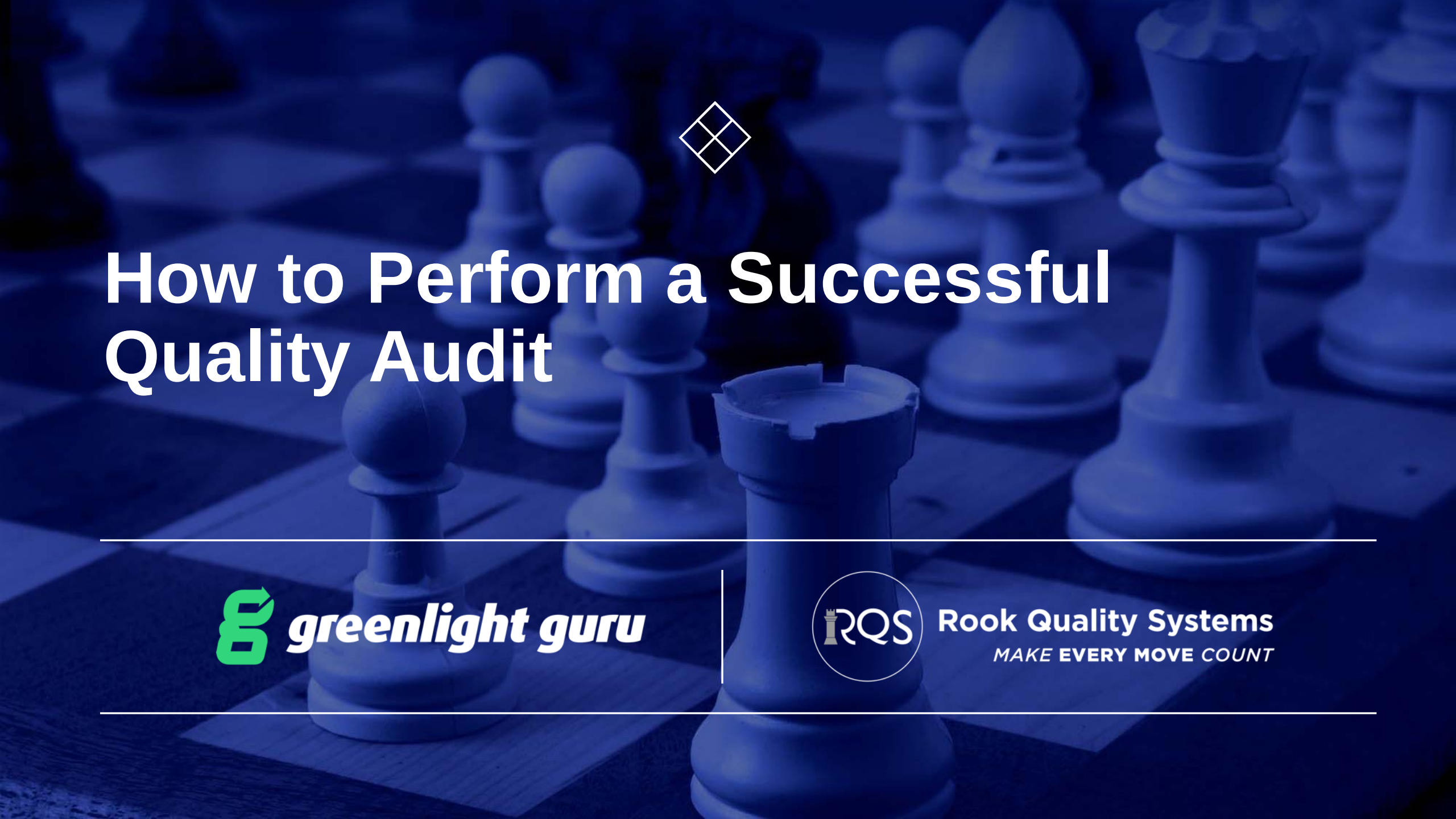

How to Perform a Successful Quality Audit

greenlight guru

Rook Quality Systems

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Rook Quality Systems is a consulting firm dedicated to helping startup to mid-sized medical device companies develop and maintain effective and efficient quality systems.

Experience

Nearly a decade working with class I-III devices, SaMD, and IVDs. Supporting companies in the very early stages of QMS and device creation, from design through commercialization and post-market monitoring.

Expertise

Rook's team of eight Certified Auditors are experts in FDA regulations, MDSAP audits, ISO 13485:2016 compliance, and MDR conformity and provide support during an external or regulatory audit.

Efficiency

We leverage experience and best practices to help build the QMS so that clients can get their devices to market faster than standard methods, and use these systems to continue producing effective, quality devices.

We provide specialized and custom consulting services for all classes of medical devices, including medical software and combination devices.

Quality System Design

DHF/ TF Creation

Audit Support

Software Validation

Design Control

Risk Management

Regulatory Submission Support (Int'l)

Quality System Training

Today's Agenda

Introduction	**2 min.**
What is an Internal Audit	**3 min.**
Description of The Audit Prep	**15 min.**
Explaining Internal Audit Process	**10 min.**
Handling Audit Findings	**10 min.**
Audit Report and Gap Analysis	**10 min.**
Common Audit Mistakes	**10 min.**
Questions?	**10 min.**

What is an Internal Audit?

What is an Internal Audit?

Definitions from the Standards

FDA QSR Sec. 820.22 Quality Audit

- Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a re-audit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and re-audit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and re-audits shall be documented.

What is an Internal Audit?

Definitions from the Standards

ISO 13485:2016 Section 8.2.4 Internal audit

- The organization shall conduct internal audits at planned intervals to determine whether the quality management system:
  a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;
  b) is effectively implemented and maintained.

What is an Internal Audit?

Definitions from the Standards

ISO 13485:2016 Section 8.2.4 Internal audit (Continued)

- The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.
- An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

What is an Internal Audit?

Definitions from the Standards

ISO 13485:2016 Section 8.2.4 Internal audit (Continued)

- Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained.
- The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

Importance of Conducting Internal Audits

- Provides outline to monitor procedure and product at planned intervals within the company.
- Helps the organization's capability to address product safety and effectiveness.
- Ensures compliance to internal procedures and applied regulatory requirements.
- Find and address opportunities for improvement before an external audit.

Preparation for a Successful Internal Audit Program

Establishing Procedures for Internal Audits

Create Dedicated Quality System Procedures for Audits

- Outline Scope and Applied Regulations/Standards
- Outline Roles for Employees involved in Audit Process
- Describe Audit Procedure

Audit Forms

- Best Practices
- Create an Audit Checklist
- Address entire scope of the audit
- Outline Each Section of the Quality System
- Provide Space to Document Audit Findings

Audit Checklist Example

	Document Number:	SOP-010-C
	Version:	0
	INTERNAL AUDIT CHECKLIST	

Purpose	
Scope	
Contact	
Criteria	
Auditor	
Date	

13485:2016 CLAUSE	21 CFR 820 SECTION	REQUIREMENT	DOCUMENT REFERENCE	CONFORMANCE		
				Y	N	N/A
1.1	N/A	Detail countries/ regions where devices designed and manufactured under this QMS are planned to be sold.		Detail relevant information in Requirement Column		
1.2	N/A	Application				
		Are any exclusions/ nonapplications limited to clause 6, 7, or 8; not customer and/or regulatory requirements; and permitted regulatory exclusions not covered by (if appropriate), defined, and justified in the Quality Manual?		☐	☐	☐
		Detail exclusion and nonapplications by clause number		Detail relevant information in Requirement Column		

Additional Forms

Audit Forms for Expanded Scope

- Create forms specific to additional regulations for products under CE Mark or MDSAP. This allows for the separation of products that may be sold in different markets.

Audit Report Form

- Develop Forms for the Audit Report outline to ensure all sections are covered in the report.
- Include a cover letter for the audit report.

Additional Forms

Audit Plan

- Planning your audit schedule is also part of the FDA and ISO Requirements
- Larger Companies – Internal Audit must be split between separate days or months
  - Ensures all sections are properly audited
  - This should be clearly defined in the Audit Plan
- Smaller and startup companies – Plan will not be as detailed but is still required
  - Plan can be detailed in the Management Review Minutes if a dedicated form is not required
- Ensure the plan meets your requirements and scope
- Any changes to the plan should be approved

Additional Forms

Audit Plan

- Risk based scheduling
  - Processes being audited
  - Results of previous audits
- Recommend annual internal audit for start-up companies
- Document record and communicate to department managers
  - Ensures all sections are properly audited
  - This should be clearly defined in the Audit Plan
- Ensure the schedule addresses entire scope

Explaining the Internal Audit Process

Conducting the Audit

Audit Logistics

- Announcement of Audit by Lead Auditor
- Identifying the Audit Team and Location
- Determining the Audit Dates and Location
- Provide a designated area for the audit to take place, meeting room, or office

Opening Meeting

- Review of audit process and key definitions
- Introduction to audit team
- Overview of audit schedule
- Record of attendees

Conducting the Audit

Initial Document Review

- Reviewing procedures for each section
- Document effective date and revision of procedures reviewed
- Ensure documents are compliant with standards and scope
- Provide supporting documentation as requested

Conducting the Audit

Record Review

Many sections of the audit will require review of actual records created within the quality system. This includes:

- QC Test Records
- Labelling and Packaging verification
- Traceability Review
- Sterilization Logs
- Records of Customer Feedback/Complaints
- Document Control and Storage
- Training Records

Conducting the Audit

Validation / Design Control / Risk Management

Records for Validation, Design Control, and Risk Management should be reviewed during the audit as well.

- Internal Audits are based on sampling
  - Not all records or reports can, or will, be reviewed during the audit
- Special Audits can be conducted to focus more directly on Validations, Design Control, and Risk Management
- Confirm evidence of risk management throughout the processes being audited
- During the audit, document specific reports and files that were reviewed

Conducting the Audit

CAPAs / Complaints

Records for CAPAs, Customer Feedback, and Complaints should be reviewed during the audit as well.

- Internal Audits are based on sampling
  - Not all records or reports can, or will, be reviewed during the audit
- Confirm that established procedures are being accurately followed
- Confirm records of investigation are sufficient for the risk of the event
- During the audit, document specific reports and files that were reviewed

Conducting the Audit

Closing Meeting

- Audit purpose, scope, and summary
- Rating criteria for findings
- Clear communication and discussion of audit findings
- Record of attendees

Professionalism During Audit Process

- All parties involved should participate in a professional manner and remember that the overall goal of the audit is to ensure patient safety and company compliance.
- Treat the internal audit like an external regulatory audit from the FDA or Registrar to provide additional practice for your company.

Handling Audit Findings

Identifying Audit Findings

Observation definition

- A problem of minor nature that does not directly affect the system, product, or process; a suggestion for improvement that does not require the creation of a CAPA

Non-conformance definition

- An identified problem where a product, process, or document does not meet expected or pre-determined requirements.

Addressing Audit Findings

Risk Based Actions for Findings

- The severity determination – tied to the Risk associated with finding
- NCRs with high risk to patient safety should be corrected ASAP
- CAPA record should be assigned and due dates identified in the report
- Multiple findings of a similar nature can be grouped into one CAPA record.
- We encourage companies to separate CAPAs into defined levels that identify timeframes for completion based on risk associated with finding.

Verification of Correction

- Specialized audits – conducted to verify the CAPA associated with any audit findings
  - Focus only on the area affected by the NCR
  - Used to verify effectiveness of the CAPA after a defined timeline for implementation

Handling Audit Findings

Audit Findings Notification

- When identified, the Audit finding should be communicated immediately to the responsible department or employee.
- Audit findings may be communicated during the audit when they are found, and again during the closing meeting

Level Determination

- More records / documentation will be requested when an Audit finding is identified
  - Additional records help to determine extent of non-conformities
  - Severity of the finding does not have to be determined immediately, but is required in the audit report

Audit Report

Audit Report Format

- Cover Letter
- Details of Audit Participants, Location, Date
- Audit Summary
- Audit Details
- Audit Findings
- Assignment of CAPAs
- Gap Analysis

Audit Summary

- Summation of the Audit, Scope, Sections Audited, and Findings.
- Should provide a clear description of the entire audit and findings.
- Does not require detailed descriptions of SOPs or Records Reviewed

Audit Details

- Detailed account of the entire audit.
- Describes each section reviewed with SOP numbers, effective date, and revision.
- Lists of lot numbers, validation reports, and test data reviewed should all be listed in the audit report.
- Audit findings should be listed in the section they were found as well as in the Audit Findings Section.

Audit Findings and CAPA Assignment

- Detailed description of each finding.
- Determination by the Lead Auditor of the level of Finding, Non-Conformity (High, Medium, Low) or Observation.
- Assignment of the department head or employee responsible for the CAPA.
- Timeline for CAPA completion and verification
- Action Plan

Gap Analysis

- Often when a major change to the QMS is being conducted a Gap Analysis is required to determine all of the gaps and prioritize them.
  - This can be conducted for changes to standard (MDR, 14971:2019), scope expansion to a foreign market, or revisiting older records that were not completed properly.
- Design Control and Risk Management for DHF / TF is a major source of Gap Analysis questions.
- Once the Gaps have been identified, they should be documented in the Audit Report and a timeline for completion should be created.
  - This timeline should be based on a Risk Analysis of the Gaps with the higher risk Gaps addressed first.

Internal Audits: Common Mistakes

Common Mistrakes- er, "Mistakes"

- Auditor audits their own work
- Internal audit findings not properly addressed, leading to repeat findings in external audits
- Audit scope does not address entire scope of the QMS or additional regulations
- Audit team includes auditors who have not been trained to the internal audit SOP
- Audit findings not closed
- Internal audits not conducted within the timeframe identified in audit schedule or SOP

Contact Rook for your Auditing Needs

www.RookQS.com
Make sure to visit our website to learn more about our services and consulting team.

Contact **info@rookqs.com** for more questions, comments, or to set up a meeting. One of our consultants will be sure to reach out to assist!

Questions?

To Get Your Free QMS Audit Consult and Checklist, Go To:

https://calendly.com/rookqualitysystems/internal-audit-consult