



# Compliance Program

LifeScience Alley  
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# Basic Elements

- Compliance Program / Code of Conduct
  - Per Guidance Documents available
- Policy Document:
  - “Guideline on Interactions with  
US Healthcare Professionals”
- Standard Operating Procedures



# Our experience: Policy

- Policy Document
  - Guidelines on Interactions with US Healthcare Professionals
  - Document provides scope & overview
    - Education & training
    - Sales force confirms understanding with signed acknowledgement



# Our experience: SOPs

- Policy document provided roadmap
- Standard Operating Procedures
  - Company Representatives in the OR
  - Physician Training
  - CME Programs
  - Off-Label Information
  - Physician Consultant Agreements
  - Research Grants
  - Promotional Materials



# Audit and review

- Policy documents & SOPs
- Employee training content
  - Recent internal audit: gap analysis
- State requirements
  - Web site declaration (CA)
- Guidance documents



# Compliance Program: Our next steps

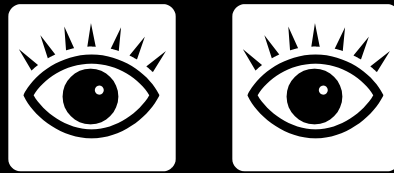
- Addition of a formal overview document
  - “7 Basic Elements”
    - Board of Directors involvement
    - Forming internal compliance committee



# Compliance Program: Our next steps

- Internal compliance committee
  - Medical Affairs, Legal, Education, Logistics
    - Broader input and perspective
  - Increased visibility within the organization
  - Increased communications to sales force
- Enhance training & feedback

# What keeps you up at night?





# Compliance Program: Potential benefits

- Build on the positives
- Strengthen the documentation package
- Enhance our ability to respond to potential issues
- Additional protection for the company
  - Take credit for things done well



Thank you!