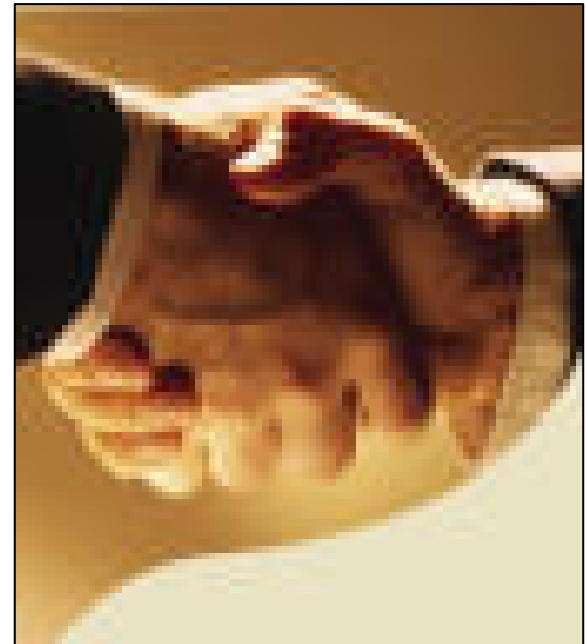
- Document that policies are being followed
- If they aren't, you want to find it and fix it yourself

## Feedback loop on effectiveness of other program elements

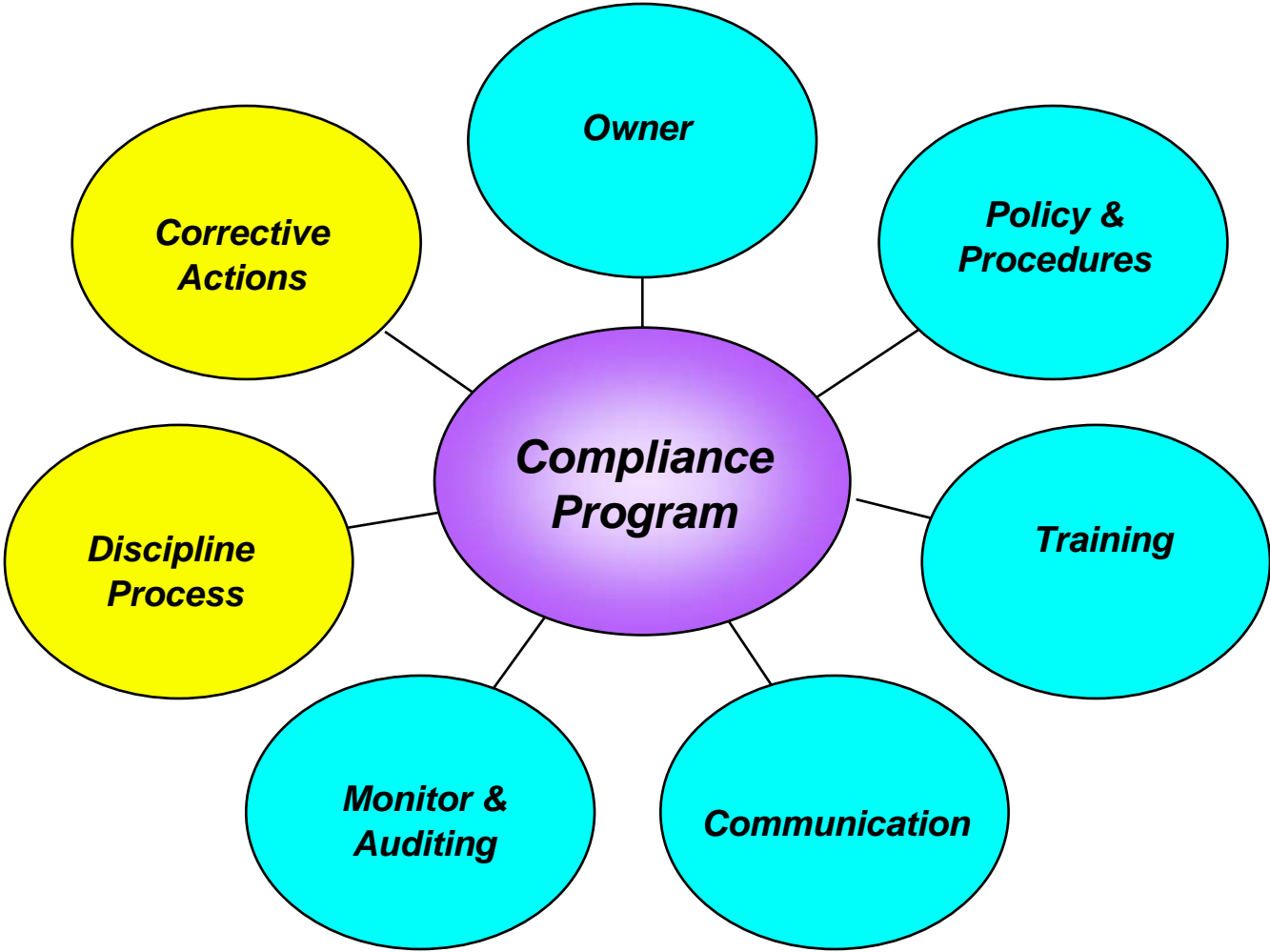
- Policy Language
- Training
- Communication programs

## 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



# Seven Elements of a Compliance Program



# Disciplinary Process

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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 Action

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“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?

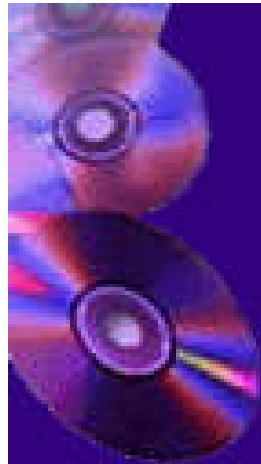
# CONCLUDING THOUGHTS

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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

