



HCCA Research Compliance Conference

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Auditing and Monitoring



Lynda Hilliard
Michelle Anderson
Deloitte & Touche, LLP
Life Sciences & Healthcare Regulatory Practice

Objectives

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By the conclusion of this session, the participant will be able to describe the regulatory basis for establishing an audit and monitoring program

Outline a business case for a viable audit and monitoring program

Describe the necessary elements for an effective audit and monitoring program, including:

- Audit content considerations for sponsor organizations
 - Scope development
 - Sampling techniques
 - Reporting
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What Are The Major Regulatory Factors Impacting Clinical Research Studies?



Life Sciences and Health Care Organizations operate in an increasingly complex environment including...

- ✓ International regulations
- ✓ Federal and State regulations
- ✓ Enforcement body guidance and rulings
- ✓ Regulatory enforcement findings

In addition to the regulatory requirements, organizations must also understand the following...

- ✓ Contractual requirements
 - ✓ Internal company policies and standards
 - ✓ Industry Standards (FDA, the Centers for Medicare and Medicaid Services)
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What are sponsors responsible for from a regulatory perspective?

Obtaining agency approval where necessary

- IND application (investigational drugs)
- IDE application (investigational devices)

Manufacturing and labeling investigational products appropriately

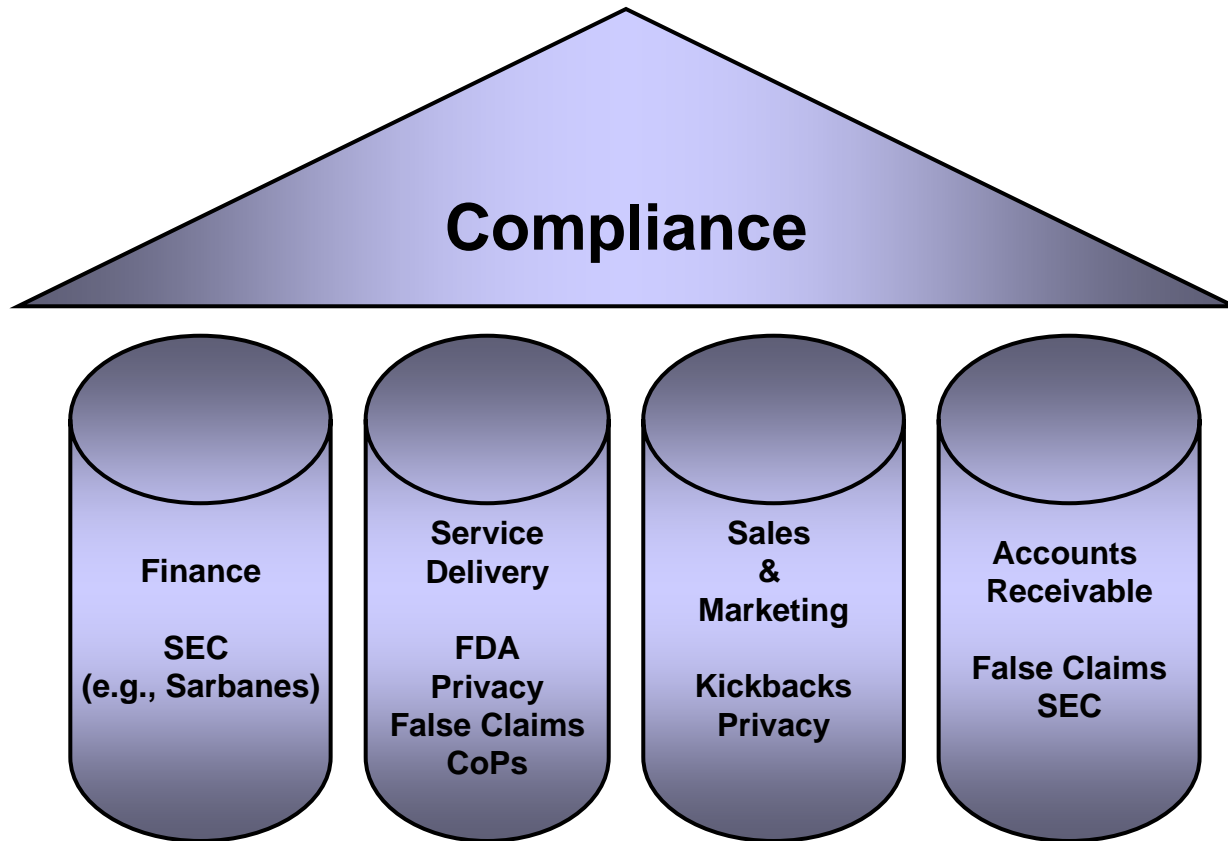
Initiating, withholding, or discontinuing clinical trials as required

Refraining from commercialization of investigational products

- Selecting qualified investigators to conduct studies
- Disseminating appropriate information to investigators
- Selecting qualified persons to monitor the conduct of studies
- Adequately monitoring clinical investigations
- Evaluating and reporting adverse experiences
- Maintaining adequate study records
- Submitting progress reports and the final study results

Foundational Concepts Traditional Model

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Quality, compliance and business risks managed in silos: Many regulatory components, some repetitive, some conflicting

“Although many monitoring techniques are available, one effective tool to promote and ensure compliance is the performance of . . . compliance audits by internal or external auditors who have experience on federal and state health care statutes, regulations and federal health care programs.”

HHS Office of Inspector General

Why develop an organization-wide compliance strategy:
Proactive vs. Reactive?

Being Proactive

Develop a process to efficiently and effectively manage risk for the organization
Ability to expand on business opportunities (e.g., product development or management)
Achieving a market leadership position

Being Reactive

- ✓ Inconsistent application across the organization
- ✓ Potential individual civil / criminal liabilities
- ✓ Reputation risk
- ✓ Restriction of business operations imposed by regulators

The Business Case for a Strong Internal Control Program

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Upside

Make better business decisions with higher quality, more timely information

Reduce potential for fraud

Gain (or regain) investor trust

Prevent loss of resources

Comply with laws and regulations

The Downside

- SEC sanctions
 - Unfavorable publicity
 - Negative impact on shareholder value
 - Misappropriation of assets
 - Lawsuits or other legal actions
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Goals of a Comprehensive Audit and Monitoring Program

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No Big Surprises



Early Warning Systems

- Systematically identify, assess and prioritize risks
- Avoid unrewarded risks and protect assets in place
- Promote organizational learning
- Reduce chance of repeat problems

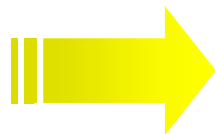
Mitigated Infrastructure

Ensure bad news travels fast internally first – early warning systems
Prevent and rapidly respond to potential catastrophic failures
Improve ability to anticipate and prepare for change
Establish a risk-based culture
Provide assurance that key risks and exposures are understood and mitigated



No Big Mistakes

No Big Missed Opportunities



Comprehensive Policies & Procedures

- ◆ Seek growth but ensure strategic and tactical risks are mitigated
- ◆ Maximize chances of success of achieving business plan goals
- ◆ Accelerate ability to respond to change and opportunities
- ◆ Install an appropriate control infrastructure

Auditing & Monitoring Process



Integrating Compliance into Operations

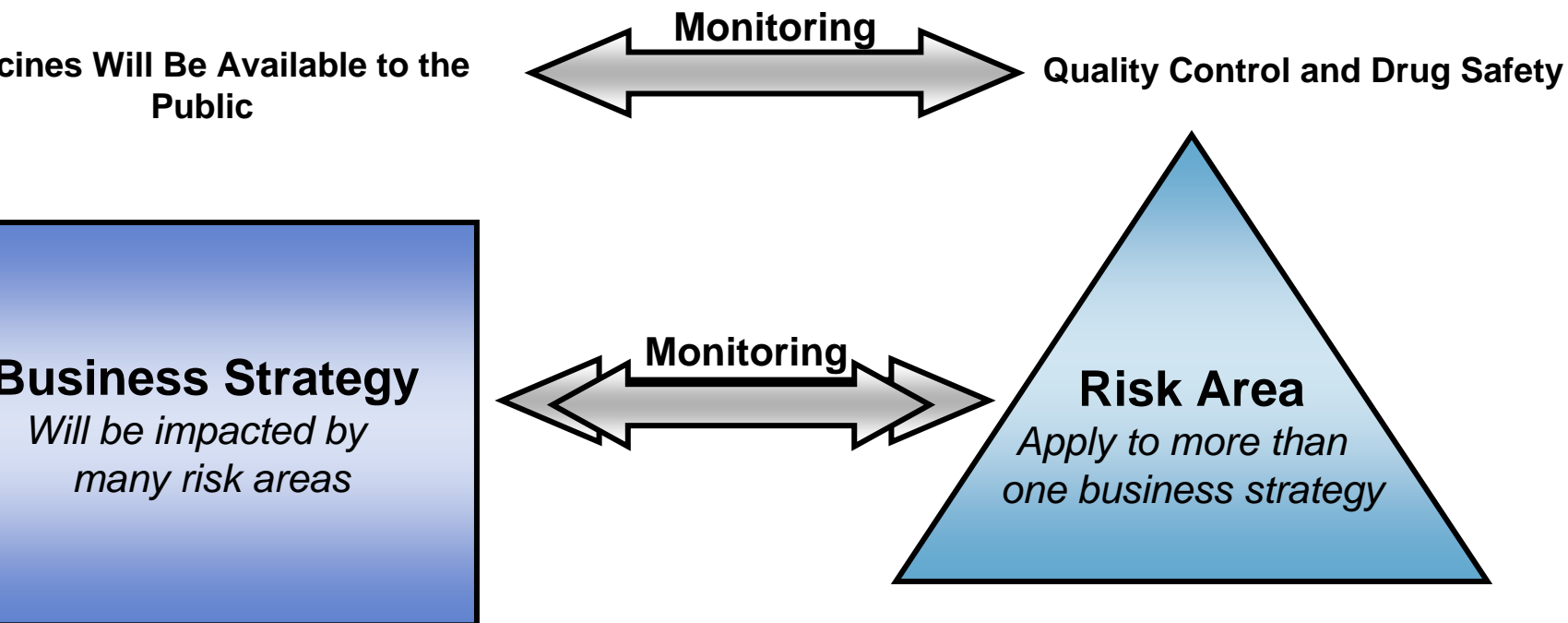


Methodologies: Create a Compliance "Cross Walk"

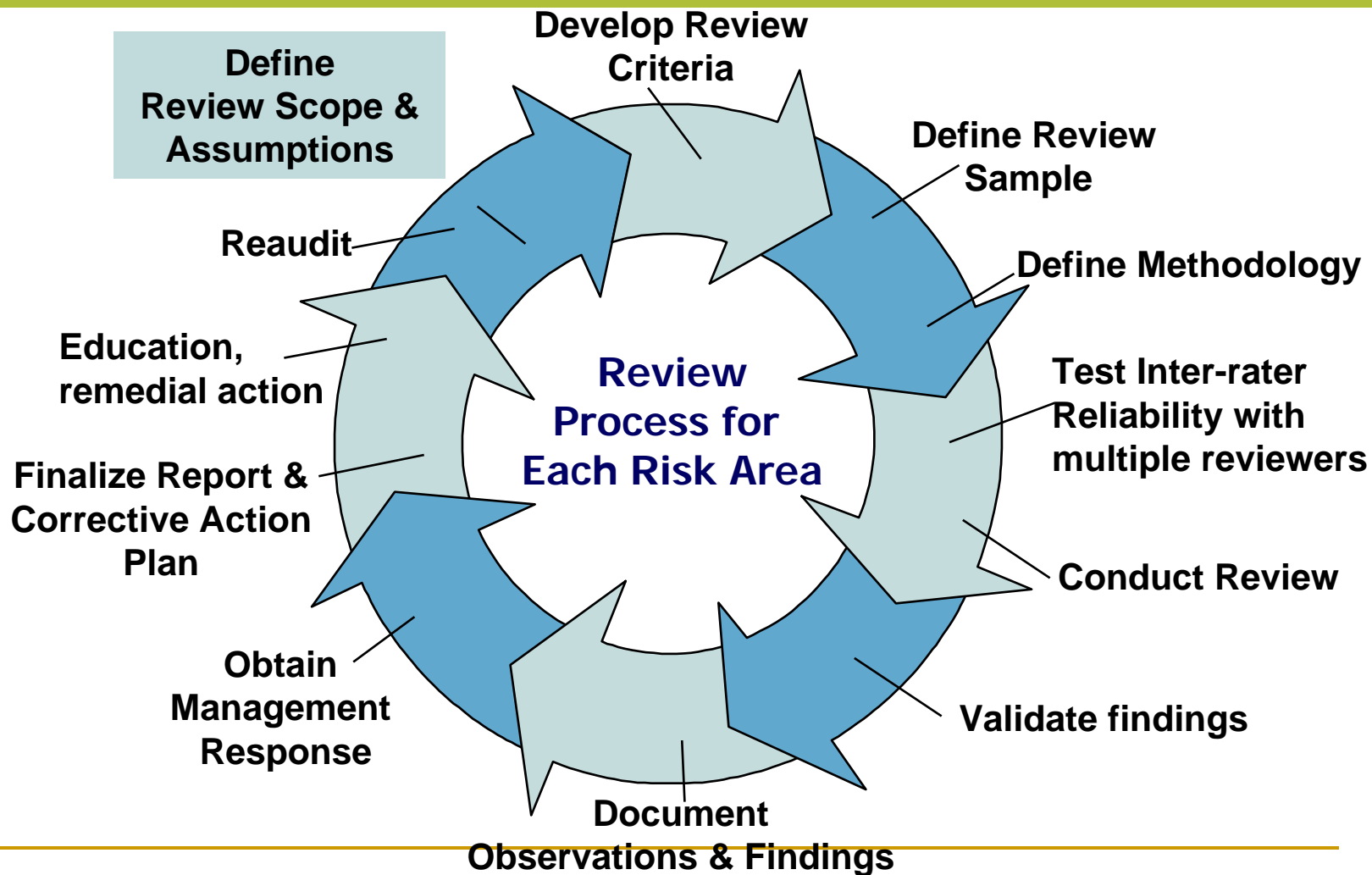


**Monitoring Plan Should Be Designed With The Compliance Program
Dilemma In Mind.**

**Monitoring Creates The Crosswalk Between The Business
Strategies And The Risk Areas**



Auditing and Monitoring Cycle



potential Audit Topics



Regulatory compliance

- IRB approval of protocol, informed consent
- 1572's
- Conflict of Interest
- Required training completion
- Communications between sponsor, IRB, investigator

Recruitment activities

- Study Participant records
 - Eligibility
 - Consent
 - Treatment
 - Adverse Events
 - Response
 - HIPAA related privacy
 - Permissible uses and disclosures
 - Elements of a valid authorization
-

potential Audit Topics



Study protocol compliance

Study drug or device

- Inventory controls
- Storing
- Compounding
- Dispensing

Adverse events or complications

- Response
 - Data management
 - Case report forms
 - Data integrity, quality control
 - HIPAA related Security
 - Billing Issues
 - Accounting
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Stark Law—General Rule

- ❑ If physician-investigator makes referrals to facility for designated health services (“DHS”), financial relationship must comply with Stark exception
- ❑ Failure to comply means DHS referrals are prohibited; facility can’t bill Medicare/Medicaid for services provided pursuant to prohibited referral
- ❑ Civil monetary penalties, possible False Claims Act liability

Primary exceptions for arrangements involving payments to investigators

- ❑ Bona fide employment relationships
- ❑ Personal service arrangements
- ❑ Fair market value compensation

Other potential financial relationships

- ❑ Rental of office space or equipment to investigator
 - ❑ Provision of staff or support services to investigator
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Focus Area: Stark Law (continued)



Compliance Tips

Identify all financial relationships between sponsor and investigator

Review terms of each financial relationship (as reflected in a written agreement, where required) for compliance with a Stark exception

Review payments to investigators to confirm they are consistent with the terms of the Stark-compliant agreements

Promptly fix any arrangements that have fallen out of compliance with Stark (or that didn't comply in the first place)

- New Stark II, Phase II regulations have exception for temporary noncompliance
 - Must have been in compliance for 180 days
 - Noncompliance not within entity's control
 - Relationship doesn't violate anti-kickback statute; bill/claim complies with all other laws/regulations
 - Only applies for first 90 days after noncompliance starts; can only use once every three years for a particular investigator
 - If exception isn't available, don't submit claims during period of noncompliance
-

Focus Area: Anti-Kickback Statute **Deloitte.**

Prohibits, among other things, soliciting, receiving, offering or paying any remuneration in return for referring a patient or to induce the referral of a patient to any person for any item or service for which payment may be made under a federal health care program

Safe harbors are available

- Bona fide employment relationships
- Personal services and management contracts
- Space and equipment rentals

Compliance tips

- Review all financial relationships with investigators who make or can influence referrals
 - Fit within safe harbor where possible
 - In all cases, ensure compensation paid by either party is consistent with fair market value
 - Ensure that there is no intent to induce referrals in violation of the statute
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Focus Area: Stark and Anti-Kickback Auditing



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Key Elements for Relationships

Written agreements

Signed by the parties

Fair market value compensation, set in advance

No services for payment until agreement is signed

Minimum term of one year

Compensation does not vary by value/volume of referral

Focus Areas: Stark and Anti-Kickback Contract Review



Possible Approach:

Review accounts payable ledger for all physician payments

Check for contract to support each payment

Evaluate payments for consistency with contract terms and required elements

Review time logs where appropriate

Types of contracts for possible consideration:

- Space Rentals
 - Equipment Rentals
 - Medical Director Agreements
 - Call Coverage Agreements
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Focus Area: HIPAA Privacy Rule



uses and disclosures of protected health information (PHI) for research purposes

- Written authorization

- Reviews preparatory to research

- Disclosures to the patient

- IRB or Privacy Board waiver of authorization

- Limited data set (with data use agreement)

- Public health activities (disclosures to monitors)

business associates?

OCR position: research is not a HIPAA covered function or one of the services listed in HIPAA's definition of a "business associate"

Business associate contract (BAC) not needed between covered entity and researcher

Even if use BAC, can't disclose PHI to researcher unless one of the above exceptions applies

Focus Area: Elements of PAA Authorization



- Description of information to be used or disclosed
 - Identification of person(s) authorized to make the use or disclosure
 - Identification of person(s) to whom disclosure may be made
 - Description of each purpose of the use or disclosure (can't authorize use or disclosure for future, unspecified research)
 - Expiration date or expiration event (not required for research)
 - Signature and date
 - Statements adequate to put the individual on notice as to:
 - Right to revoke in writing (including any exceptions)
 - Ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization
 - Potential for information to be redisclosed by recipient and no longer protected by HIPAA
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Review subject screening and recruitment practices for HIPAA compliance


Ensure all investigators, recruiters, and other personnel are aware of HIPAA requirements

Obtain HIPAA-compliant authorizations from subjects as early as possible in the recruitment process

Need to track disclosures (but not uses) of PHI for research to be able to provide an accounting of disclosures

- Accounting requirement does not apply to disclosures to patient/subject, disclosures pursuant to written authorization, or disclosures as part of a limited data set

Don't rely on business associate contract to make disclosures of PHI for research

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- I. Develop Review Criteria**
 - II. Define the Sample**
 - III. Select Methodology of Review**
 - IV. Determine Inter-rater Reliability**
 - V. Validate Findings**
 - VI. Document Observations and Findings**
 - VII. Corrective Action Plan**
 - VIII. Remediation**
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Reports and Feedback

- Recommend corrective measures, including the development of revised policies and procedures to meet regulatory requirements
 - Significant findings and action taken should be documented and communicated to senior and governance leadership
 - Performance assessment of trends identified as control weaknesses and compliance violations
 - Re-audit as necessary based upon initial findings and associated risk
 - Conduct Special Audits, as needed, i.e. follow up after resolution processes put into place
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Corrective Action Plan



Area of Focus	Finding	Recommendation	Management Action Plan Acct/Timeframes
Contract load	<ol style="list-style-type: none">1. 20% data errors in contract load2. Etc.	Periodically review data entry Etc.	Develop a periodic review system John Smith, VP 2 nd Quarter Etc.

Considerations

- Who needs to know about findings
 - What is the “frame of reference”
 - When is the best time for reporting results
 - How should you communicate, ie: summary, verbally, factual information related to error rate, etc.
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An effective Auditing and Monitoring approach provides a method to:

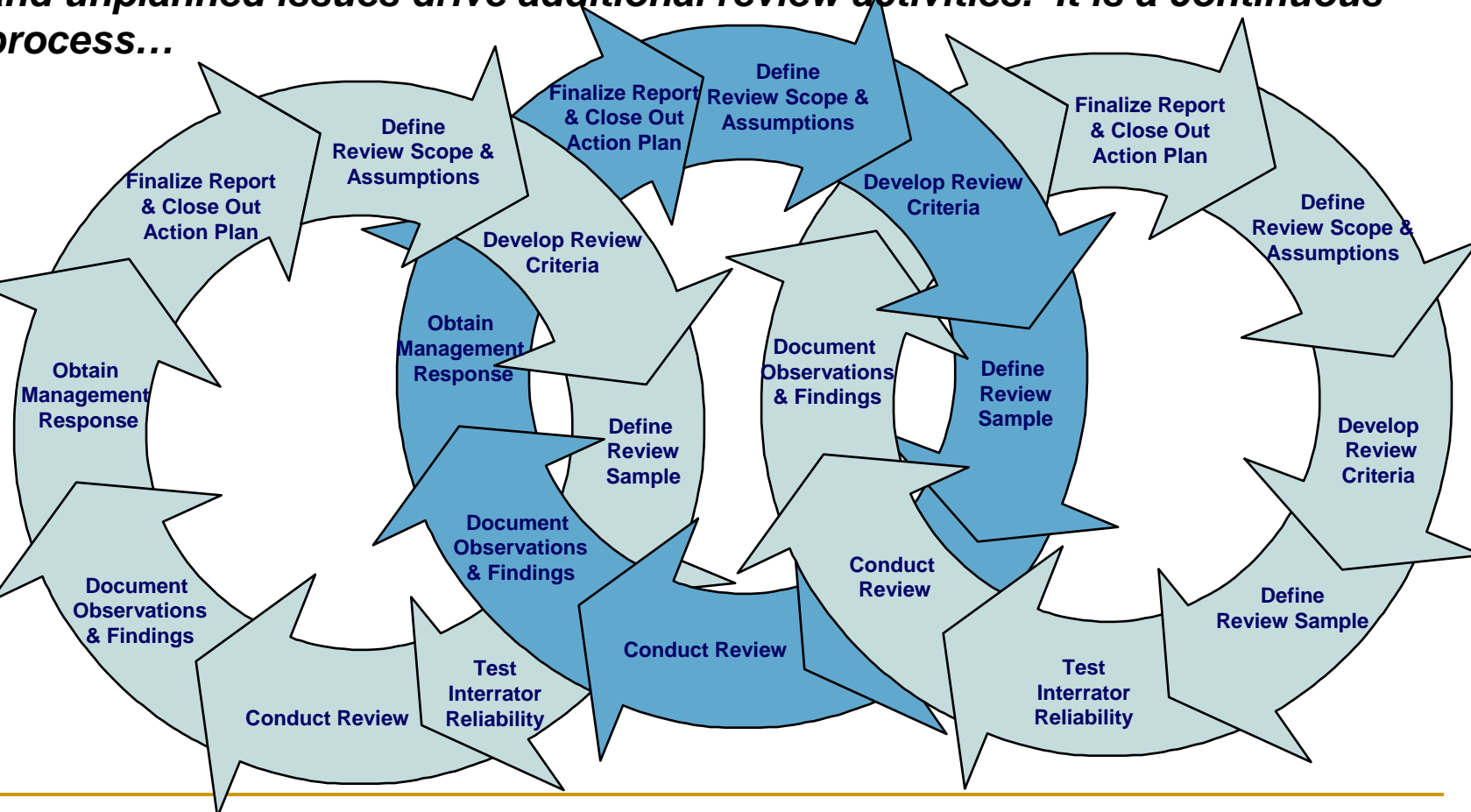
- **Assist in identifying risk to the business that may have been otherwise undetected internally**
- **Assist by identifying if the controls developed to remediate a risk are working and have actually helped to mitigate the risk**
- **Assist with preventing a real and/or potential risk from escalating by early detection through auditing which may help avoid additional harm to the company's business**
- **Provides a “good faith” organization the ability to approach their real and/or potential risk weaknesses with a reasonable, scalable method**

Auditing and Monitoring is a critical element for an effective compliance program which helps to drive compliance and behavior.

Monitoring Plan



Monitoring never ends... each review leads to the next, and the monitoring plan and unplanned issues drive additional review activities. It is a continuous process...



Questions/Answers

