Mastering Your Next Audit:
Proven Strategies for Success

Presented By Kyle Rose, CEO of Rook Quality Systems

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Rook Quality Systems

Rook Quality Systems is a consulting firm dedicated to helping startup to Fortune 500 medical device companies develop and maintain effective and efficient quality systems.

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

Webinar Agenda

1. Preparing for an FDA Inspection
2. Preparing for an ISO Audit
3. FAQs
4. Q/A

FDA Inspections

FDA Inspections - Discussion Points

- Understanding what happens during an FDA Medical Device QMS Inspection
- FDA QSIT Methodology
- What FDA Inspectors look for
- What happens at the conclusion of an FDA Inspection

What Happens During an FDA Medical Device QMS Inspection?

→ **There are simply too many medical device manufacturers for FDA to inspect annually.**
- FDA prioritizes its limited inspection staff according to the risk posed by manufacturers and their devices.

→ **In general, Class II and III manufacturers can expect an FDA visit every two years.**
- The risk-based approach means companies with new or existing Class III devices are the highest priority, especially those making implantable and life-supporting devices.

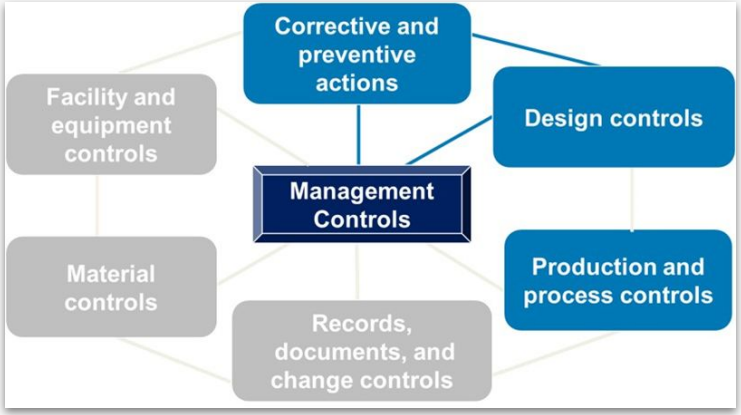
→ **Class II manufacturers (the bulk of the volume) are next in line, along with any companies that have recently introduced a device via the 510(k) process.**
- Occasionally, FDA will inspect higher-risk Class I manufacturers, distributors, and contract manufacturers.

FDA QSIT Methodology

→ QSIT stands for **Quality System Inspection Technique**
- FDA document describing the way FDA approaches inspections of Quality Management Systems (QMS).
- Defines the FDA approach of focusing on reviewing procedures and then examining records associated with them.

→ **The QSIT process focuses on four main subsystems** (as shown in blue in the adjacent image) with the ultimate question being: **"Did the management team provide the necessary resources to establish and maintain an effective QMS?"**
- The other three subsystems are reviewed via links with the four main subsystems.
- All seven subsystems orbit around Management Controls.

The Seven QMS Subsystems

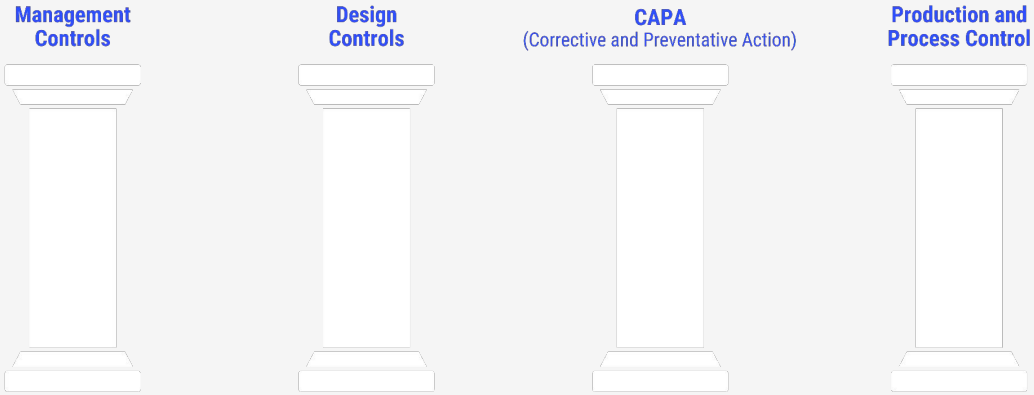


What Are FDA Inspectors Looking For?

→ **FDA Inspections begin with a review of your procedures related to the seven subsystems.**
- Following the review of the procedure, the inspector dives into a random sampling of associated records.
- The inspector(s) may dig deeper beyond their initial sample if they find an area of concern.

→ **As they proceed through the inspection, they will point out any identified Form 483 observations in real time.**
- These are more serious areas of concerns rather than “discussion items,” which get documented in the final report but could later be elevated to observations.

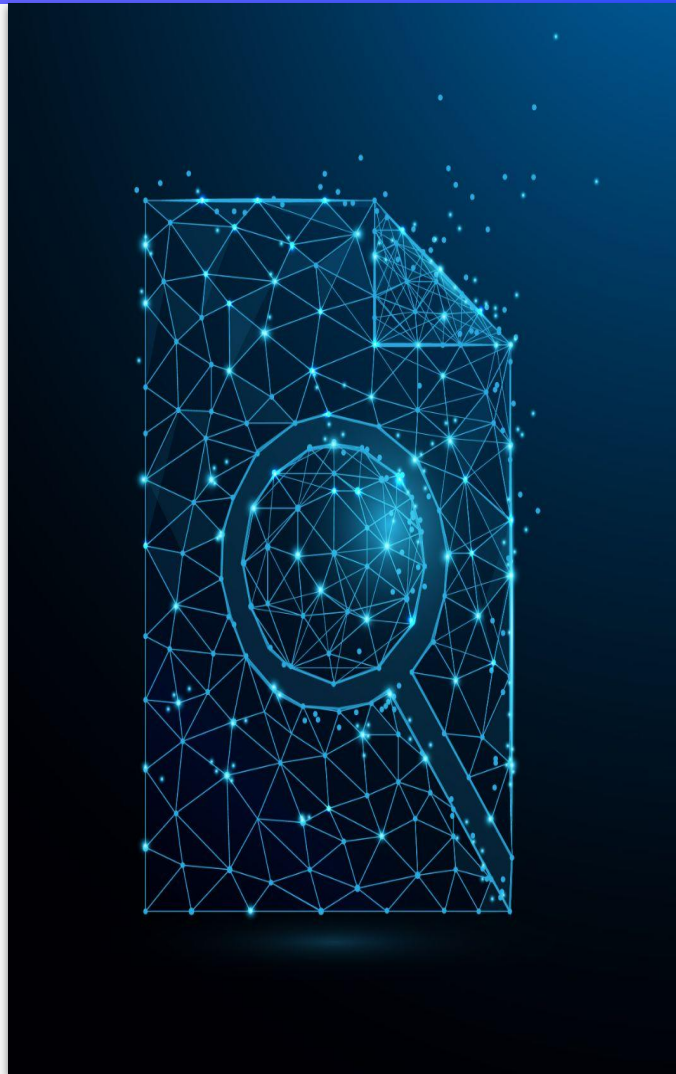
Four Pillars of the Audit



During the Audit

Ensuring the audit progresses in a timely fashion is critical for FDA audits.

- → Attempt to discuss the plans for the audits and what records the auditor would like to review in the next session / days of the audit.
- → FDA Audits can extend past set deadlines and can in some cases go on for more than one week.
- → FDA Auditors have authority to look at financial data regarding sales and clients so don't be surprised if that is requested.
- → Schedules for FDA audits might also be affected by other priorities so there may be a day or two break in the audit and then the auditor will return to finish.
- → Auditors can also request files to be reviewed offline outside of audit hours as well.



Conclusion of the Audit

At the conclusion of what is sure to be an exhausting and stressful week for you, the investigators will meet with management to review all observations and discussion points.

→ The inspectors will give management an opportunity to defend or clarify their position and will document everything in an Establishment Inspection Report (EIR).

→ **BE CAREFUL** in what is said while attempting to defend your position.

- It can often be more harmful than good.
- Ask questions for understanding rather than defending nonconforming findings.

You can request a copy of your EIR within 60 days. If things did not go well, the inspectors may issue an FDA Form 483.

→ You will have 15 days to respond to the FDA Form 483.
→ Failure to respond will lead to the FDA taking further action.

ISO Audits

ISO Audits - Discussion Points

- What is an ISO audit?
- Who is subject to ISO audits?
- Different types of ISO audits
- How to prepare for an ISO audit
- Conducting an ISO audit
- What happens after an ISO audit?

What is an ISO Audit?

→ ISO Audits are performed by accredited registrars to verify your compliance with a particular ISO standard in order to issue ISO certifications.

- For Medical Device manufacturers, the QMS is audited to ISO 13485:2016.

→ These certifications are an easy way to demonstrate QMS effectiveness to customer and regulatory requirements.

→ ISO 13485:2016 has overlap with 21 CFR Part 820, but there are some key differences.

- A successful ISO audit does not guarantee a successful FDA inspection.
- Likewise, a successful FDA inspection does not result in a successful ISO audit.

Who is Subject to ISO Audits?

Being subject to ISO Audits is dependent upon your target markets and business agreements.

- → In the United States, these audits / certifications are completely optional. QMSR alignment will require compliance in the future but not a certification.
- → In Canada, ISO 13485:2016 compliance is mandatory, but there is a different audit / certification process (MDSAP).
- → In the European Union, ISO 13485:2016 is the only recognized QMS standard for medical devices.
    - While technically voluntary, it is **HIGHLY** encouraged.
- → Some customers may require you to maintain an ISO certification as a business requirement.

The Different Types of ISO Audits

→ **Initial Certification**
- **Comprised of two different audits – Stage 1 and Stage 2.**
- Stage 1: Used to determine readiness and plan for the Stage 2 audit. Not all QMS records are required.
- Stage 2: All relevant QMS records are required and reviewed. Following a successful Stage 2 audit, the organization received their QMS certification.

→ **Surveillance Audits**
- **Required annually.**
- These audits review management, previous nonconformities, and a sample of your QMS processes.

→ **Recertification Audits**
- **Required every three years.**
- Includes full review of management, the QMS, and previous nonconformities.
- More burdensome than surveillance audits.

Stage 1 vs Stage 2 ISO Audits

Initial Certification Audits

- → **Stage 1:** Used to determine readiness and plan for the Stage 2 audit. Not all QMS records are required.
- → Stage 1 is a review of the high-level SOPs to ensure you are ready for Stage 2 and have an established QMS.
- → Auditors will also review that a Management Review meeting and Internal audit have been completed.
  - If these are scheduled to be done before Stage 2 but not complete that is fine as well.
- → Typically, there are no findings in Stage 1 only a recommendation to move to Stage 2 or a not ready indication.
- → If you do not complete your Stage 2 audit within a certain time frame you may be required to conduct another Stage 1.
  - Can range from 90 days to 6 months depending on registrar.
- → Stage 1 audits should be able to completed in 0.5 - 1 day.

Stage 1 vs Stage 2 ISO Audits

Initial Certification Audits

- → **Stage 2:** All relevant QMS records are required and reviewed. Following a successful Stage 2 audit, the organization receives their QMS certification.
- → Stage 2 is the deep dive into the actual records showing compliance to the standards / regulations as well as your SOPs.
- → Records should be reviewed prior to the audit and prepared based on the audit plan to expedite the process.
- → Stage 2 typically takes 2 - 5 days depending on the size of the company.
- → The audit plan provided by the auditor will outline the topics covered each day and the estimated time for review.
- → In some cases, the contract manufacturer will need to be audited as well during your initial Stage 2 audit.
- → You do not have to be finished with Design V&V to achieve ISO certification.

How to Prepare for an ISO Audit

→ **Familiarize yourself with ISO 13485:2016**
- The standard can be a very dry read. We recommend attending a training session.

→ **Review the audit plan**
- This will be provided by your registrar in advance of the audit.

→ **Determine responsibilities for the audit**
- Based on the audit plan, assign who will represent which functions / processes during the audit, who will gather additional records when required, and who will be the lead auditee(s).

→ **Prepare your documentation in advance**
- This will save time and resources during the audit and allow you to review relevant records prior to review by an auditor.

→ **Relax!!!**
- Auditors are not there to look for nonconformities. This goal is to find evidence of conformity.

Preparing Your Documentation

Have the following documents / records reviewed and prepared in advance:

- → Quality Manual & Quality Policy
- → Organizational Chart & Training Records
- → Relevant SOPs & Work Instructions
- → Management Review Agenda / Report
- → Internal Audit Plan / Reports
- → Document Approvals & Change Orders
- → Design & Risk Files (MDF, DHF, DMR, RMF)
- → Purchasing Records (Approved Supplier List, Quality Agreements, P.O.s)
- → Production / Inspection Records (DHRs, Batch Records, Test Records)
- → Calibration / Preventive Maintenance Records
- → Nonconformities & CAPAs (including nonconformities from previous audit)
- → Complaints & Adverse Event Reports

Conducting an ISO Audit

DO:

- → Prepare the documentation well in advance.
- → Ensure you have an adequate environment for the audit (including a functional virtual environment, if applicable).
- → Be respectful to the auditor.
- → Provide all requested documentation.
- → Be prepared to point to corresponding records for various procedures.
- → Only provide what is requested (virtual environments can make this a challenge).
- → Answer all questions honestly.

DO NOT:

- → Try to talk your way out of clear nonconformities.
- → Overshare with the auditor (including screen-sharing in virtual environments).
- → Leave the auditor waiting for documents, records, or answers.

What Happens After an ISO Audit?

Following the ISO Audit closing meeting, you will receive an Audit Report.

- → The Audit Report contains the results of the audit, including any nonconformities and response due dates.
- → Auditors should communicate nonconformities to you as they are detected and at the closing meeting, so nothing in the Audit Report should come as a surprise.

Nonconformities are categorized into one of the following categories:

- → Major Nonconformity: A failure which represents the total breakdown of the QMS or one of its processes.
- → Minor Nonconformity: A failure to conform to a requirement that is not likely to result in a failure of the QMS.

What Happens After an ISO Audit?

- → All nonconformities listed in the Audit Report must be resolved.
- → This is accomplished by feeding the nonconformities into your CAPA process.
  - Determine if any immediate actions are necessary based upon risk.
  - Perform a thorough investigation and root cause analysis.
  - Plan and implement corrective actions.
  - Verify these corrective actions.
  - Prepare records of these activities for review by your ISO registrar.

What Happens After an ISO Audit?

Major Nonconformities:

- → Must be verified to be resolved by your registrar PRIOR to receiving any certification or recertification. In some instances, this may require an additional on-site visit.
- → Recommendation for certification / recertification follows the acceptance of the evidence of the actions taken.
- → Stricter timeline for action implementation and review.

Minor Nonconformities:

- → Must have an accompanying corrective action plan which is provided to the registrar for review.
- → Recommendation for certification / recertification follows the acceptance of this plan.
- → The implementation and effectiveness of this plan will be verified at the next audit.

FAQs

- Am I required to be inspected by the FDA?
- Can you “fail” an FDA inspection?
- How do I prevent an FDA warning letter?
- How do I resolve 483s?
- Do I need to have an ISO certification?
- Who performs ISO audits?
- Can you “fail” an ISO audit?
- How do I resolve nonconformities?

FAQs

Am I required to be inspected by the FDA?

→ **If you are a manufacturer of medical devices, you are subject to an FDA inspection.**

- This includes contract manufacturers, design specification developers, repackagers, relabelers, and contract sterilizers.
- The FDA had limited resources, so a risk-based approach is taken.
- The CDRH selects a few high-risk Class I firms each year.
- Class II and III manufacturers are subject to biennial inspections.

FAQs

Can you “fail” an FDA inspection?

→ **The FDA can leverage various actions against manufacturers who fail to meet requirements such as:**

- FDA Form 483
- Warning Letters
- Seizure / Injunction
- Fines / Criminal Charges

→ The FDA typically starts with Form 483 and escalates their actions based on their further engagements with the manufacturer.

FAQs

How do I prevent an FDA warning letter?

→ **Take your Form 483 seriously!**

- Failing to adequately resolve observations listed on Form 483 can and will lead to a Warning Letter.

→ **Be cautious of claims made online.**

- Websites and marketing material for medical devices are considered device labeling and subject to FDA regulation.
- Making unsupported claims online can lead to a Warning Letter.

FAQs

How do I resolve 483s?

→ **Feed your Form 483 observations into your CAPA process and take action without delay.**

- Determine corrections, root cause, and corrective actions for each observation.
- Implement and verify the corrections / corrective actions as necessary.

→ **Provide the corrections / corrective action evidence to the FDA contact listed on your Form 483.**

- For issues that may take a while, provide status updates to the FDA every 30 days.

FAQs

Do I need to have an ISO Certification?

- → **United States – Optional but encouraged.**
- → **Canada – Yes**
  - Canada requires a MDSAP certification which includes ISO and FDA requirements.
- → **European Union – Legally, no. Practically, yes.**
  - The E.U. MDR requires manufacturers to establish a QMS and ISO 13485:2016 is the only recognized QMS standard.
- → **Most Other Countries – Legally, yes.**
  - Many countries require an ISO certificate for all imported medical devices.

FAQs

Who performs ISO audits?

→ **ISO Audits are performed by an accredited registrar, also called an accredited certification body (CB).**
  - These organizations are recognized for their competence to audit and issue certification that an organization meets the requirements of a particular ISO standard.

→ CBs are accredited to perform audits / issue certifications for certain (not all) standards.

→ There are many different options for CBs, and you get to choose.
  - If you are in the E.U., this will likely be your notified body.

FAQs

Can you “fail” an ISO audit?

- → **Minor nonconformities** are not considered an audit “failure,” as these will not delay your certificate if you provide an adequate corrective action plan to the registrar.
- → **Major nonconformities** can cause delays to your certification / recertification, as any associated corrective actions must be verified, not just the plans.
  - You have an opportunity to resolve major nonconformities, so this is still not a “failure” in the traditional sense.
- → Your registrar will work with you to communicate expectations for the resolution of nonconformities.

FAQs

How do I resolve nonconformities?

→ **Feed your Audit Report nonconformities into your CAPA process and take action without delay.**

- Determine corrections, corrective actions, root cause, and due dates for each observation. This is your action plan.

→ **Provide the corrections / corrective action evidence to your registrar.**

- For minor nonconformities, you provide the action plan immediately. Actions are reviewed at the next audit.
- For major nonconformities, your must provide all evidence for review prior to your next audit.

Look To Rook!

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

Contact info@rookqs.com for a copy of our Pre-Audit Checklist to ensure you are ready for your next audit!