Embracing a Culture of Self Correction

Making the Most of Internal Audit Programs

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Principal, BioTeknica

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Introduction

Where I have been

- ASCP Certified Medical Technologist

- Rush St. Luke's Presbyterian

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Introduction

Where I have been

- Over 20 years industry experience in quality roles in pharma, and medical devices, held internal audit positions at business and Corporate levels

  Worked on multiple FDA inspections, warning letters, Quality System remediations

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Introduction

Where I am now

- Principal Consultant and partner at BioTeknica

  Continue my work with auditing and assessments, FDA inspection preparation and support, 483 / WL responses, creating and remediating Quality Systems

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Introduction

What I have learned

- Companies that truly commit to their internal audit process solve problems.

- Culture of self correction is key

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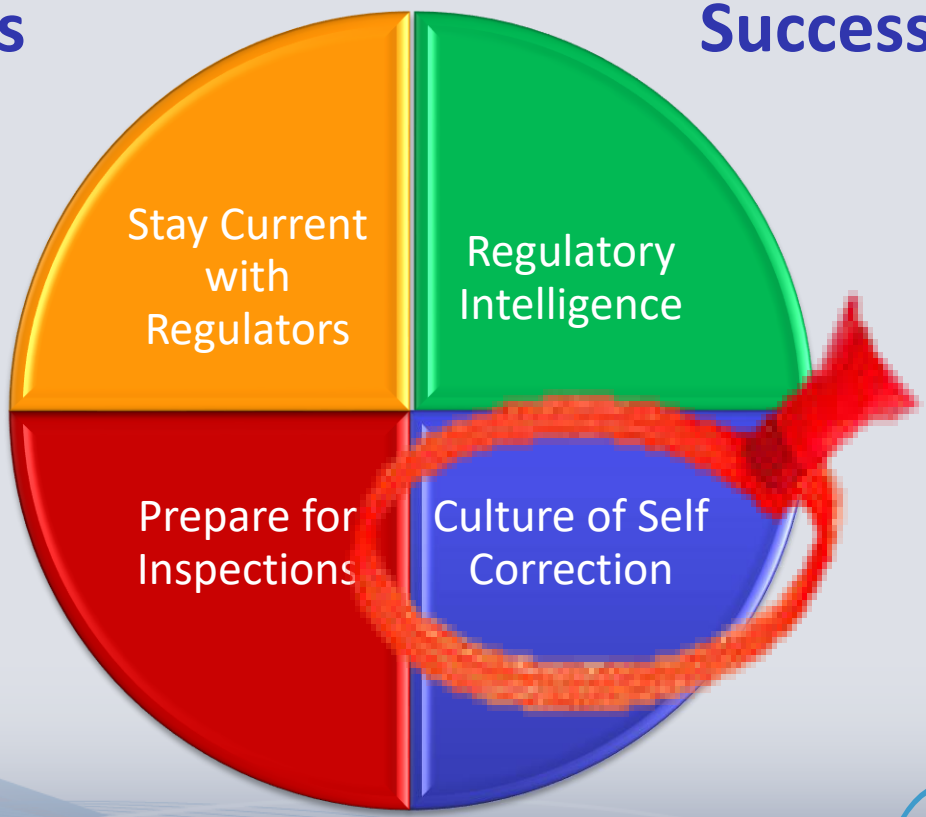
A Culture of Self Correction, What's the Secret?

Best Practices

Success Factors



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What Happens When?

- “Why didn’t our internal audit program catch this?
- “I wrote that observation, but management refused to address it”
- “Yah, we have a CAPA for that, but it never completed its investigation phase”

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Challenges

Management Challenges

- Recognize the importance of quality
- Get the resources to set up a quality system
- Ability to find the problems
- Be receptive to hearing about problems
- Provide support to fix quality problems once discovered

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Audit Survey

- 103 RA / QA officials filled out a 15 question survey
- Results follow

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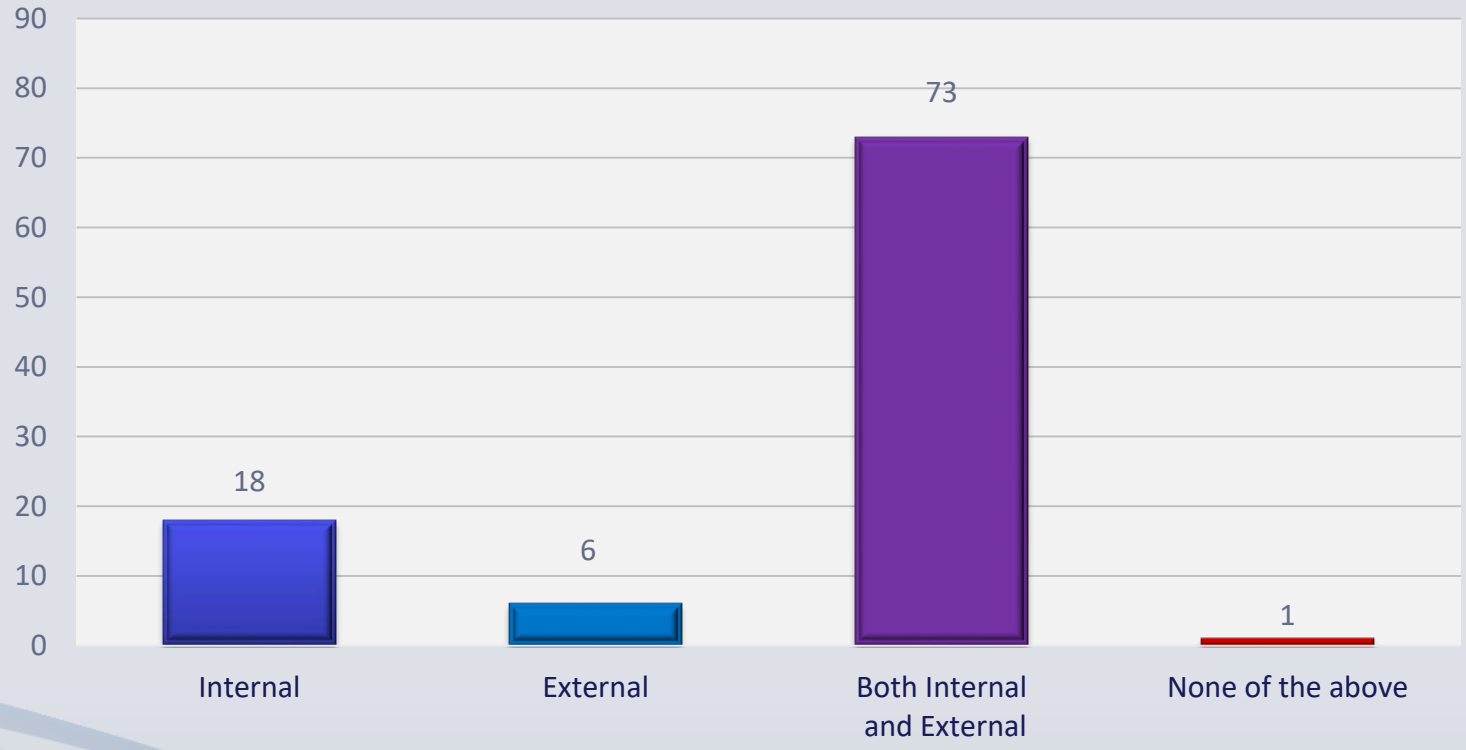
What resources do you apply to your auditing program?



Advantages of Internal Auditors

- Less expensive
- More familiar with products lines
- Understand acronyms
- Understand the culture
- Great access to internal records

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Advantages of External Auditors

Comparison to other firms

Practice for personnel in working with outside auditor

Greater Freedom

Lower headcount

Unbiased opinion

Look at your system like an external agency would

Management may be more likely to take third party advice

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Advantages of Using External and Internal Auditors

- Training for internal auditors
- Use internal auditors for more routine audits
- Use external auditors
  - New products
  - New requirements
  - Ensure appropriate action to 483 observations

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FDA Requirements

Small manufacturers must generally establish independence, even if it means hiring outside auditors because the failure to have an independent auditor could result in an ineffective audit.

Manufacturers must realize that conducting effective quality audits is crucial. Without the feedback provided by the quality audit and other information sources, such as complaints and service records, manufacturers operate in an open loop system with no assurance that the process used to design and produce devices is operating in a state of control. ISO 9001:1994 has

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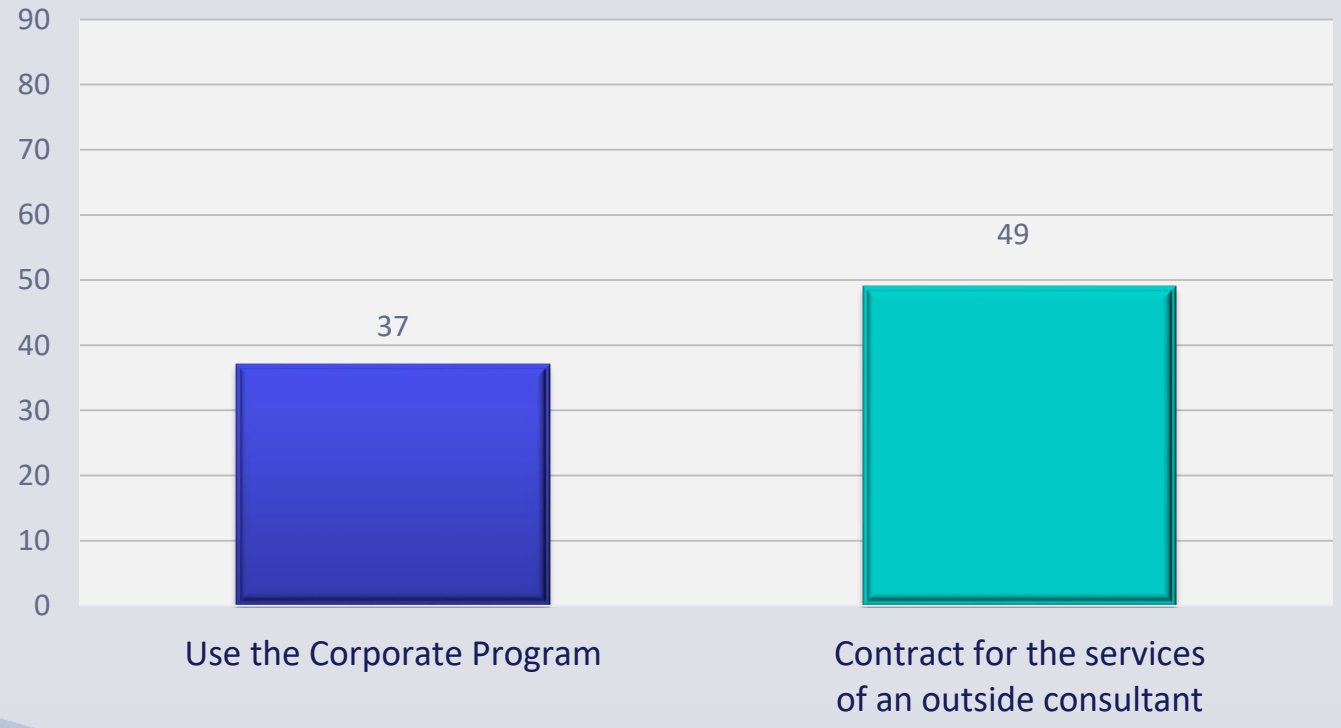
If your auditing program is external, how are audits performed?



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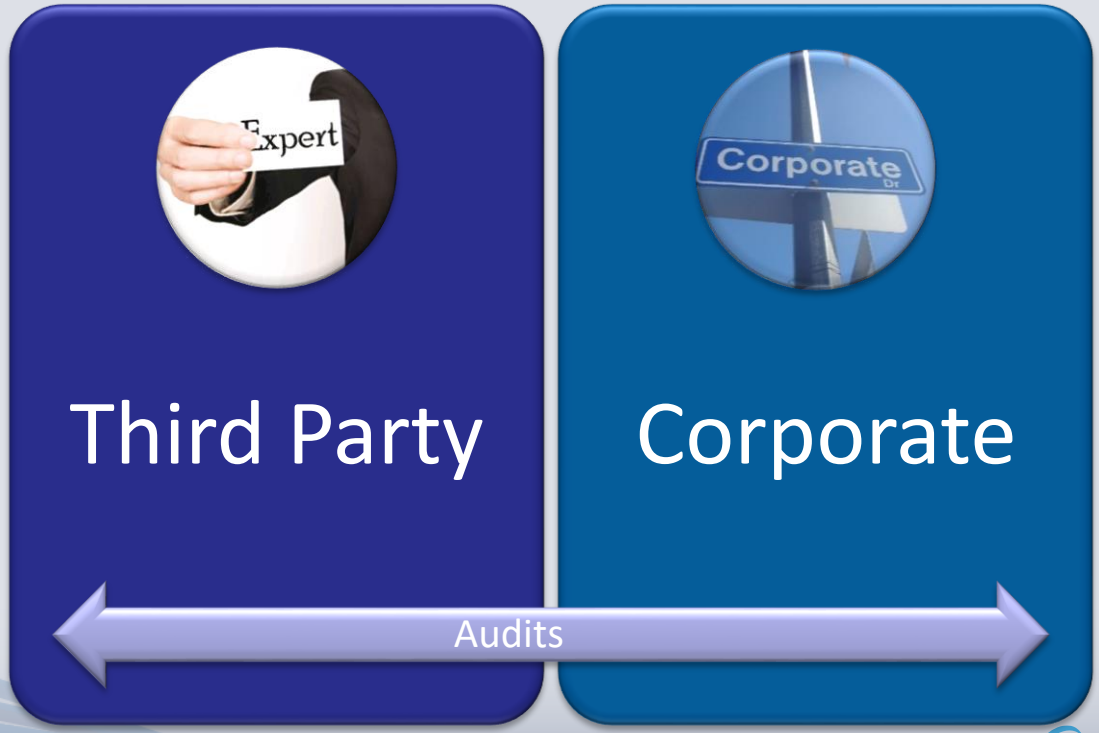
Techniques

- Majority of companies use contract service
- Some companies have a corporate auditing group



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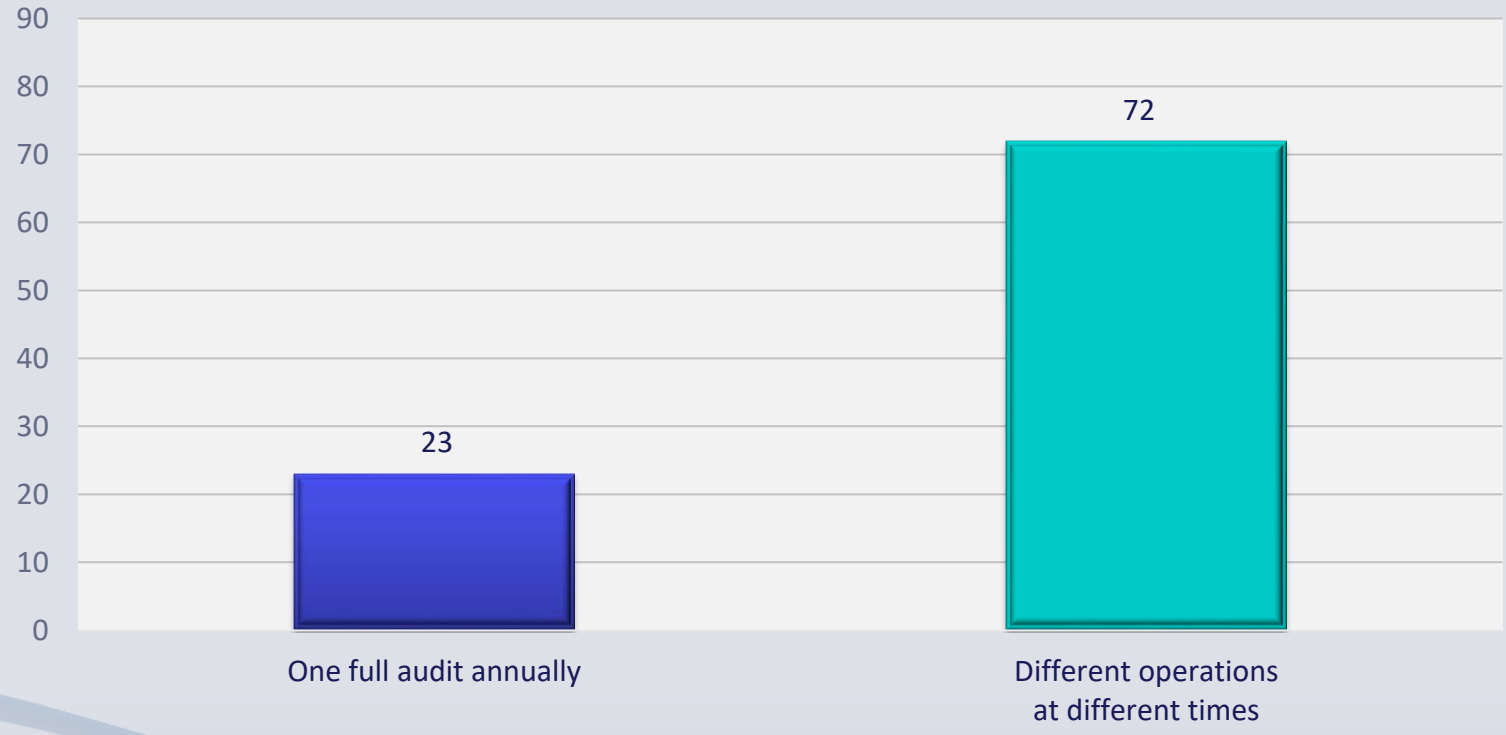
How often do you schedule audits?



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Scheduling

- Firms can comply with regulations by one full audit annually
- Use of focused audits on different areas
- Risk Based

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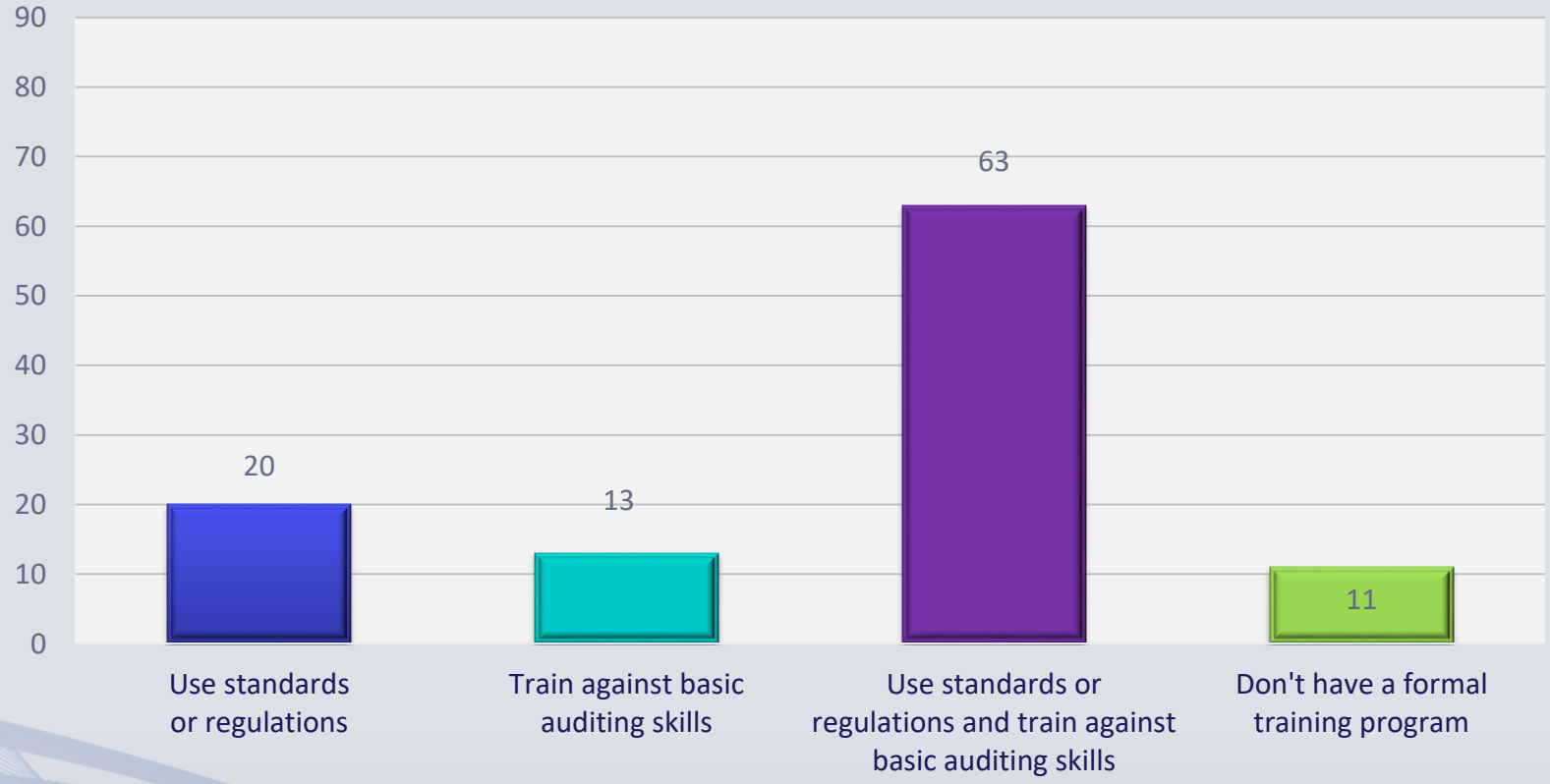
If you use internal resources, how do you train your auditors?



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Methods

Establish and use a standard training program

ASQ certification is a pre-requisite

Coursework consists of comprehending standards, regulations, and auditing techniques

In-person training

Shadowing an experienced auditor

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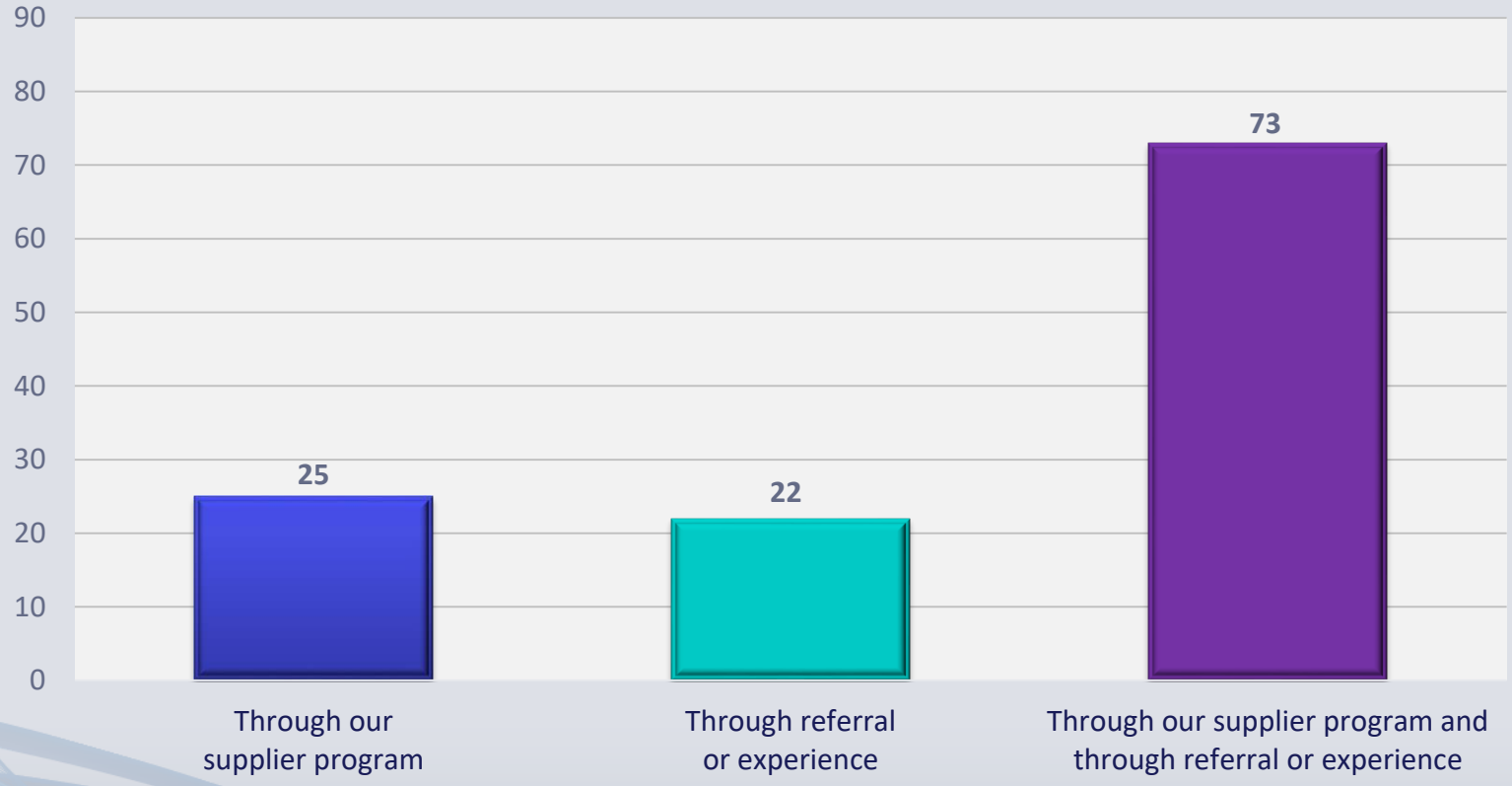
If you use external resources, how do you qualify external auditors?



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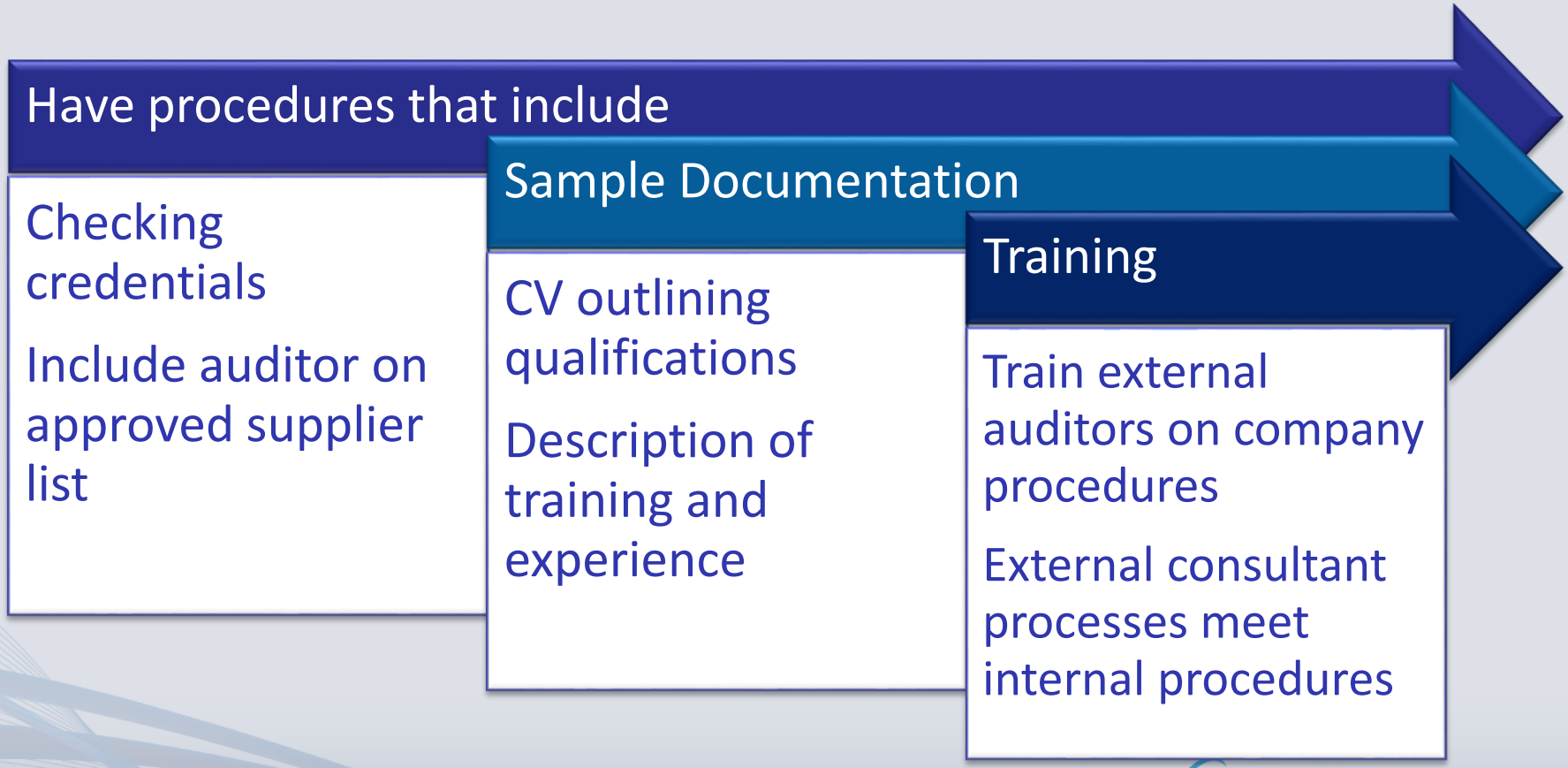
Steps



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Steps

V. QUALITY SYSTEMS ASSESSMENT OBSERVATIONS

1) Auditor/Assessor ***NAME***: ***List the quality subsystems that were covered by the auditor/assessor per the audit/assessment schedule***

Quality Area Reference Number Team Member	**Observations**	**Risk Level**
SEE EXAMPLE BELOW… ***Subpart J— Corrective and Preventive Action § 820.100*** CAPA-01 M. Neaves	***SEE EXAMPLE BELOW…*** **Summary Observation:** Corrective actions are insufficient to resolve the identified root cause(s). **For example:** • CAPA 001322, associated with the incorrect pairing of wires in a harness. The investigation determined that the root cause was that a person not qualified to perform the change was assigned the task. The corrective action did not include a systemic solution that would prevent the issue from recurring. Additionally, this CAPA did not: ○ Investigate whether other design changes could of ben impacted by this root cause ○ The effectiveness check was insufficient in that the only criteria for effectiveness was to continue to monitor complaints.	***SEE EXAMPLE BELOW…*** Level II

I. EXECUTIVE SUMMARY

A Quality Systems compliance audit/assessment was conducted at the ***Client, onsite location name, e.g. City, State, Country*** from ***Audit/Assessment Start Date*** through ***Audit/Assessment End Date*** with a focus on:

- 21 CFR Part 820 Quality Systems Regulation
- Part 803 Medical Device Reporting
- Part 806 Reports of Corrections and Removals

This assessment report includes independent observations that were made by the team.

Overall x (x) observations were identified and key areas of concern are summarized below:

# of Observations	Associated Quality Subsystem, e.g., CAPA, Handling & Storage	Specific areas of concern summary
e.g., Six (6) observations	***Corrective and Preventive Action***	***Specific areas of concern includes adequacy of corrective actions, identification of quality trends, robustness of effectiveness checks, evaluation of potential systemic issues (preventive actions), and verification of solutions prior to implementation.***
e.g., Five (5) observations	***Acceptance Activities***	***Specific areas of concern included first article inspection process deficiencies and documentation, recording of actual data in some product Device History Records (DHR), inadequate documentation for product release, and clarity of acceptance criteria in some testing procedures.***
XX (X) observations	***XXXXX***	***XXXXX***

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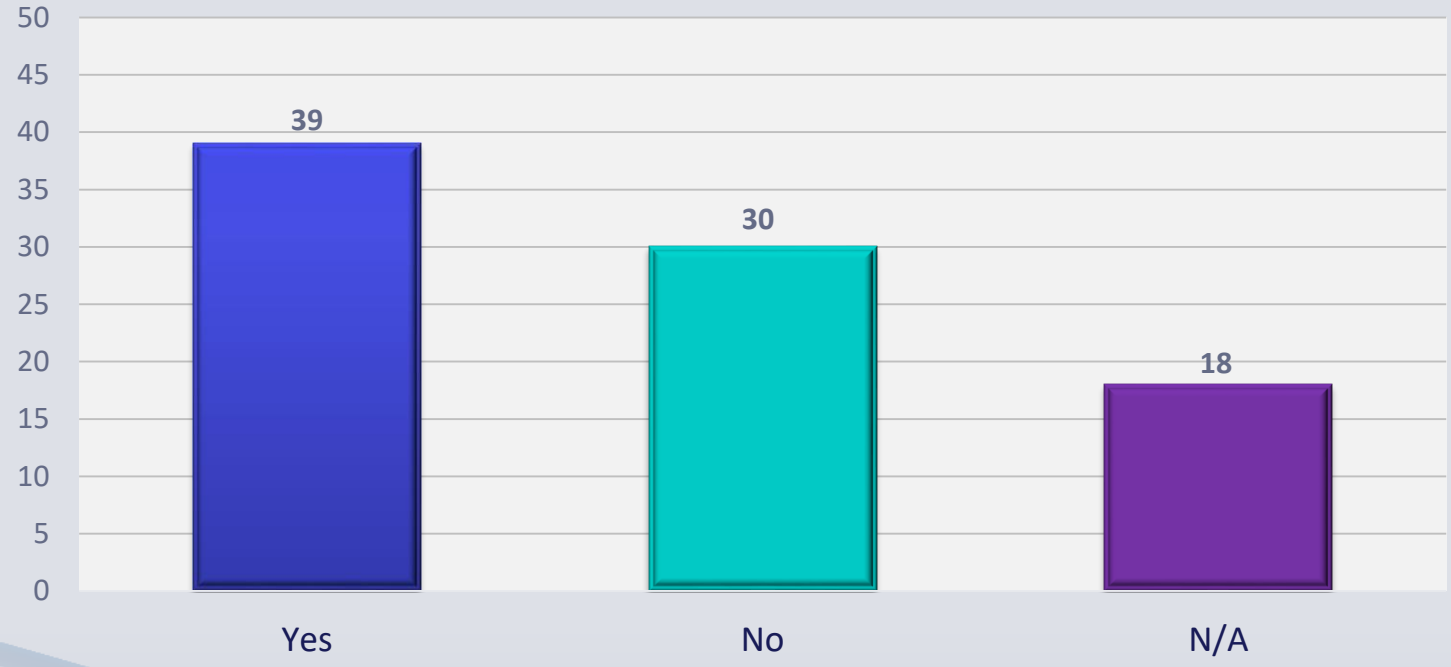
Do you see any difference in terms of the quality of the observations found by your internal auditors vs external contract auditors?



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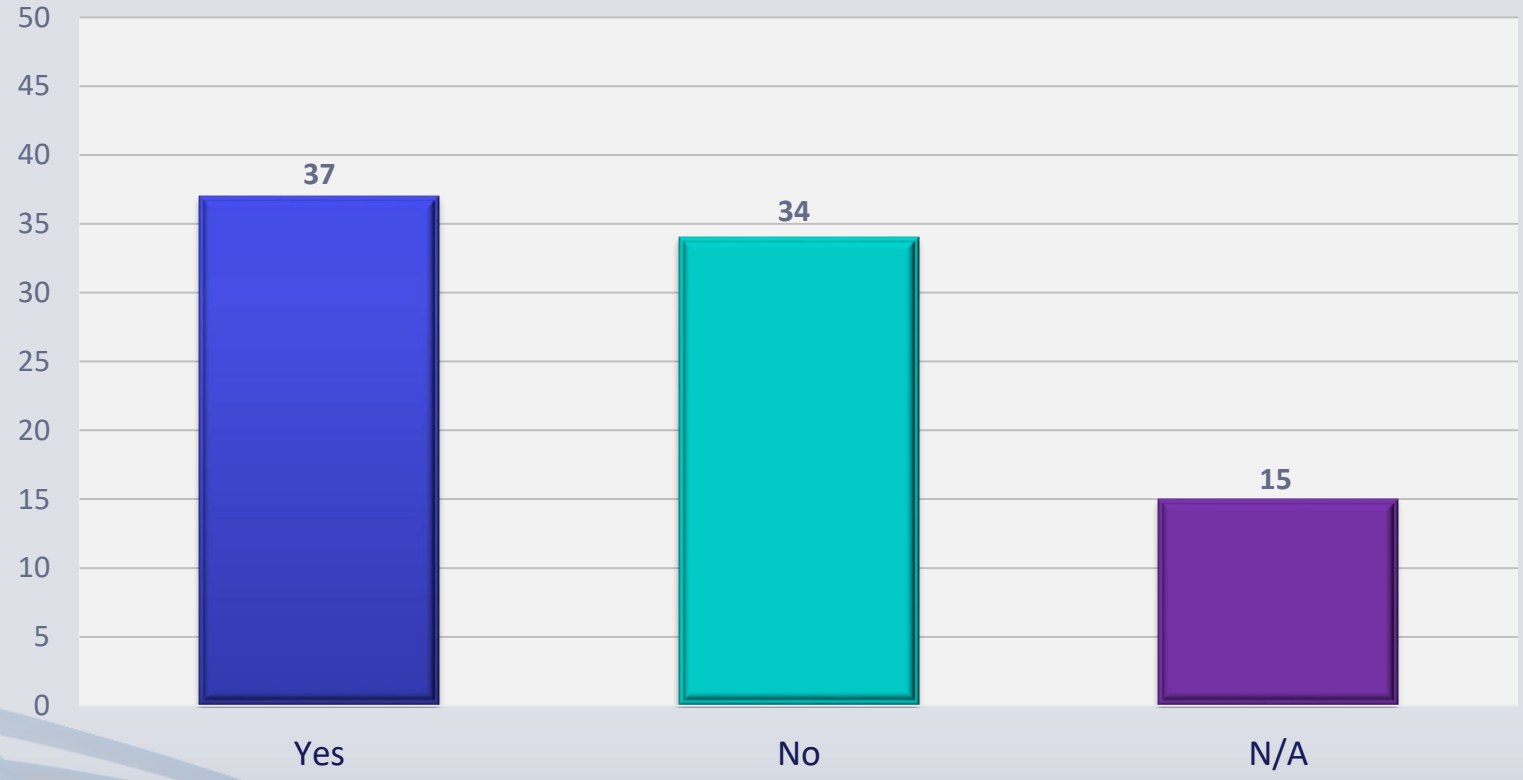
Do you see any difference in getting buy-in for corrective actions found by your internal as compared to your external contract auditors?



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Reasons

Reasons more than half saw differences include:

- Political
- Greater depth of knowledge by auditor
- Lack of bias

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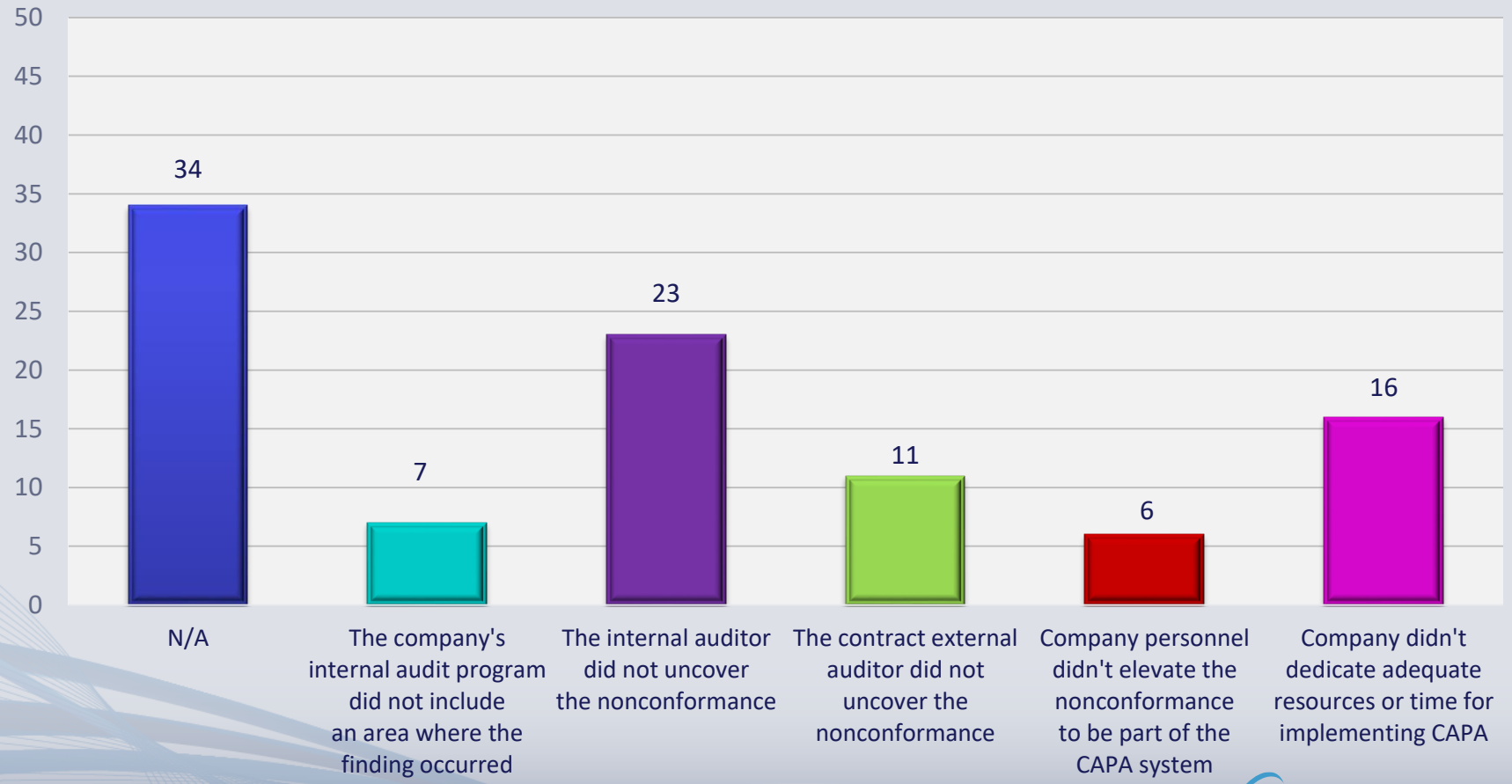
Have you ever had a 483 observation in an area where the company had previously done an internal audit?



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Thoughts

- Firms get 483 observations for not correcting deficiencies in their quality system
- QA can tell management, however if management doesn't listen, they still get blamed
- Best argument for external – internal auditor might not
  - Process the knowledge
  - Have the necessary clout to correct the deficiency

- FDA expects a closed loop system and have firms find their own problems – self correcting !

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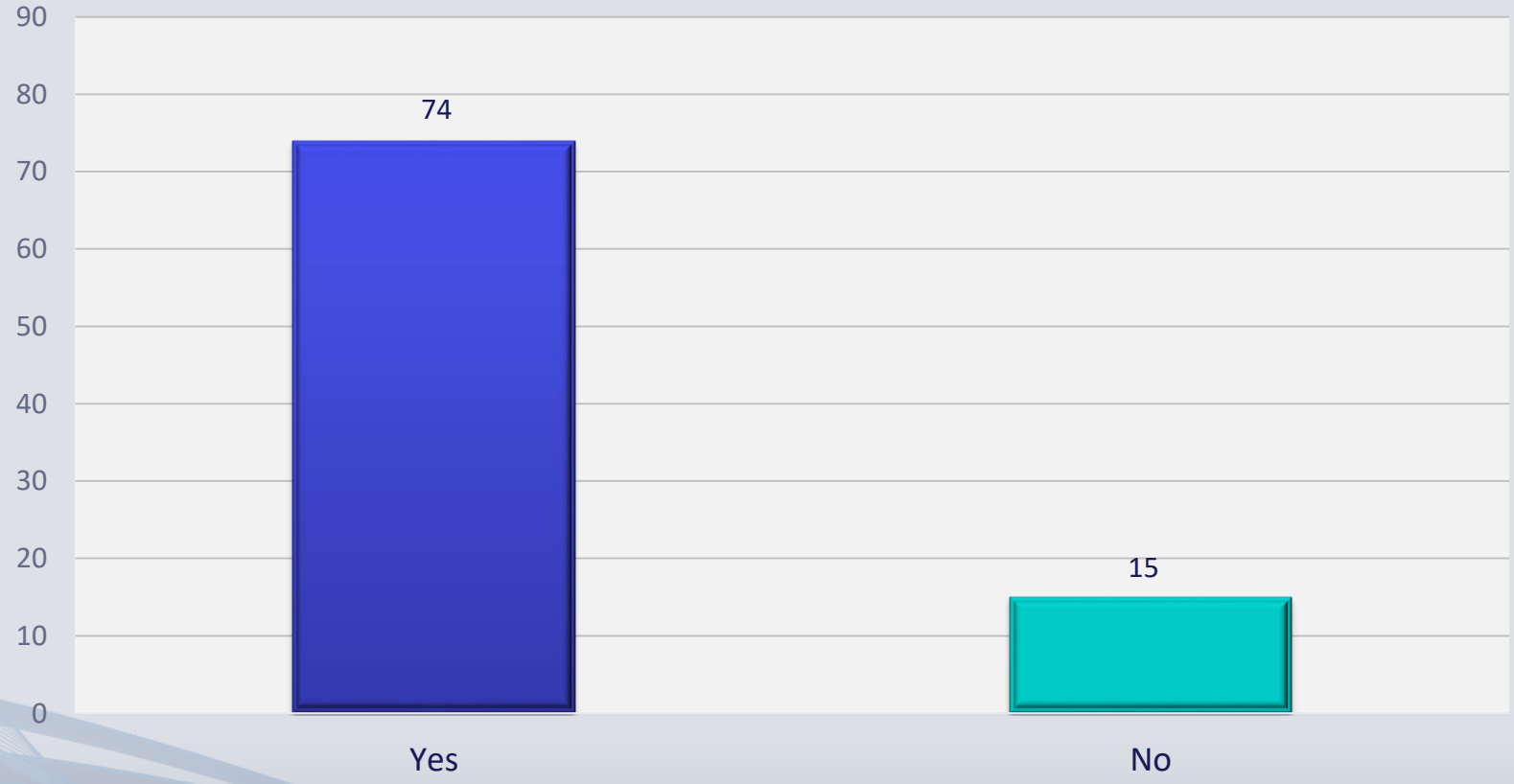
Do you follow the same process for audit findings and nonconformances?



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Thoughts

- Audit findings need the same attention as other inputs

- Firms should be more concerned with solving problems than hiding their existence

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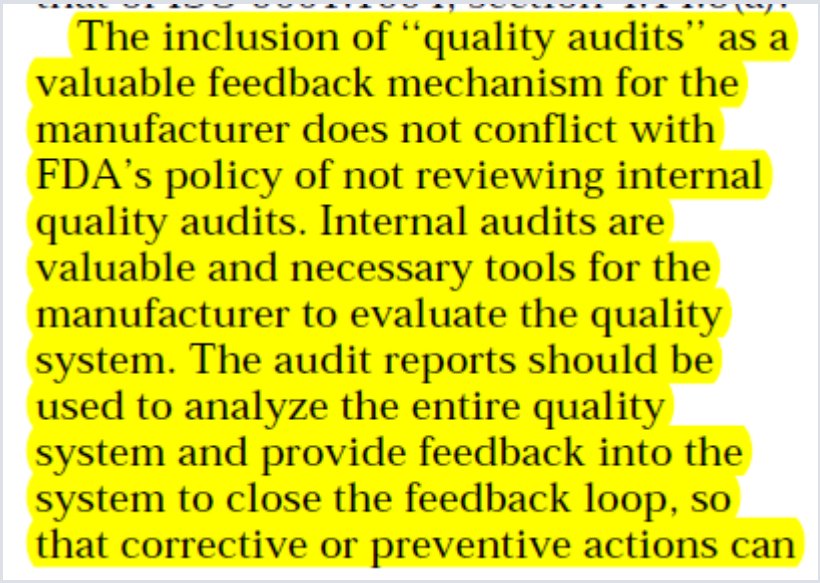
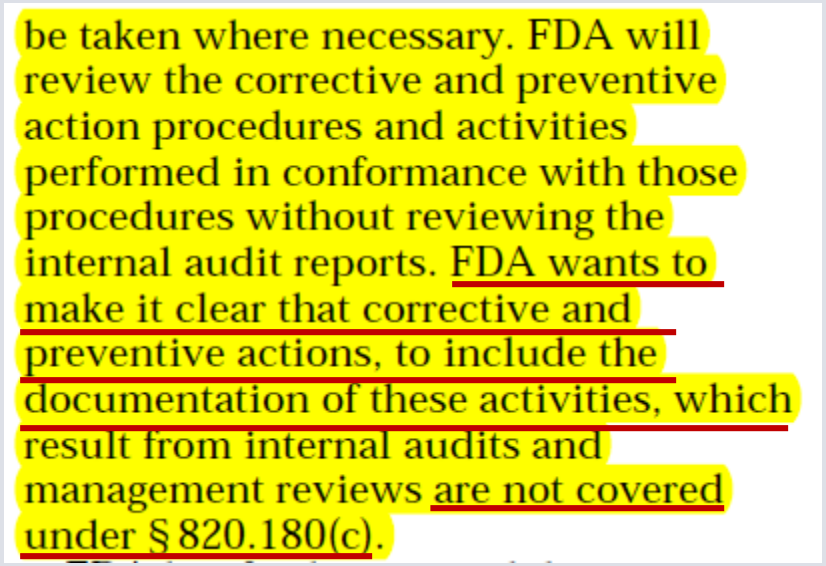
FDA Requirements



The inclusion of "quality audits" as a valuable feedback mechanism for the manufacturer does not conflict with FDA's policy of not reviewing internal quality audits. Internal audits are valuable and necessary tools for the manufacturer to evaluate the quality system. The audit reports should be used to analyze the entire quality system and provide feedback into the system to close the feedback loop, so that corrective or preventive actions can



be taken where necessary. FDA will review the corrective and preventive action procedures and activities performed in conformance with those procedures without reviewing the internal audit reports. FDA wants to make it clear that corrective and preventive actions, to include the documentation of these activities, which result from internal audits and management reviews are not covered under § 820.180(c).

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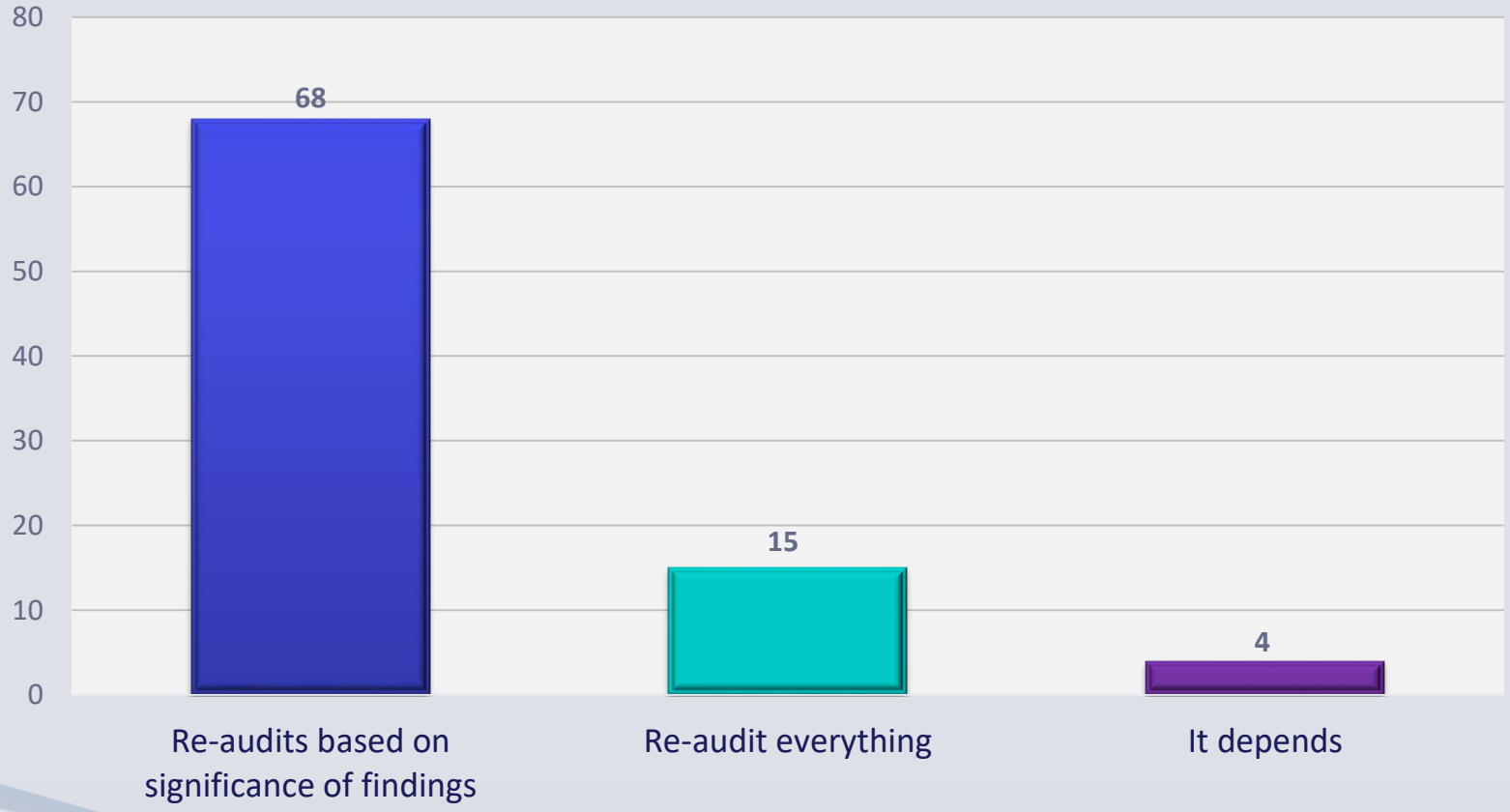
How do you handle re-audits?



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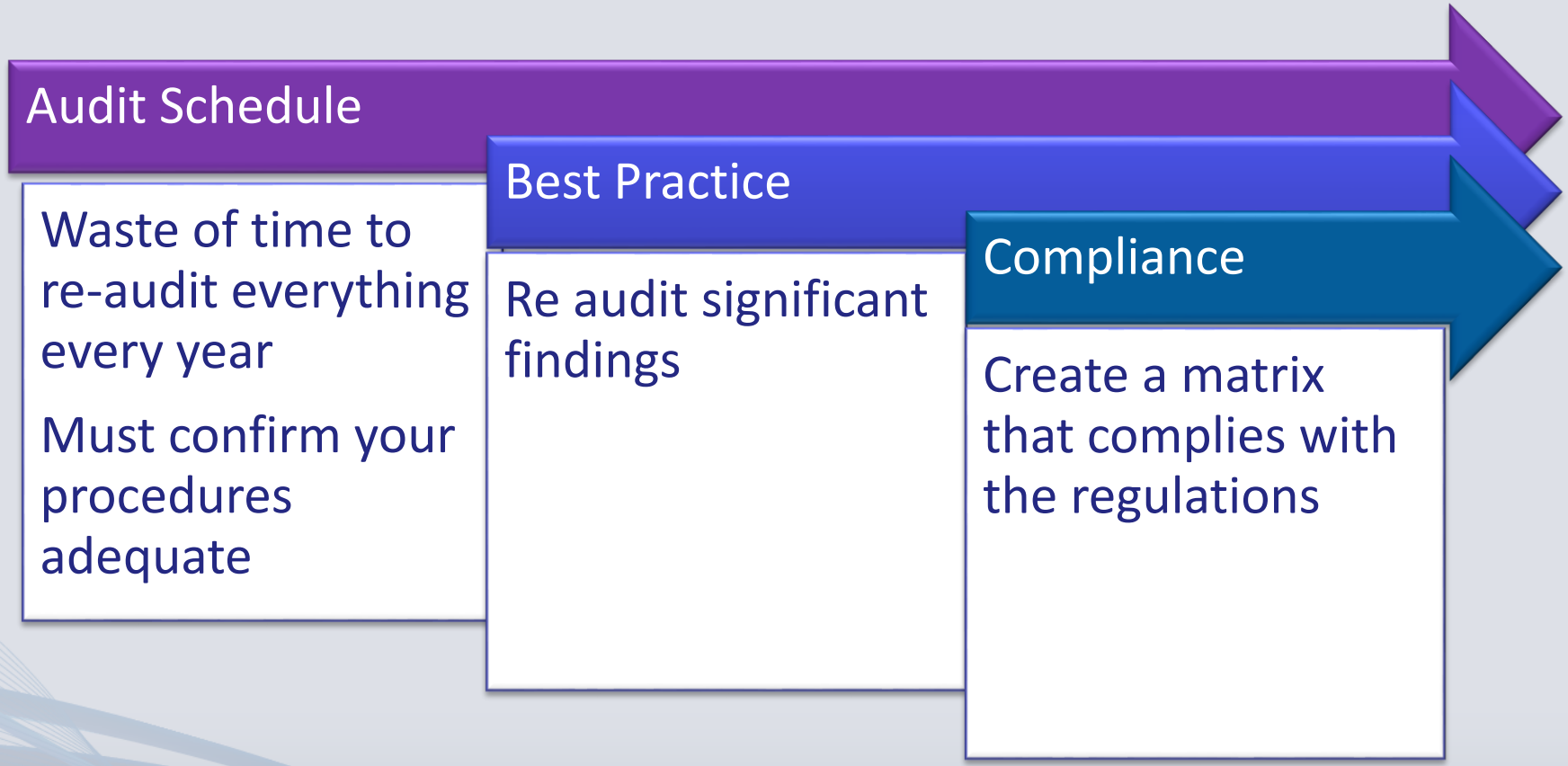
Thoughts



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FDA Requirements

6. Verify that quality audits, including re-audits of deficient matters, of the quality system are being conducted.

Review the firm's quality audit schedules to assure quality audits are being conducted with sufficient frequency. It is recommended that the time between quality audits not exceed a 12-month period. More frequent audits may be recommended if the firm has a serious Quality System Regulation problem.

Quality audits should consist of a formal, planned check of all elements in the quality system. They are **NOT** product audits. Quality audits must be conducted using adequate detailed written procedures by appropriately trained individuals. If conducted properly, a quality audit can detect system defects and, through isolation of unsatisfactory trends and correction of factors that cause defective products, prevent the production of unsafe or nonconforming devices. *Without an effective quality audit function the quality system is incomplete and there is no assurance the manufacturer is consistently in a state-of-control.*

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How is management made aware of internal audits?

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Thoughts

Management should be included in the distribution of the report

Management review should include

- The most important findings
- Actions being taken to address them

Pertinent findings are an input to the CAPA program

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Culture of Self Correction

Strong Internal Audit Program

Utilizes independent third parties

Communicated to management

Root Causes identified
Actions taken

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