



# Twelfth Annual Pharmaceutical Regulatory and Compliance and Best Practices Forum

Preconference II: Practical Approaches to Implementing an Aggregate Spend Program

## **Audit Ready for Sunshine?**

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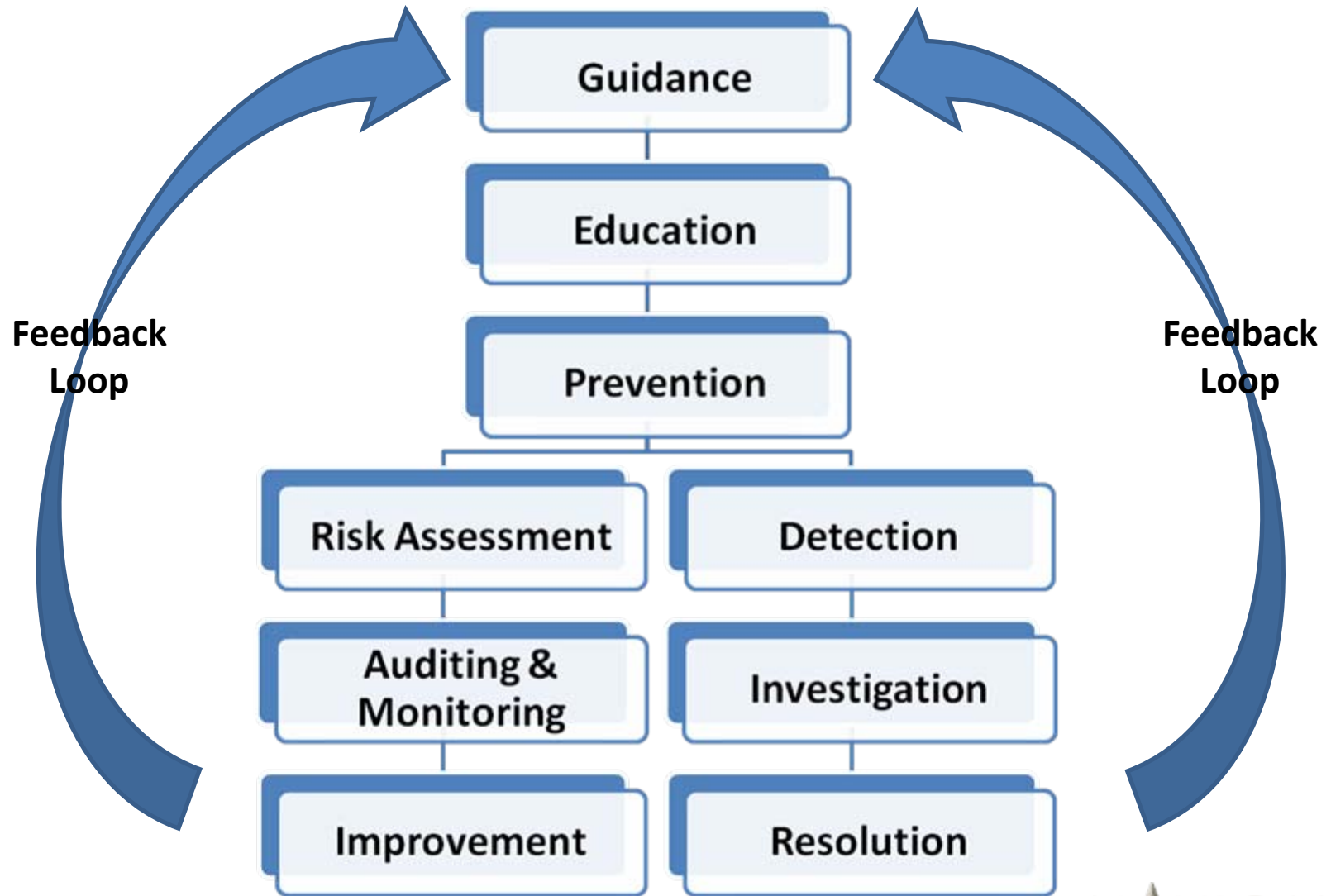
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# Audit Readiness

# External Expectations: Compliance Effectiveness



# What is Audit Readiness?

*The ability to effectively communicate a comprehensive understanding of the appropriate compliance issues, company compliance infrastructure, and historical and prospective compliance actions to an outside entity.*

# Why is Audit Readiness Important?

- Short time in the face of an external inquiry to demonstrate compliance competency.
- Single most important factor in expedient abatement and risk management associated with external inquiry.
- Your first opportunity to educate the potentially uneducated about the issue, and your control and accountability measures, before (too much) bias and skepticism set in.

# What are the Triggers of an Inquiry?

- Trending
- Targeting
- Whistleblower
- Office, Regional, National initiative
- Suspicion by association
- “Sunshine”

# Panel Questions/Discussion

# Big Questions (i.e., rhetorical)

- Will your organization be ready in late 2013 to respond quickly and effectively to a Sunshine-related Inquiry?
- Will you be able to demonstrate an effective program – i.e., one that can justify that the money spent on HCPs was for legitimate business needs?
- Are you thinking about these questions now as you build/enhance your program?



# Panel-Specific Questions

- Policies and SOPs
  - How aligned are your actual processes to your documented processes throughout your various HCP arrangements?
  - What can be done efficiently to test these questions?

# Panel-Specific Questions

## ➤ Training and Education

- Is your company leaving evidence indicative of an effective training program – i.e., educating the right people in your organization at the right time with relevant policies and SOPs?
- How are you making sure these questions are being addressed as you implement?

# Panel-Specific Questions

- Control and Accountability
  - Will relevant justifications (e.g., needs assessment, rationale forms, etc.) related to different types of spend be easily accessible?
  - Will history of contract and payment approvals demonstrate checks and balances (e.g., committee approvals, monitoring of individual approvals or other controls)?
  - Will you have evidence that services were in fact provided in relevant HCP arrangements? (e.g., work activity reports)

# Panel-Specific Questions

- Evidence: Document Accessibility
  - Are policies and SOPs related to 'HCP spend' documented and archived consistently?
  - Will both training records and training materials be easily accessible?
  - Does your document management system allow you to query, sort and retrieve on demand?
  - Have you tested this?

# Closing Thoughts

# The Importance of Auditability

*The single most influential factor in mitigating negative outcomes associated with an external review, audit or inquiry is the integrity, timeliness and auditability of the information put before them.*

# The Best Defense is a Good Offense

- Binders, binders, binders (even if they're dusty!)
- Demonstrated Executive involvement and commitment of resources, time and focus
- Justification and explanation of spend!
- Proactive risk identification process that drives consistent auditing and monitoring program
- Company execution of baseline performance improvement measurement

# Considerations to Help Prove Effectiveness

