6 Steps to Effective Supplier Quality Audits

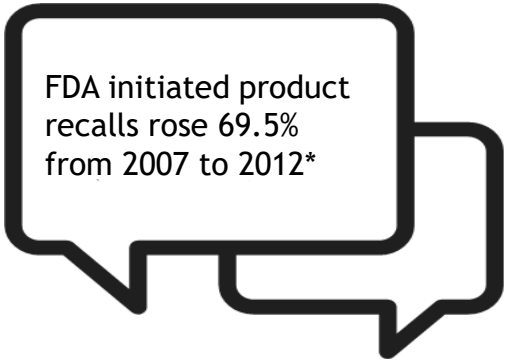
A Guide For Medical Device Companies

Sparta Systems

Why Supplier Quality Audits Matter

Recent issues impacting consumer safety have required organizations to re-examine the way they approach their quality management practices. Medical Device companies are increasing their efforts to inspect and audit the quality of their own operations both internally and throughout the supply chain network of partners and suppliers.

Audits evaluate processes, systems, product and materials, people or other corporate operations. Audits can be run internally, by partners, customers, regulatory agencies, or third parties.



* Source: FDA Enforcement Statistics Summary

Manual vs. Automated Supplier Audits

During external audits with suppliers, the auditor documents information before, during and after the audit. Documentation is needed to both record the results of the specific audit and support future tracing and trending efforts. Manually capturing results cause inefficiencies, inconsistencies and redundancies. An organized approach to audit management allows companies to leverage technology that enables holistic end-to-end automation across their entire supply chain auditing process and their global organization.

Manual

- Ineffective supplier communications
- Siloed processes/Disconnected systems
- Incomplete or inaccessible documentation
- Inconsistent audit results
- Lack of oversight

Automated

- Integration for a closed-loop process
- Consistent templates
- Data management to protect company's interest agreements with suppliers
- Reduce time and cost per audit

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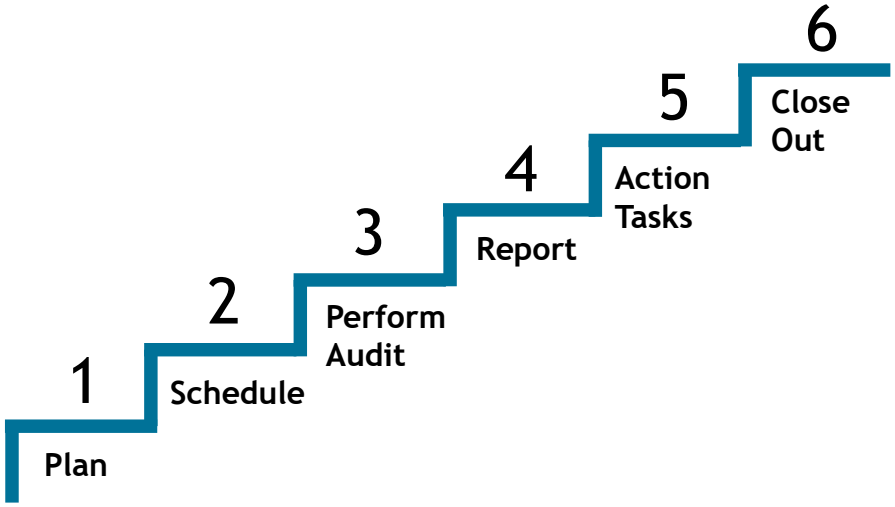
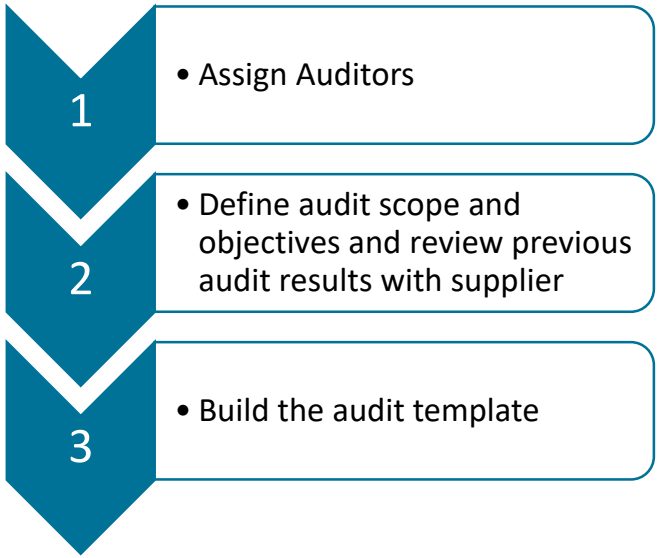


Step 1: Plan

Proper planning results in an audit that flows smoothly and logically, minimizing backtracking and repeat visits that take time and effort without adding value. An audit management system can aid with supplier planning processes that include:

- ✓ Assigning appropriate auditors to lead and assist with the auditing effort
- ✓ Specifying which processes and sub processes will be audited, as well as the results from the previous audit;
- ✓ Defining the supplier's audit scope, objectives and agenda;
- ✓ Determining which audit template to use;
- ✓ Developing a chronology of the audit from start to finish;
- ✓ Determining the types of resources and documents needed from the supplier's process owner.



Step 2: Schedule

- Handle all calendar and workload aspects of the supplier audit, and incorporate the strategic use of reminder and tracking systems
- Manage multiple audits simultaneously
- Balance workload and conflicts
- Communicate schedule to auditors

An automated audit system can simplify the process of scheduling audit dates, manage resource conflicts, including automatic reminders to initiate and assign audits to ensure that tasks don't fall through the cracks.

Automated scheduling is particularly useful when multiple supplier audits are occurring at the same time because it eliminates personnel conflicts.

Robust reports can subsequently be produced that allow key stakeholders to achieve a macro view of audit activity across the supply chain, understand auditor utilization, and identify proper workload balancing and conflicts.

Step 3: Perform Audit

Audit management systems help the lead auditor manage the overall supplier audit process, including gathering required data; recording audit findings and objective evidence for each question; issuing action items to address discrepancies; managing and communicating any changes to the supplier audit plan; communicating progress to all stakeholders; and ensuring that the schedule stays on track.

Auditors can electronically document audit results whether they have internet connectivity or not — at a customer site, on an airplane, or at their desk. This allows auditors to document everything once (including all of the classifications management needs for future tracking and trending), and eliminates the copy/paste challenges common in audits. This capability is enabled by modern lightweight technology that allows auditors to conduct work while disconnected from the internet. This approach is a complete departure from legacy work methods like MS Excel, which are loosely controlled and emulate the manual processes audit management systems are striving to replace.

Benefits of a properly executed supplier audit
Recommendations and CAPAs often arise
Document findings and objective evidence
Identify and address discrepancies
Manage and communicate any needed changes
Keep schedule on track and document audit results

Step 4: Report

Once the appropriate criteria are evaluated, auditors can generate a formatted report that includes the written audit observations of good practices, and risks and problems identified. This report forms the basis of the discussion about the audit results and findings.

An audit management system provides reporting capabilities that also generate trends and metrics against data gathered across reports. In systems that track multiple auditing groups, risk and prioritization can be rolled up and used to determine prioritization of resources across groups, not just on a siloed basis within each group.

Reports that are written and organized well allow both the manufacturer and supplier to understand and benefit from the audit process

1. Provide a formal audit report with appropriate trends and metrics analysis
2. Significant attention should be given to the quantity and type of data collected, report formatting, and diversity of readership
3. Effective communication is key

Step 5: Action Tasks

Action tasks must be assigned priority

Lack of follow-through creates major deficiency and liability

- Effectively and efficiently manage a CAPA process
- Address Discrepancies

The supplier must respond to audit findings by their respective due dates. The response must include a probe into the root cause, a proposed corrective action and a completion date. An integrated CAPA management solution is highly recommended to effectively and efficiently manage the CAPA process based on the priority, criticality and the risk factor of the finding. For supplier audits, the offline capabilities now allow auditors to email the audit findings directly to the supplier. The supplier can respond electronically, which helps ensure that the response fulfills the expectations of the organization's quality system.

Step 6: Supplier Close Out

This final step is to assure nothing has been overlooked, guaranteeing audit integrity

- Ensure all action items are addressed
- Ensure responses are captured
- Ensure appropriate sign-offs are received

A supplier audit can be completed and closed-out once all the action items are addressed, and the responses and appropriate sign-offs are received. A final audit report can be generated to document the audit for inspection, or the audit management system can be used as the official system of record.

Medical Device Company Benefits

1	Verify whether the correct SOP is being followed
2	Check for supplier quality agreement compliance
3	Alert the company of any supplier deficiencies
4	Help identify and correct minor issues before major issues develop

Avoid

- Human Injury
- Legal Liability
- Financial Loss
- Public Relations Disaster

Benefits for a medical device company to build an audit process include the opportunity to create a consistent format. When it sends in different auditing groups such as accounting, IT systems, HR, engineering, or materials, each of those groups can access the shared supplier information. This streamlines all audits with multiple suppliers by eliminating duplication of effort and variability of outcome. Audit steps and reporting formats require a uniform and consistent appearance, making everyone's job easier, faster, and more efficient. Audits help identify and correct minor issues before major issues develop, leading to proactive resolution.

This can mean the difference between a simple supplier process correction versus human injury, legal liability, financial loss, and the associated public relations disaster.

Medical Device Partner/Supplier Benefits

1. Audit data sharing and standardizations can reduce the staff time and expense associated with multiple audits
2. Strengthen supplier reputation via a history of audit cooperation and successful results
3. Help suppliers better understand strengths and areas of opportunity

Strengthens the partner-supplier relationship

Medical Device companies and suppliers mutually benefit from the auditing process. Suppliers can incorporate insights and findings into processes and thereby become best-in-class. This strengthens the partner-supplier relationship and enhances the supplier's standing in the marketplace.

Audits involve inspections of data, processes, metrics, and onsite equipment across the supply chain. Effectively addressing risk areas, assuring regulatory compliance, reducing costs, and enhancing visibility are the four main reasons to establish a global audit process. The global audit process maximizes the benefit throughout the organization and critical suppliers are better managed within this close working relationship.

Conclusion

A centralized and automated audit management solution enables strong collaboration with partners and suppliers across the medical device value chain. Automated solutions improve auditors' productivity, provide more accurate results, and make it easier to identify trends across the global organization, thus, helping to improve operational processes and controls throughout the supply chain.

As a result of this integrated end-to-end solution, enterprises reap the benefits of lower audit costs, greater productivity, and less operational risk, which ultimately leads to better product quality.

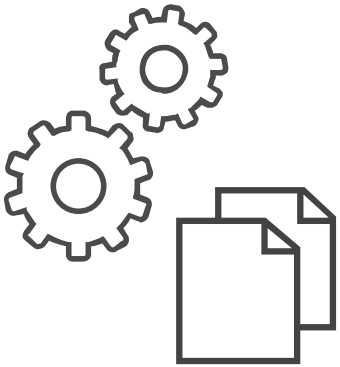
Supply Chain Challenges

- Efficiency
- Product Quality
- Regulatory Compliance
- Safety
- Cost Containment
- Quality Assurance
- Public Relations

Audit Solutions

Raise performance levels and strengthen relationships while improving patient-care quality for Medical Device companies and their suppliers

Resources



To learn more about audit management, please visit www.spartasystems.com or check out the following resources:

Whitepaper: Automated Audit Management

Whitepaper: Conducting Effective Internal Audits

Datasheet: Audit Management

Founded in 1994, Sparta Systems is the world's premier provider of cloud and on-premise quality management software. We offer the solutions, analytics, and expertise that speed up quality and compliance. Companies in life sciences, consumer products, discrete manufacturing and more, rely on Sparta.

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