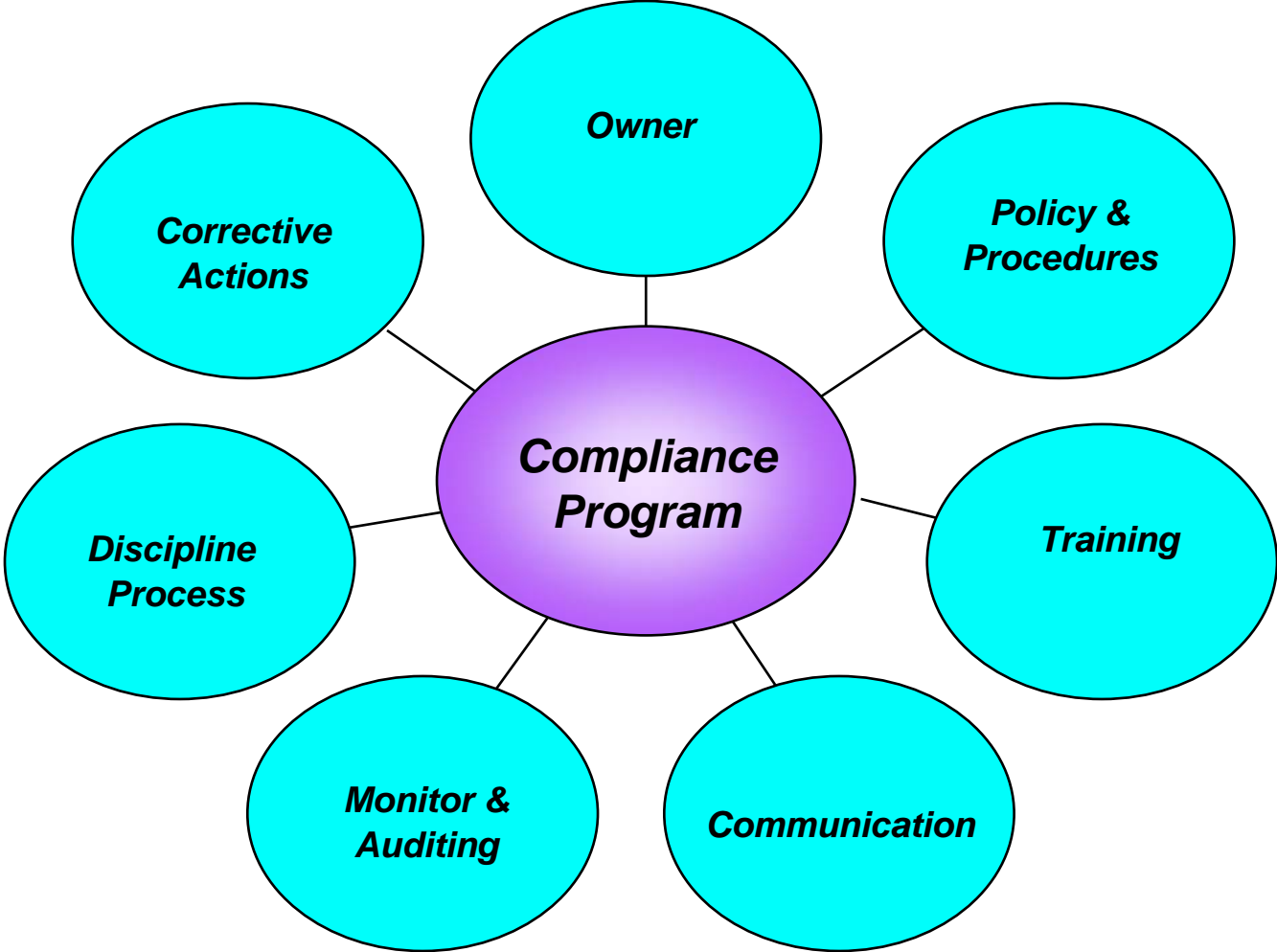
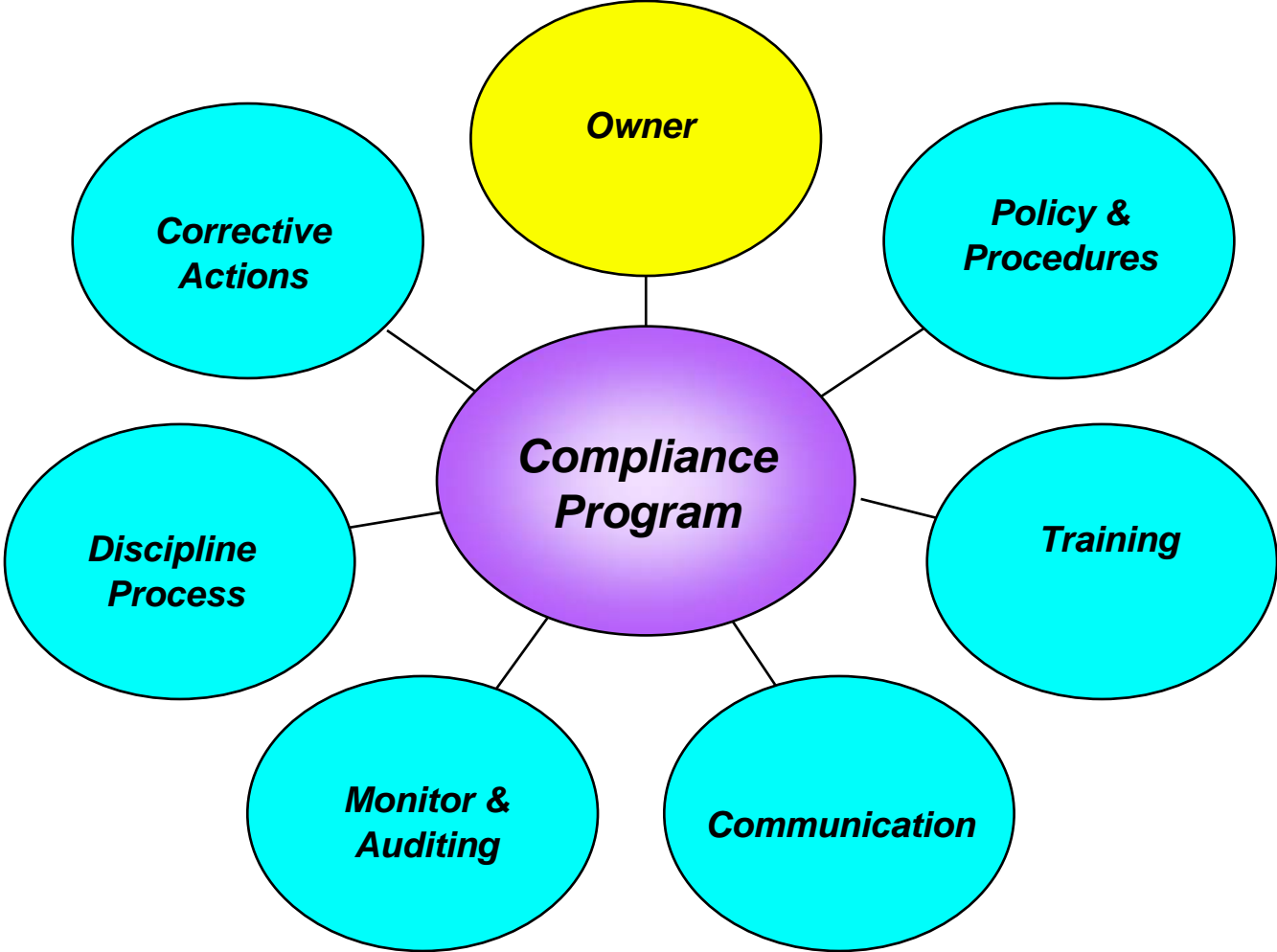

Considerations for Developing an Effective Compliance Program for Pharmaceutical Sales and Marketing Personnel

**Kelly B. Freeman, Ph.D.
Director, US Affiliate, Compliance and Ethics
Eli Lilly and Company**

Seven Elements of a Compliance Program



Seven Elements of a Compliance Program



Owner

A designated Compliance Officer

- Senior level with access to President or CEO, Board, and Legal Counsel

And a Business “Owner”

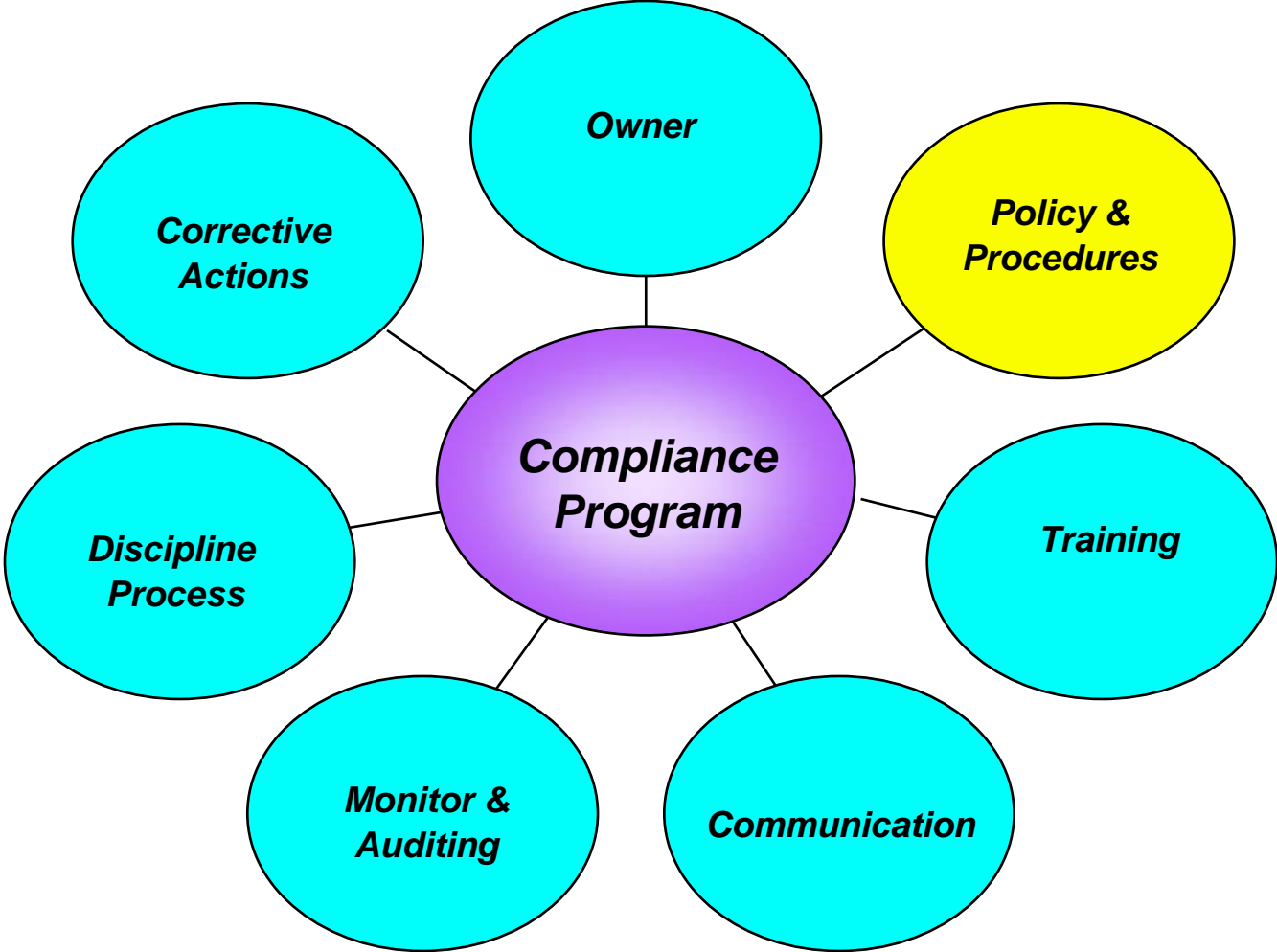
- Supports the Compliance Officer
- Provides adequate resources
- Sets the tone



Success of the program depends on the “Tone at the Top”

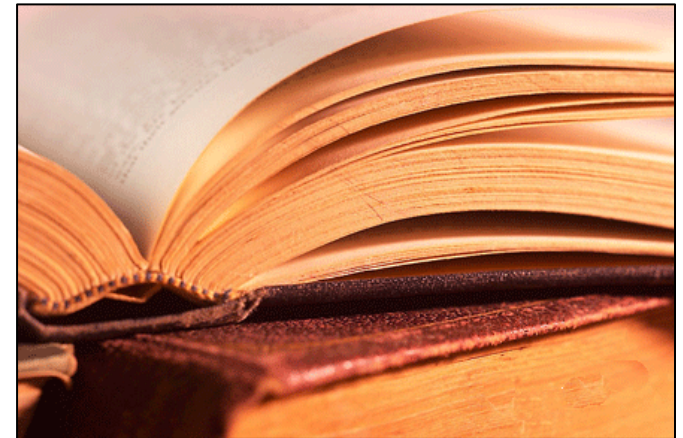
- Integrity
- Consistent, Frequent Demonstration of Senior Leadership Commitment
- Walks the Talk

Seven Elements of a Compliance Program



Pharmaceutical Sales and Marketing Compliance

- Federal Food Drug and Cosmetic Act
- Federal Healthcare Program Laws
- Anti-Kickback Laws
- Prescription Drug Marketing Act
- FDA Regulations
- OIG Compliance Guidance
- State Laws and Regulations
- PhRMA, IFPMA, and AMA Codes
- Consent Decrees and Corporate Integrity Agreements



Policies and Procedures

Company Code of Conduct

- Many companies are posted on the web
- Departmental Policies and Procedures
 - Policies are the What's and Procedures are the How's
 - Cover all key business areas and legal/ regulatory risks
 - Wherever possible, translate legalese into everyday language
 - Order procedural steps in sequence

Sales and Marketing Topic Areas for Policies and Procedures

Promotional Materials

Speaker Programs

Business Meals

Educational and Practice-Related Items (EPRIs)

Samples

Exhibits

Medical Information

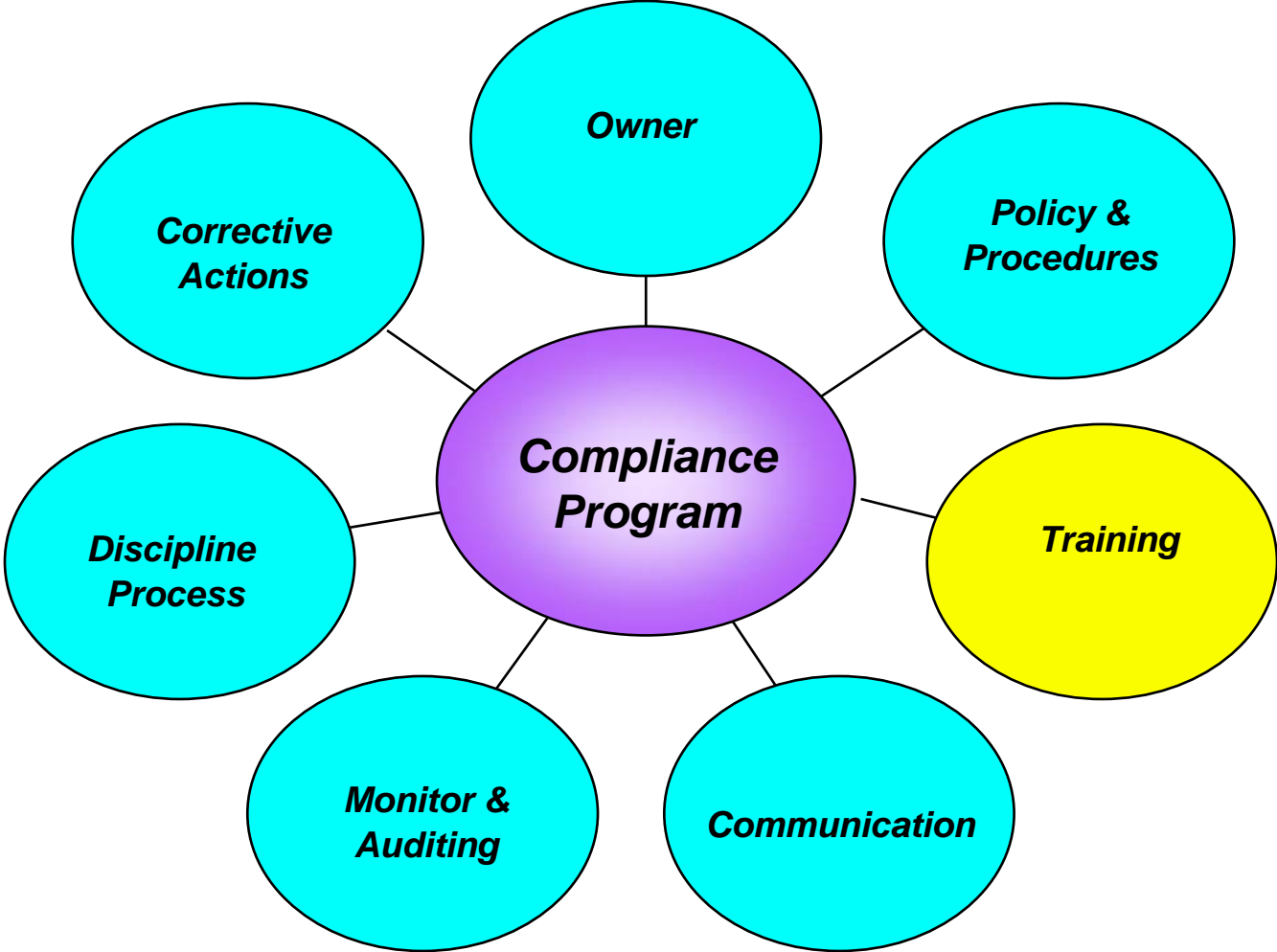
Grants and Charitable Contributions

Consultant Services and Market Research

Contracts and Rebates

Privacy

Seven Elements of a Compliance Program



Training

More than just “checking the box”

- Impact and Retention

It's about the Learner's needs

- Learning styles
- Engaging

Reinforcing good behaviors
or implementing new ones

- How long does it take to develop a new habit?



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

Use adult learning principles

- Tell them, and tell them the WIFM
- Let them practice
 - Active participation fosters competency
- Separate material into manageable chunks

Content development

- Include people with marketing and sales experience as well as compliance, legal and regulatory
- Translate policy from “legal-ese” to marketing and sales language
 - Training should help with policy interpretation
 - Teach how to find the answers in the policies
- When using off-the-shelf solutions, consider the Learner and company’s culture

Explain the “whys” behind the rules

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

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

Self Study Training Development

Computer Based Training

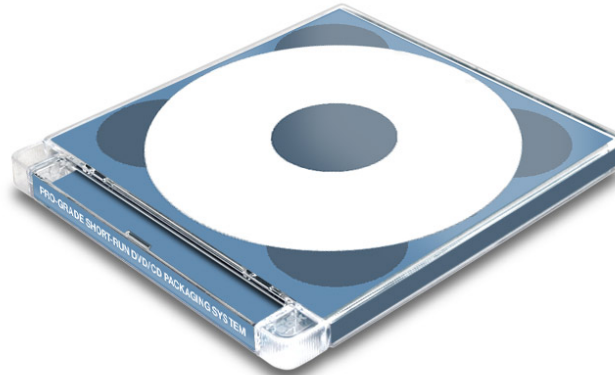
- Work well for administrative topics
 - Sample Accountability
 - Expense Reporting
 - Adverse Event / Product Complaint Reporting
- Quick Checks and Scenario Challenges
 - Knowledge of policies
 - Application of policies



Individualized Training

- Situations not applicable to entire audience (e.g., state requirements)
- Situations occurring rarely (“On time” training)
- Need to know vs. “nice to know” 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 process

- New employee orientation and new rep sales schools
- Ongoing training
 - Live training at meetings such as brand team or sales meetings
 - Spread out over the year - not crammed into one day a year
- Manager training
 - Must have understanding and “buy in” from the top down
 - Develop specific training applicable to managers
- Incorporate Compliance into other trainings (disease state, selling skills) to reinforce learning

DVD Scenario Training Development

Model appropriate responses to the tough situations

- Practice- just like message practice
- Create realistic scenarios to assist with understanding
- Use “actors” that the learner recognizes
- Cater training to audience background & education level

Include introductions from Senior Leadership

- Tone from the Top
- Reinforces importance of training
- Puts names and faces together
- Makes large companies seem personable

PhRMA Code Example

Issue:

Spouses or guests attending meals or presentations by a pharmaceutical company

Question:

Under the code may a Healthcare Professional's (HCP) spouse or other guest be included in a meal, if the HCP pays?

Answer:

No, A spouse or guest is not appropriate regardless of who pays unless they are an HCP for whom the information is appropriate.



Voluntary PhRMA Code became law in California 7/1/05

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 Lilly 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

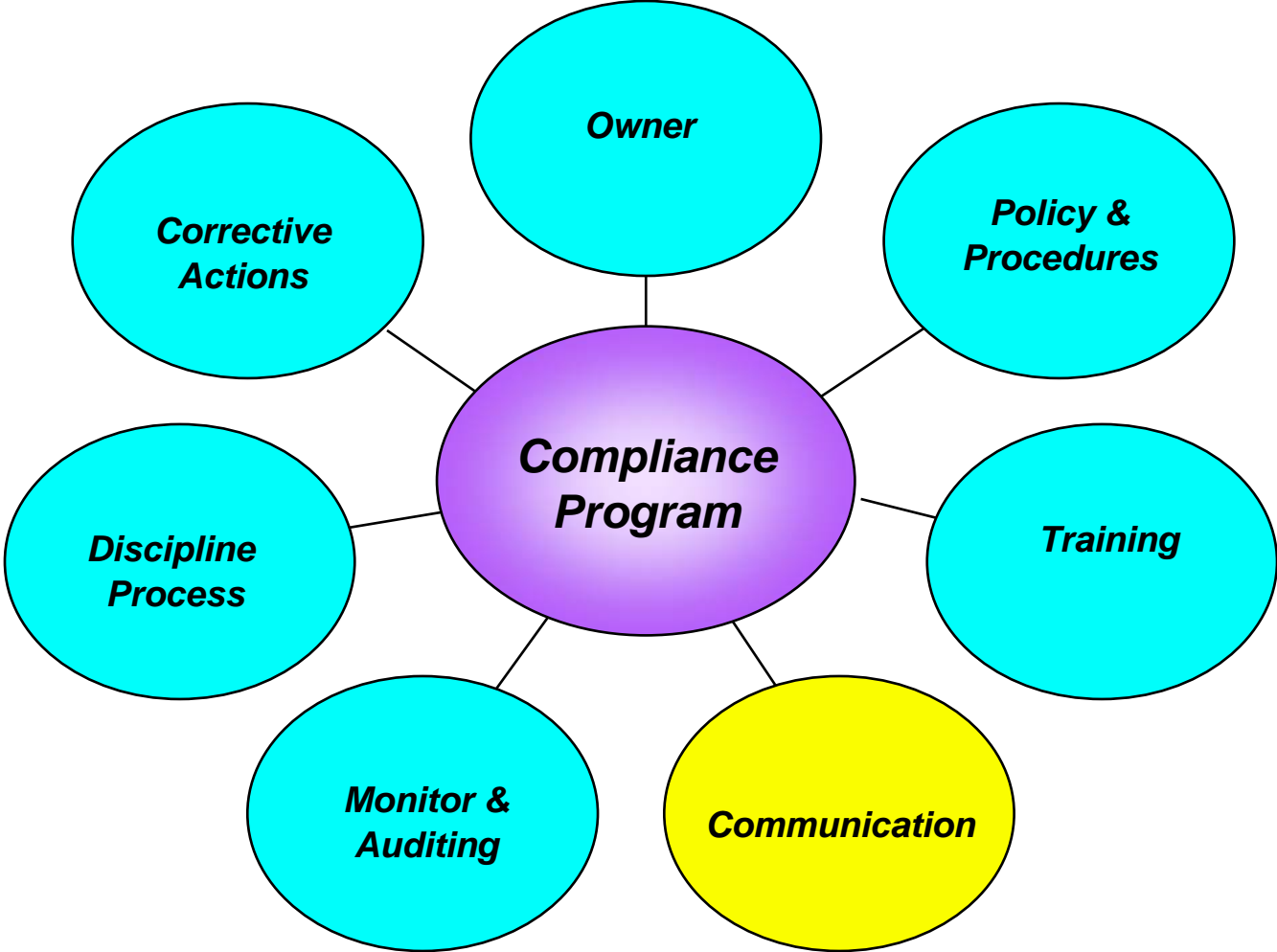


Testing and Tracking Completion

Validate Training and Testing

- Use trainers, education experts, and/or sales and marketing personnel to review training
- Validated tests
 - Align questions to training objectives & desired behaviors
 - Develop a pool of rotating questions
 - Allow for feedback loop to give correct answers for any missed questions
- Track completion
 - Hold management accountable for their employees completion

Seven Elements of a Compliance Program



Communications

Provide resources for questions and guidance

- 1-800 number to reach compliance team
- Intranet Database / Website
- E-mail
- Conference calls
- Field Compliance Experts: Field Managers, Trainers, Senior Reps

Create opportunities for dialogue

- Attend meetings
 - Stay for breaks and meals
- Attend trainings
- Routinely schedule Rides with Reps

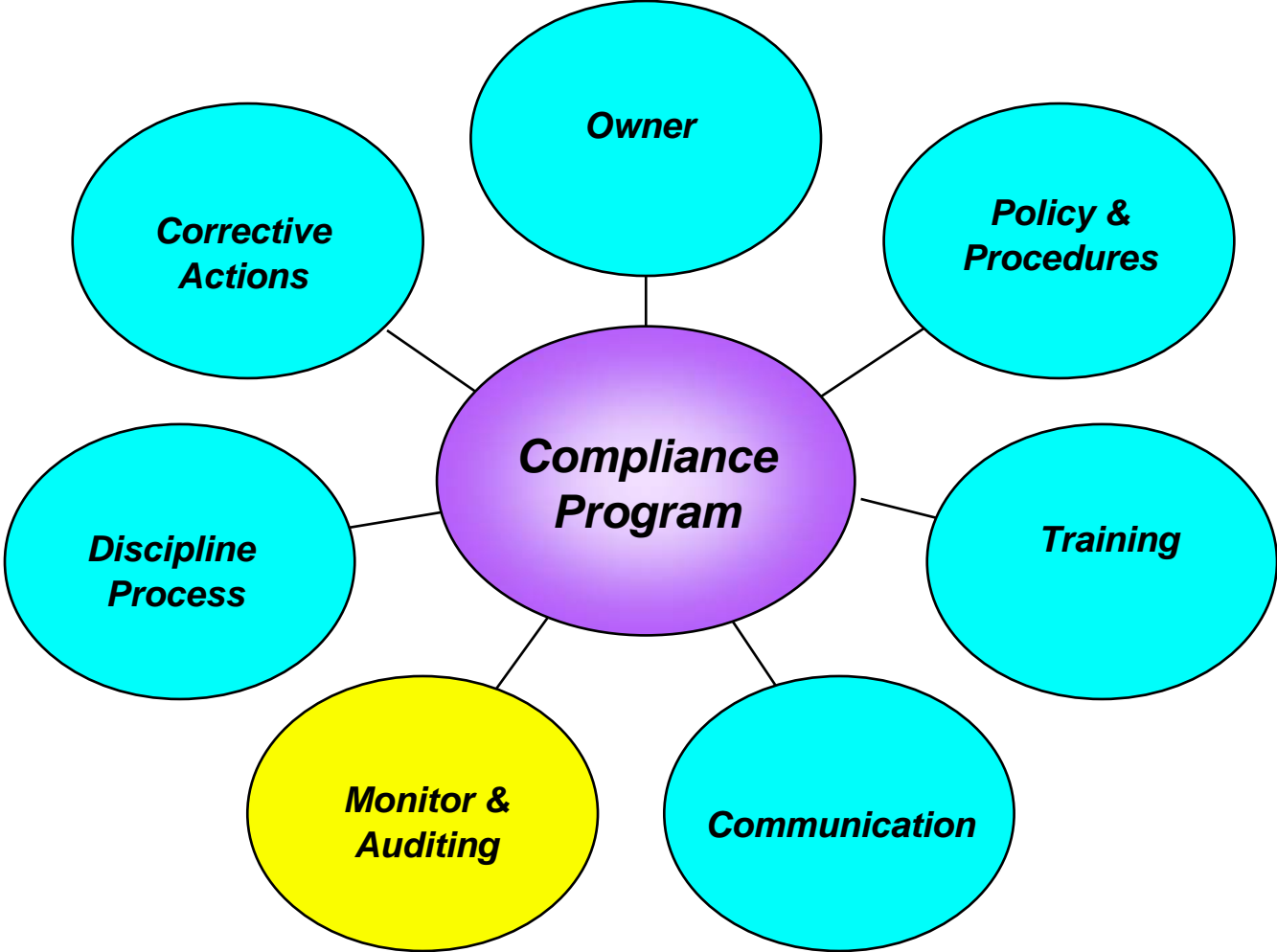


Communications

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
- Surveys
- Exit Interviews

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

Sales and Marketing Monitoring Plan

Areas covered

- Sales school programs
- Rep ride-alongs
- Speaker Training
- Speaker Programs
- Sales/Brand Meetings
- District reviews (GBPs)
- Exhibits
- Advisory Boards



Sample size determined by statistical analysis

- Annual target based on volume of business activities
- Weighting across areas based upon perceived risk
- Assure coverage across business units and brands

Monitoring Process

Protocols and checklists directly from policies

- “Open book” test

Random selection of events and unpredictable notification

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

Randomly 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



Good Business Practice Review (GBP)

In-depth review of a sales district's adherence to policies

Pre-work Review

Expense reports, sample accountability, performance management documents, field visit or call notes, action plans, district expenses, speaker program database, compliance training records, violation log

On-site

Ride with one representative
Meet with district manager
and review information

Post-work

DM investigation and corrective
action on any findings
Final report issued to Area Director
and Business Unit Leader



Speaker Training

Observations

- Venue
- Educational or Practice-related Items
- Business Meal policies
- Appropriate Attendees
- Coaching on handling unsolicited questions
- Presentation
 - Were all mandatory slides presented
 - Were Compliance materials presented
- Contracts and Expenses



Opportunity to Explain the Benefits of a Compliance Program

Speaker Programs

Observations

- Invitations
- Venue
- Business Meal policies
- Appropriate Attendees
- Presentation
 - 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



Congresses/Exhibits

Observations

- Interactions with customers
- Adverse event and product complaint reporting
- Promotional materials
- Educational or Practice-related Items
- Proper handling of questions

Opportunities

- Observe many sales force interactions during short time frame
- Interact with Brand team organizers
- Observe Medical information interactions



Monitoring Results

Provide on-going Dashboard metrics for Business units

Integrate Partnership with the Business

Compile annual monitoring results for Senior Management Reviews

Look for trends and patterns and use as feedback loop for training and policy adjustment

Findings may identify need for in-depth audit



Auditing Program

Annual plan

- By geography, business unit, and/or functional area
- Define the population and sampling approach

For-cause audits

- Need could be identified from monitoring results, hotline report, or management request

Sales and Marketing audits have some aspects unique from traditional financial auditing

- Intent, content, and context of activities are as important as following standard procedures

Benefits of Monitoring and Auditing

Assure compliance with policies

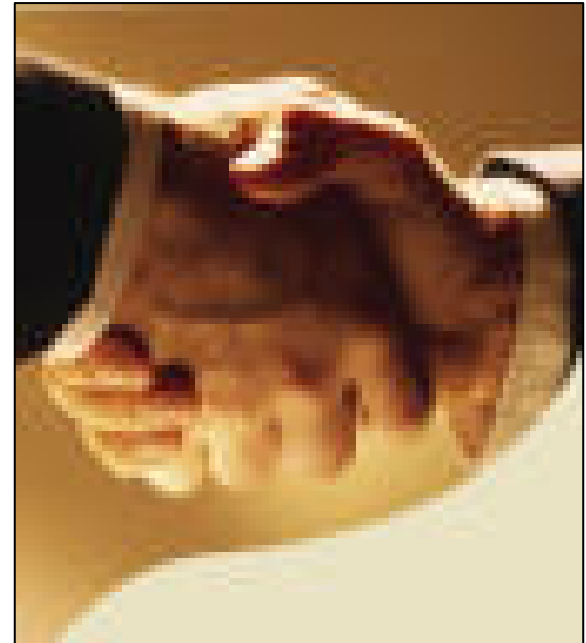
- Document that policies are being followed
- If they aren't, you want to find it and fix it yourself

Feedback loop on effectiveness of other program elements

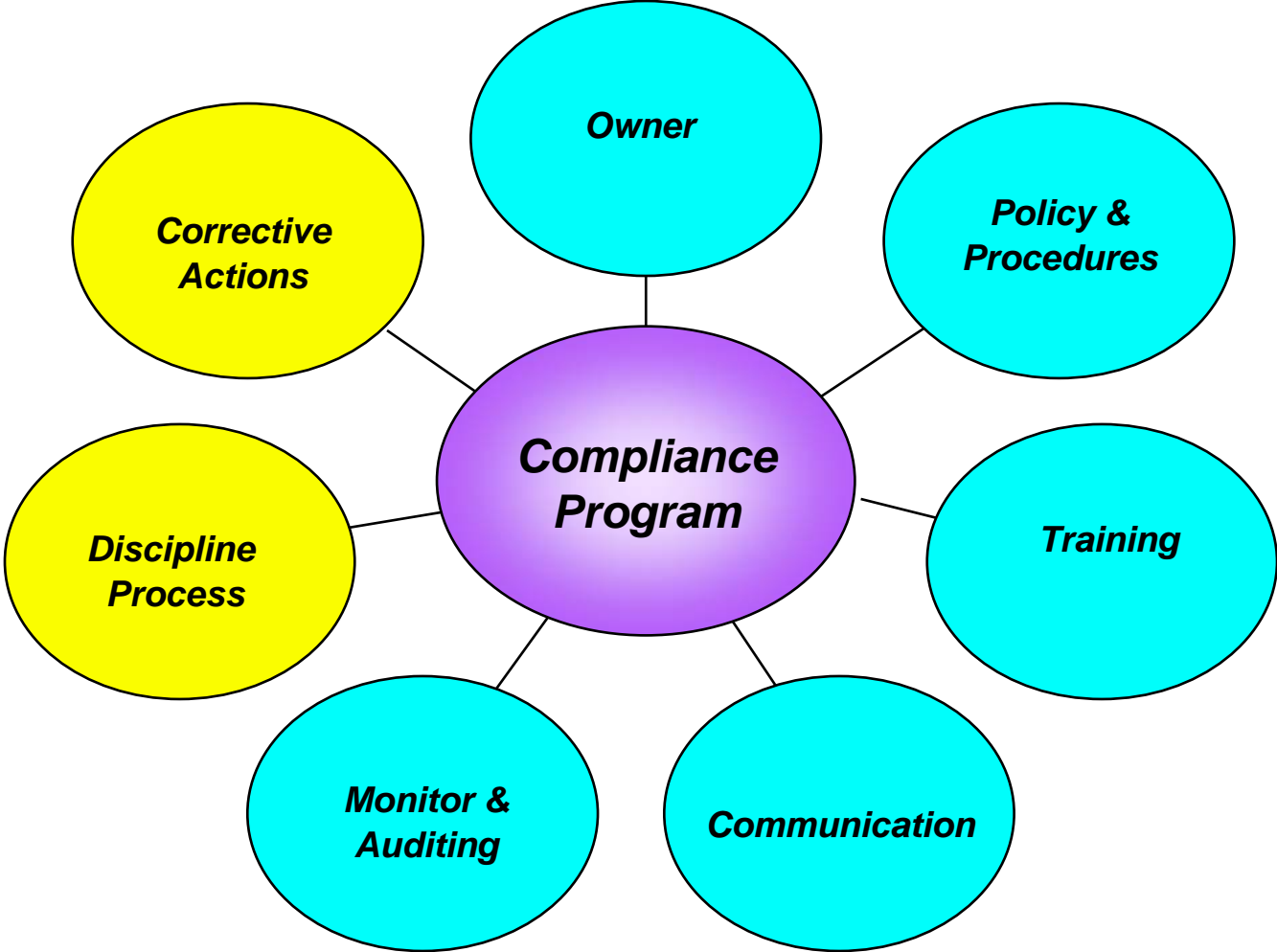
- Policy Language
- Training
- Communication programs

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

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

Consequences for management failure to detect

Role of Human Resources and Line Management

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

Corrective Action

“Learn and Grow”

Does it require reporting to the government or law enforcement?

Do you understand the root cause?

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

Questions

