6 Strategies for Internal Audit Success

An Essential Guidebook for Internal Auditors
Introduction

Why do you perform internal quality audits?

Most quality and regulatory professionals would say that they perform internal audits because they are a requirement for regulatory compliance. You must continuously audit your quality system to ensure that it is effective and compliant.

You may also aspire to perform audits that benefit your business and drive continuous improvement.
Another important aspect of performing internal audits is that they are your primary way to prepare for future regulatory audits. Internal audits are your opportunity to take a step back and scrutinize your organization the way a regulator would. You can use this opportunity to identify compliance gaps before they’re found by an external party.

Whether you’re primarily concerned with maintaining compliance, improving quality, or impacting continuous improvement, this book can help guide you to internal audit success.

Read on to discover expert tips for improved audit planning, performance, follow-up, and reporting that can help you gain maximum value from your internal audit program.
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Lay the Groundwork for Success
Design a Sound Process

One key idea in quality management is that solid, thoughtful design leads to the creation of a high-quality product. This idea holds true for both product and process design.

So when you’re performing audits, it’s important to realize that planning and preparation lay the groundwork for effective internal quality audits.
There is a link between the effectiveness of your audit process and the effectiveness of your overall quality system.

If your audit processes are sound, you are more likely to be in compliance with regulatory requirements.

✔️ In a recent FDA study, manufacturers with an adequate quality audit system were in **compliance** with approximately **96%** of their GMP requirements.

✔️ Those that did not have an adequate audit system were in compliance with only **70%** of their requirements. *(Source: www.fda.gov)*

“Without an audit, the quality system becomes an open loop without feedback to management and without corrective action.”

*FDA*
An Effective Process

What makes an internal audit process more effective? Here are some questions to ask yourself as you create or improve your process:

• How often should I conduct audits?

• What standards (ISO, GMP, etc.) am I auditing to? Have I audited to these standards before?

• How do I communicate with my audit team and my auditees?

• Have I created the right documents and SOPs to support my audit process?
An Effective Process

Additional questions include:

• Do I have enough trained auditors? What are their time constraints?
• How do I want to record and maintain audit results?
• How can I best integrate my audit results and findings with the rest of my quality system?
• What can I do to increase management’s support for the internal audit process and in any resulting continuous improvement efforts?

Once you’ve defined your answers to these questions, you can begin to define your audit schedule. That’s where risk comes into the picture.
Use Risk to Build Your Schedule
Did you know that not every process needs to be audited annually? But most organizations perform annual audits on most processes.

In reality, your organization should conduct audits at a frequency that matches the risk and importance of each product or process. *(McClain, 2011)*

As a lead auditor or quality professional, you have the best insight into your quality system, and how changes within your organization should affect your audit schedule.
When and What Should I Audit?

Some risk-related points to consider when formulating your annual audit plan can include:

- How does each audit fit into your company’s strategic goals?
- How mature are your products? Are your manufacturing processes stable?
- Which areas or processes have had critical audit findings in the past?
- Are there any other indications of problems that need closer scrutiny?
- Where is change happening? Are there any products, processes, or departments that need a closer look due to change or turnover?

And remember, be sure to document your plan once you’ve determined it.

Sources: (McClain, 2011), (Robatiaille, 2007)
3 Invest in Your Team
A novice auditor can easily damage the credibility of the program by being uninformed, inflexible, or unrealistic.

Konyika Nealy
Vice President of QA and Validation
Pilgrim Quality Solutions
Selection is Key

Choosing the right people and training them well are crucial steps to building an effective audit program. The auditors you choose should be:

- Honest
- Respectful
- Ethical
- Open-minded
- Diplomatic
- Observant
- Flexible
- Decisive

Source: http://www.slideshare.net/hejaij/iso-internal-auditor
Training Techniques

In addition to preparing by reading and understanding regulatory standards, SOPs, trends, and reports, your auditors may benefit from the following:

- Performing Mock Audits
- Role Playing
- Competency Evaluations
- Shadowing Other Team Members

(Nealy, 2011)
Don’t Rush to the Lead

Well-trained, experienced auditors “make or break” your audit process. So it is important not to rush auditors onto the team, or into the role of lead auditor. Take the time to train and mentor each new auditor under the guidance of your more seasoned team members.

Effective auditor training can help your auditors become partners in process improvement throughout your organization. (Nealy, 2011)
Give Your Auditors Time

Beyond training, one of the best ways to be sure that audits are effective is to dedicate time to prepare for them.

The level of preparation needed will likely be related to the experience and preferences of your audit team. Seasoned auditors may be less likely to use a checklist to perform an audit. But are there certain questions or topics that should be covered during each audit? These should be prepared and documented before the audit begins.

Your team also needs time to read more than just SOPs. Previous audit reports, workflows, and department metrics can help your auditors quickly hone in on potential problem areas and maximize the value of each audit.
Round Out Your Team

Your audit team can include external consultants. Adding external resources can be costly, but can bring new perspectives, industry best practices, and the assurance of auditor independence to your internal audit program.

External knowledge can be especially valuable when you are auditing to a new standard. Your internal staff can learn a great deal from a consultant’s preliminary audit. You’ll gain a better interpretation of new standards so your team can better prepare for future audits.
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Stay Independent
The Importance of Independence

If you want your internal audits to be compliant and value-added, they must be conducted independently.

“Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited.”

FDA 21 CFR Part 820 (Section 820.22)

Simply put, an auditor cannot audit his own work.
A Good Result or a Good Audit?

Your auditors can also fail to be independent when they are pressured to provide a good result, rather than to perform a good audit. (McClain, 2011)

It is important to keep in mind that auditors are responsible for assessing compliance alone.

A good audit is objective and should measure your organization against a defined standard or criteria. The audit team should be empowered to point out nonconformities and suggest appropriate fixes. The auditor is not responsible for correcting deficiencies or for the costs associated with corrections.
If the audit program isn’t independent, the auditor might hesitate to point out nonconformities due to the perceived cost in correcting problems. However, if an auditor is carrying out his responsibility, which is to assess an organization against a set of requirements, then nonconformities simply point out something that should have been done in the first place.

Bill McClain
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Share Your Results
Requirements for Follow-up

The audit isn’t over when your checklist is full. According to the FDA, follow-up and management review are required steps:

“A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audits. The dates and results of quality audits and reaudits shall be documented.”

FDA 21 CFR Part 820 (Section 820.22)
Make Reporting Consistent

As an auditor, you plan and prepare, form a great team, hone in on trouble spots, and identify opportunities for continuous improvement. But the key to communicating audit results lies in your report.

Follow-up reports are required for compliance purposes, but are also your opportunity to share your findings (good and bad) with your management team.
Audit Reports should be...

- **Timely**
  Publish and share within one week

- **Clear**
  Highlight areas for improvement

- **Consistent**
  Use a standard template every time

(Source: Emergo Group)
Tips for Effective Audit Reports

✔ Grab your reader's attention! Begin the report with your positive observations and comments.

✔ Create and use a template for your audit report so it will be consistent and easy to complete every time.

✔ Cover all of the basics. Be sure to detail audit dates, areas audited, standard user, lead auditor, audit team, and names of persons interviewed. (Robaitaille, 2007)
Tips for Effective Audit Reports

✔ Focus on your observations and findings, rather than just presenting checklist results.

✔ Rank findings by risk to clearly communicate their importance.

✔ Use standard terminology for findings, severity, and root cause for purposes of clarity and later analysis.
Remember to Share

Once your report is complete, be sure to share it with your team, management, and your auditees. Reports should be shared soon after the audit — typically within a week. Timely report distribution can increase the likelihood of timely follow-up actions.

Finally, don’t forget to share findings or potential improvements with other departments or sites throughout your organization. This is a great way to let your “lessons learned” drive improvement.
Use Technology to Improve
Technology Can Help

The audit process, especially scheduling and reporting, can be difficult to manage in a manual system.

Unless an integrated quality system is in place, most departments and sites track and trend their own data on their own systems, marking it hard for management to see a corporate-wide compliance picture.

Automated systems allow you to trend, communicate, share, and innovate in ways that are impossible with manual systems.
Technology Can Help

Automated audit management software can help you:

- Reduce schedule conflicts.
- Maintain control over checklists.
- Standardize data and categories for analysis.
- Decrease time needed to create audit reports.
- Share results throughout your organization.
- Integrate audit results with the rest of the quality system.
Learn More
SmartSolve® Audit Management

SmartSolve Audit Management is a comprehensive solution to plan, manage, and conduct audits. Audit Management can help you:

- Simplify audit planning
- Improve audit efficiency
- Manage audit findings
- Share results and reports

Would you like to learn more about how Audit Management can help you build a better internal audit process?

Learn about Audit Management
Audit Management Data Sheet
Solutions for Quality & Compliance

Pilgrim Quality Solutions is a leading global provider of enterprise quality management software and services for the Life Sciences and other highly regulated industries.

We’ve pioneered quality management software solutions for more than 20 years.

Our on-premise and cloud technologies reflect quality industry standards and include electronic signatures, audit trails and validation packs — helping our customers more easily achieve compliance and pass regulatory audits.

With Pilgrim Quality Solutions as your partner, you are prepared to succeed.
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