AUDIT INTERVIEW GUIDE

50+ Typical Auditor Questions with Best Practice Answers

Introduction

This guide prepares your team for internal and external audits by providing typical auditor questions and guidance on how to respond effectively. Remember: Auditors are looking for evidence that your QMS is implemented and working, not perfection.

KEY INTERVIEW PRINCIPLES

✓ Answer only what is asked - do not volunteer extra information
✓ If you don't know, say so and offer to find the right person
✓ Show, don't just tell - have evidence ready
✓ Be honest about problems and how you addressed them
✓ Stay calm and professional - auditors are not adversaries

1. General QMS Questions

Question	Best Practice Answer
Can you show me where to find the quality policy?	Point to posted policy, intranet, or ID badge. Key: Know where it is, not recite it verbatim.
How is the quality policy relevant to your job?	Explain how your specific tasks contribute to product quality and customer satisfaction.
What are the company's quality objectives?	Know at least 2-3 objectives and where they are tracked (dashboard, reports, etc.).
How do you know if you're meeting quality objectives?	Reference KPIs, metrics, or reports you regularly review. Show a recent example.
Where is the Quality Manual?	Know the location in your document management system. Show how to access it.

2. Document Control Questions

Question	Best Practice Answer
How do you know you're using the current version of a procedure?	Explain your DMS (version control, approval dates, revision history). Show an example.
What do you do if you find an outdated document?	Report to QA/document control, dispose of printed copy properly, get current version.
How are document changes communicated?	Training notifications, email alerts, change history summary, affected personnel sign-off.
Can you show me your training record for this procedure?	Know where training records are stored. Access your own record and demonstrate.
How long do you retain records?	Know the retention policy (typically device lifetime + 5 years for MedTech).

3. Training & Competence Questions

Question	Best Practice Answer
What training have you received for your role?	List key trainings: role-specific, GMP/QMS, procedures relevant to your tasks.
How is training effectiveness evaluated?	Tests, practical demonstrations, supervisor sign-off, on-the-job assessments.
What happens if someone isn't qualified to do a task?	They can't perform the task until trained. Supervision or reassignment until qualified.
How do you know which procedures apply to your job?	Training matrix, job description, onboarding, supervisor guidance.

4. CAPA Questions

Question	Best Practice Answer
What is CAPA and when would you initiate one?	Corrective/Preventive Action. For systemic issues, repeat problems, audit findings, serious NCs.
How do you determine root cause?	5 Why analysis, Fishbone diagram, fault tree. Key: Document the methodology used.
How do you verify CAPA effectiveness?	Defined criteria, monitoring period, evidence that problem doesn't recur, formal closure.
Can you show me a closed CAPA?	Know where to find CAPA log. Show complete record with root cause, action, verification.

5. Nonconformance Questions

Question	Best Practice Answer
What do you do if you find a defective component?	Stop work, segregate the item, label it, notify supervisor/QA, document on NC form.
How is nonconforming product prevented from use?	Quarantine area, hold labels, system blocks, physical segregation, QA approval required.
What disposition options exist for NC product?	Rework, use-as-is (concession), scrap, return to supplier. All require documented approval.
When does an NC require a CAPA?	Repeat occurrences, systemic issues, high-risk impact, customer complaints, regulatory findings.

6. Production & Process Control Questions

Question	Best Practice Answer
How do you verify you're using the correct materials?	Check part numbers, lot/batch numbers against work order/BOM, incoming inspection records.
How is equipment calibration managed?	Calibration schedule, stickers with due dates, out-of-tolerance notifications, calibration records.
What would you do if calibration is due/overdue?	Don't use equipment, notify QA, assess impact on product tested since last calibration.
Show me the Device History Record for lot X.	Know where DHRs are stored. Be able to retrieve and walk through components.
How is traceability maintained?	Lot/serial numbers, work orders, batch records, component tracking from receiving to shipment.

7. Design Control Questions

Question	Best Practice Answer
Where are design requirements documented?	Design input documents, requirements specification, user needs in DHF.
How do you verify design outputs meet inputs?	Verification testing, traceability matrix linking inputs to outputs to verification evidence.
How are design changes controlled?	Design change request, impact assessment, review/approval, revalidation if needed.
How is risk management integrated into design?	Risk analysis per ISO 14971, linked to requirements, risk controls in design outputs.

8. Supplier Management Questions

Question	Best Practice Answer
How are suppliers qualified?	Risk-based evaluation, questionnaire/audit, quality agreements, performance monitoring.
How do you ensure supplied materials meet requirements?	Incoming inspection, CoC/CoA review, supplier audits, defined specifications.
What happens when a supplier issue is identified?	NC documentation, SCAR if systemic, re-evaluation, supplier corrective action tracking.
Where is the approved supplier list?	Know the location in QMS. Show current list with approval status and scope.

9. Cross-Functional Questions (Design ↔ Risk ↔ CAPA)

These questions assess integration between QMS processes - a key focus area for experienced auditors:

#	Question	Expected Answer	Red Flag Answer
1	How does your risk management process feed into design reviews?	Risk analysis reviewed at each design phase; risk controls verified before release	*"We do risk management separately at the end"*
2	When a CAPA identifies a design-related root cause, how is it escalated?	Design change process triggered; risk file updated; DHF amended	*"We handle it in CAPA only"*
3	How do you ensure post-market feedback updates your risk analysis?	Complaint trending feeds back to risk file; annual risk review process	*"The risk file is frozen after product launch"*
4	Can you show me a CAPA that resulted in a design change?	[Should provide documented example with traceability]	*"That hasn't happened"* or unable to provide example
5	How do you verify that risk controls are effective after a CAPA?	Effectiveness check includes risk re-assessment; updated residual risk documented	*"We close CAPAs without updating the risk file"*

10. Red Flag Answers (What Auditors Don't Want to Hear)

These responses trigger deeper investigation. Train your team to avoid them:

Topic	Red Flag Response	Why It's a Problem
Training	*"Everyone knows what to do"*	No documented evidence of competency assessment
Document Control	*"We always use the latest version"*	No visible version control system or distribution log
CAPA	*"We don't have many CAPAs"*	May indicate under-reporting culture or weak problem identification
Complaints	*"We rarely get complaints"*	Possible gaps in customer feedback collection mechanisms
Risk Management	*"It's all in the risk file"*	Static document; not a living, updated analysis
Supplier Quality	*"We trust our suppliers"*	Inadequate supplier controls, no incoming inspection data
Calibration	*"We send it out for calibration"*	No internal oversight, status tracking, or certificate review
Change Control	*"We just update it when needed"*	No formal change management process; uncontrolled changes

Audit Interview Do's and Don'ts

DO ✓	DON'T ✗
Be honest - even about problems	Make excuses or blame others
Answer only what is asked	Volunteer unnecessary information
Say 'I don't know, let me find out'	Guess or make up answers
Show documented evidence	Say 'we always do it this way'
Stay calm and professional	Become defensive or argumentative
Admit when a process needs improvement	Hide problems or mislead the auditor
Ask for clarification if needed	Interrupt the auditor
Know where to find documents	Panic if you can't find something immediately

Mock Interview Script (15 Minutes)

Use this to practice before audits:

Time	Questions to Ask
0-3 min	What is your role? How long have you worked here? Can you show me the quality policy?
3-6 min	Walk me through a typical task you perform. What procedure do you follow? Show me.
6-9 min	What training did you receive? How do you know this is the current version? Show records.
9-12 min	What would you do if you found a defective part? How would you report it? To whom?
12-15 min	What are the quality objectives for your area? How do you contribute to them?

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