

Mock Inspection Kit: companion guide

A clear, practical rehearsal plan for your inspection team: assign roles, locate controlled records, answer with evidence and turn drill findings into accountable improvements.

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Workbook + guide · \$299 USD one-time · Applicable taxes may apply

Online guide: <https://medtech.cahir.ai/mock-inspection-guide>

In this guide

1. Start here: rehearse the evidence, not a script
2. Orient the exercise to the six QMS areas
3. Your workbook map
4. Step 1: build a calm, accountable inspection team
5. Step 2: map the records before testing speed
6. Step 3: run the request drill and interview rehearsal
7. Step 4: add the device-specific questions that matter
8. Step 5: turn the rehearsal into improvement
9. Common questions during a first drill
10. Vetted references and next reading

Start here: rehearse the evidence, not a script

A mock inspection is an internal rehearsal of how your organization explains its QMS and retrieves supporting evidence. The Cahir MedTech CP 7382.850 Mock Inspection Kit helps coordinate that exercise; it is not an FDA inspection checklist or a promise of what an investigator will request.

FDA's QMSR took effect February 2, 2026. FDA now uses CP 7382.850 for medical-device inspections rather than QSIT. The program describes a risk-based approach, not a fixed order that every inspection follows. Choose an exercise scope based on your devices, risks, site and inspection history. [FDA QMSR overview](#) · [CP 7382.850](#)

Save a controlled working copy of the workbook. Set the exercise scope and date, choose a mock investigator sufficiently independent of the processes reviewed, and appoint a lead. The existing Mock Inspection workbook starts with Request Log; unlike some other Cahir workbooks, it does not contain a separate Universal Baseline tab. Use the core tabs as the common workflow, then add relevant category overlays.

- Define the site, devices and processes covered.
- Assign primary and backup roles with contact details.
- Choose evidence samples based on risk and relevance.
- Confirm current record access and locations.
- Set internal drill targets and a debrief time.
- Protect authentic records; keep the exercise distinct from an actual FDA inspection.

Orient the exercise to the six QMS areas

CP 7382.850 organizes inspection coverage into six QMS areas. The workbook uses some practical labels: CAPA and feedback corresponds mainly to Measurement, Analysis, and Improvement; Production and process controls sits within Product and Service Provision. Use the official names when mapping your coverage and preserve the workbook's row identifiers.

Official CP 7382.850 area	Evidence trail to rehearse — examples, not exhaustive
Change Control	A change from rationale and risk review through V&V, approval and release
Design and Development	User need, design input/output, verification, validation and transfer records
Management Oversight	Quality objectives, management review, internal audits and decisions
Measurement, Analysis, and Improvement	Complaint / feedback signals, investigation, CAPA and effectiveness
Outsourcing and Purchasing	Supplier selection, risk-based controls, monitoring and outsourced-process oversight
Product and Service Provision	Production, validation, acceptance, traceability, installation and service as applicable

The program also considers four Other Applicable FDA Requirements: medical device reporting, corrections and removals, unique device identification, and tracking. Assess applicability rather than assuming each applies to every device. Part 821 tracking, for example, is not universal for implants. FDA can choose applicable areas and evidence based on risk and inspection type. [CP 7382.850](#)

The former 21 CFR 820.180(c) exception for management-review, internal quality-audit and supplier-audit reports was not retained in QMSR. Do not treat those records as categorically exempt from FDA review. Ensure your team can identify and retrieve them and knows how to route actual requests for appropriate review. [QMSR final rule](#)



Your workbook map

Prepare the roster and retrieval list before the drill. During the exercise, keep one Request Log and use the interview prompts to test whether people can explain the evidence, not memorize a model answer.

Tab	What you complete	What it gives the team
War-Room Roster	Primary, backup and contact channel for every role	Clear ownership and coverage
Retrieval Tracker	Record location/system, pre-staged status, reviewer and revision	A reliable route to authentic current records
Request Log	Time requested, runner, target, status, delivered time and notes	A trace of each request and any delay
Interview Guide	Rehearsed? field for management, CAPA, design, suppliers and complaints	Evidence-backed conversations and identified gaps
SaMD / IVD / Implantable / Capital Equip / Consumable Overlay	Rehearsal status for applicable device prompts	Device-specific coverage without irrelevant checks
Sources and Applicability	References, scope notes and limitations	A starting point for checking requirements

The mock workbook's request/question prompts and core structure are protected. Use the unlocked fields to record outcomes. Put additional exercise questions or findings in controlled drill notes and link their IDs in Notes or the team workspace; do not delete branding or hidden identifiers to customize the sheet.

Step 1: build a calm, accountable inspection team

In War-Room Roster, assign a primary and backup for each role. The inspection lead is the main contact; the scribe records requests and answers; the back-room coordinator assigns retrieval tasks and reviews document relevance; runners retrieve controlled records; SMEs explain their processes; the regulatory lead evaluates FDA-specific questions; and the executive sponsor supports management oversight.

Practice what happens when two requests arrive together, a record cannot be located or an SME is unavailable. Agree one channel for requests so parallel messages do not produce duplicate or inconsistent answers. The team's purpose is to provide complete, accurate information—not obstruct access, conceal records or coach misleading answers.

A useful opening check is to ask each backup to retrieve one record without assistance from the primary. If access depends on one person, record the continuity gap and owner. Use real access controls; do not copy sensitive files to uncontrolled personal folders for convenience.

Step 2: map the records before testing speed

In Retrieval Tracker, record the system and exact location, pre-staged status, reviewer and last revision for each document. The starter list covers the quality manual, management review, CAPA, complaint records, design history, supplier controls, validation, change control and internal audits. Choose samples relevant to your products and scope; the seeded requests are rehearsal examples, not mandatory FDA sampling periods.

Check that the record is authentic, complete and the appropriate approved revision. Distinguish a current procedure from historical records generated under an earlier revision. Link the evidence trail across

processes—for example, a complaint to investigation, reportability decision, risk review and any corrective action. Do not revise or recreate historical evidence to make a drill appear successful.

Retrieval problem	Appropriate drill response
Record not found	Log the missing record, owner, location searched and follow-up
Multiple revisions	Identify the controlled version and explain historical context
Access blocked	Route to an authorized record owner; preserve access controls
Scope unclear	Ask a clarifying question and record the agreed scope
Delay	Log why, who is resolving it and the next status update

Reviewing records before delivery checks relevance and completeness; it must not become a reason to suppress unfavorable evidence. Handle actual inspection requests using applicable requirements and your organization's reviewed procedures.

Step 3: run the request drill and interview rehearsal

For each Request Log row, record Time requested, Runner, Target (min), Status and Time delivered. Use Notes for clarification, delay reasons and references to controlled drill findings. The starter 15/30-minute targets are suggested internal exercise goals, not FDA deadlines. Adjust them to your systems and scope. The workbook does not automatically judge inspection readiness or calculate an FDA outcome.

For an illustrative drill, ask for the most recent applicable process validation report. The runner locates the controlled report; the SME explains the validation decision, acceptance criteria, results, deviations and approvals. The scribe records whether the explanation matches the evidence and whether the requested scope was met.

Use Interview Guide to rehearse concise answers: answer the question asked, name the process owner, explain the actual process and offer relevant records. If uncertain, say what needs checking and locate the right evidence. Avoid speculation, unsupported opinions and rote answers. Mark Rehearsed? only after the discussion; it means the rehearsal occurred, not that the process is compliant.

- Management: connect quality objectives, review outputs and follow-up decisions.
- CAPA owner: trace the issue, investigation, action and effectiveness evidence.
- Design lead: show how changes are assessed, verified/validated and approved.
- Supplier quality: explain the risk basis for selection and monitoring.
- Complaint handler: show documented reportability decisions and timing.

Step 4: add the device-specific questions that matter

Select only applicable overlay prompts. Use documented applicability decisions, not a device label alone. Some examples invoke standards or expectations that depend on device characteristics; check current regulations, commitments, recognized standards and source notes before treating a prompt as mandatory.

Overlay	Rehearsal focus	Evidence examples
SaMD	Current release anomalies, third-party software and vulnerability monitoring	Release records, anomaly evaluation, SBOM and triage where applicable
IVD	Lot genealogy and labeled performance/stability	Material records, CoAs and stability protocols/data
Implantable	Sterilization evidence and tracking where required	Validation/requalification and applicable tracking records
Capital Equip	Service-to-complaint review and installation controls	Service trends, installation acceptance and approvals
Consumable	Critical-process control and packaging/shelf life	Process data and applicable aging/integrity evidence

Do not assume ISO 11607 applies to all packaging or Part 821 to every implant. Document why a prompt is applicable or not applicable in your controlled exercise notes. Use the workspace item notes for short rationale and references while maintaining detailed evidence in your QMS.

Step 5: turn the rehearsal into improvement

Hold a debrief after the exercise. Separate retrieval delays, explanation/training gaps and potential QMS nonconformities. Record the evidence, scope, owner, next action and target date for each finding. Use your controlled nonconformity and corrective-action procedures to decide whether CAPA is appropriate; a mock observation does not automatically require CAPA or constitute an FDA Form 483.

Track assignments and progress in the team workspace. Item notes can capture a short decision and a controlled evidence reference; activity history helps colleagues see updates. The dashboard checklist does not edit the downloaded workbook. Reconcile both with approved QMS records rather than treating a percentage complete as a compliance score.

- Every request has a recorded outcome or follow-up.
- Missing or conflicting evidence has an accountable owner.
- Interview gaps have appropriate training or process actions.
- Potential nonconformities are assessed under the QMS.
- Actions have dates, evidence and any necessary effectiveness checks.
- Management reviews significant risk and unresolved issues.
- A focused repeat drill checks whether the identified weaknesses improved.

Common questions during a first drill

Do we have to deliver every document in 15 or 30 minutes?

No. These are adjustable internal drill targets, not FDA requirements. Accurate, complete and authentic evidence matters more than meeting an arbitrary timer. Record delays and work on their cause.

Can we use the kit as our entire internal audit program?

No. An inspection rehearsal is not a substitute for the internal-audit requirements and controlled audit program applicable to your QMS. It can reveal weaknesses that inform that program.

Can we skip management review and internal audit records?

Do not rely on the former QS regulation's audit-records exception; it was not retained in QMSR. Include current record-location checks and appropriate review of actual requests.

What if a protected cell will not accept a new question?

Use the unlocked outcome fields and controlled drill notes for added scenarios. Preserve branding, structure and hidden identifiers. Ask [Cahir MedTech](#) if a required input field is inaccessible.

Does a successful rehearsal guarantee a favorable inspection?

No. FDA's inspection scope, evidence selection and conclusions depend on the facts and applicable requirements. The exercise improves coordination and exposes gaps; it cannot predict or guarantee the outcome.

Vetted references and next reading

References reviewed for this edition on October 29, 2026. The workbook's roles, retrieval targets, samples and drill sequence are Cahir MedTech recommendations. FDA sources and current regulations establish the applicable context; use an authorized ISO 13485:2016 copy for exact incorporated clause text.

- [FDA CP 7382.850](#) — current medical-device inspection program, QMS areas and risk-based coverage.
- [FDA QMSR overview](#) — February 2, 2026 effective date and replacement of QSIT.
- [Current 21 CFR Part 820](#) — incorporated QMS and FDA-specific requirements.
- [QMSR final rule](#) — regulatory changes, including removal of the former audit-records exception.
- [FDA CDRH compliance programs](#) — role and scope of compliance programs.
- [21 CFR Part 821](#) — device tracking, where applicable.

Continue with [the six QMS areas](#), [QMSR implementation](#), and the [Form 483 Response companion guide](#). [Cahir MedTech Copilot](#) can help organize preparation material; qualified people must verify it against actual evidence.

This guide is an educational and operational aid, not an FDA publication, legal advice or a substitute for applicable requirements and inspection-specific facts. It does not establish compliance, guarantee a classification or prevent enforcement. Consult qualified regulatory and legal advisers as appropriate.