

Turn quality issues into clear, owned action.

The Quality Management Buyer Guide is for quality, regulatory and operations teams choosing quality management software (QMS): how issues, evidence, owners, corrective and preventive actions (CAPA) and effectiveness checks should connect — and where people must decide.



The issue-to-closure map

What each stage should record, and the decisions that stay with people.

Documents to suppliers

Revisions and training, deviations, out-of-spec results and CAPA, audits, complaints and supplier quality.

Evaluation tools

Requirement vs workflow vs lab-system table, risk-based evaluation steps, decision checklists, RFP and scoring.

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Who this is for

Quality managers, regulatory and compliance leads, and operations teams moving from spreadsheets, email and shared drives — or from a standalone QMS disconnected from production — in food, supplements, pharma, devices, chemicals, cosmetics and other regulated manufacturing.

How to use it

- Pick one real quality event from last year and use it in every demonstration.
- Use page 8 to separate what the law asks, what your procedure configures, and what needs a laboratory system.
- Score suppliers on page 11 with your own event, not a scripted one.

Important. A QMS supports your procedures; it does not decide root causes, product disposition or compliance. This guide is not legal or regulatory advice.

1 • THE PROBLEM

Why quality systems stall

Quality events rarely fail on the first step. They fail in the middle — evidence chased by email, actions without owners, and closures nobody checks.

WHERE IT STALLS	TYPICAL CAUSE	WHAT THE SYSTEM SHOULD PROVIDE
Evidence chased	Event logged apart from the batch, lot or document it concerns	Issue linked to the production record, lot, step, document or supplier
Investigation drifts	No structure; root cause by opinion	Structured investigation with root-cause method your procedure uses
Actions orphaned	Actions in meeting notes or a separate tracker	Each action has a named owner, due date and status
Overdue work invisible	No escalation	Overdue items visible to owners and managers
Closed but recurs	Closed on completion, not effectiveness	Effectiveness check with criteria, before closure
Change without training	SOP revised; people still on the old version	Revision triggers training before people can work to it
Audit scramble	Evidence spread across drives	Records retrievable with their audit trail

The outcome to buy. Every issue has evidence attached, an owner and a due date, and is closed only when a person confirms it worked.

Beware form builders. Configurable forms are useful, but ask to see the links: from the issue to the lot, and from the action to the effectiveness check.

2 • THE EVIDENCE MAP

From issue to closure

The same pattern applies to deviations, complaints, audit findings and out-of-spec results. Ask suppliers to show each stage with your event.

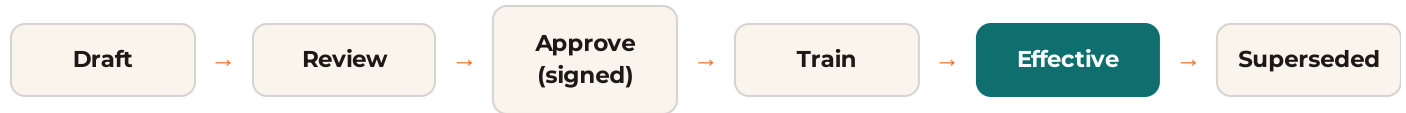
1	Issue raised From the floor, the lab, a customer, an audit or a supplier	RECORDED What, where, when, who raised it, initial risk	WHO DECIDES Anyone authorised; triage by quality
2	Containment Immediate action to protect product and people	RECORDED Holds, segregation, correction taken	WHO DECIDES Quality / supervisor
3	Evidence linked Batch record, step, lot, document, supplier, equipment	RECORDED Links to source records, attachments	WHO DECIDES Investigator
4	Investigation Root cause using your procedure's method	RECORDED Method, findings, root cause, impact assessment	WHO DECIDES Investigator; reviewed by quality
5	Owner and actions Corrective and preventive actions planned	RECORDED Action, owner, due date, linked changes and training	WHO DECIDES Quality approves the plan
6	Actions done Changes made, people trained	RECORDED Completion evidence per action	WHO DECIDES Action owners
7	Effectiveness check Agreed criteria checked after a defined period	RECORDED Criteria, data reviewed, result	WHO DECIDES Quality
8	Human closure Decision recorded with signature and meaning	RECORDED Closure decision, signer, date/time	WHO DECIDES Authorised quality person — never automatic

Ask: "From this closed CAPA, show me the deviation, the lot it affected, the SOP revision it changed, who was trained, and the evidence that it worked."

3 · DOCUMENTS & TRAINING

Documents, revisions and training

Controlled documents are where quality meets the floor. A revision is only effective when the right people have been trained on it.

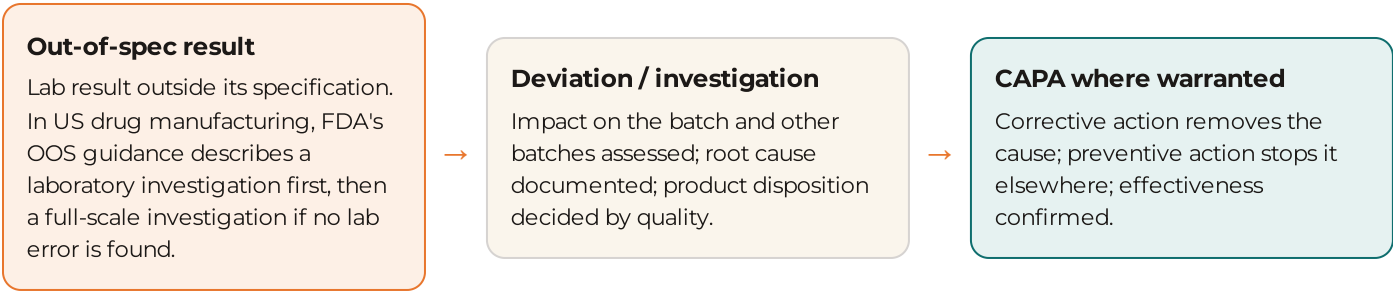


CHECK	WHAT GOOD LOOKS LIKE	OK
One current revision	Only the effective revision is available for use; superseded versions are retained but marked.	☐
Approval with signature	Approvers sign with meaning; approval routes follow your procedure.	☐
Change reason	Each revision records why it changed and links to the CAPA or change request.	☐
Training assignment	A new revision assigns training to the affected roles.	☐
Training before work	Where you require it, people cannot perform the task until trained on the current revision.	☐
Periodic review	Review dates are tracked and overdue documents are visible.	☐
Retrieval	Any past revision and its approval history can be produced for an audit.	☐

DOCUMENT TYPE	TYPICALLY CONTROLS	LINKED TO
SOPs and work instructions	How tasks are done	Training, execution steps, CAPA
Specifications	Materials, products, tests	Receiving, lab results, release
Master records / formulas	What is made and how	Work orders, change control
Forms and templates	What evidence is captured	Records produced

Deviations, out-of-spec results and CAPA effectiveness

Treat these as linked workflows, not separate registers. An out-of-specification (OOS) result or deviation should lead naturally to an investigation and, where needed, to CAPA.



EFFECTIVENESS CRITERION	EXAMPLE	GOOD EVIDENCE
Recurrence	No repeat of the same deviation on any line for 3 months	Deviation trend filtered by cause
Process measure	Seal check failures back within the normal range	In-process check data
Training	All affected operators trained on revision D before working	Training records vs roster
Audit	Follow-up audit finds the control in place	Audit record
Supplier	Next 5 deliveries meet the specification	Receiving inspection and CoA data

Define criteria when you plan the action, not when you close it. "Training done" is completion, not effectiveness.

AI can help, people decide. Suggested classifications or draft investigations save time only if an investigator reviews and owns them.

Audits, complaints, supplier quality and traceability

Audits

Internal and supplier audits planned, performed and recorded; findings routed to the right workflow — nonconformance, CAPA, hold or training — with owners.

Complaints

Intake with product, lot and customer; investigation linked to the production record; trend by cause; reportability assessed by your team.

Supplier quality

Qualification, approved status, certificates and their expiry, ongoing monitoring and scorecards; corrective action requests to suppliers.

TRACEABILITY QUESTION	WHY QUALITY NEEDS IT	ASK THE SUPPLIER TO SHOW
Which lots used this raw material lot?	Scope a supplier problem or recall	Forward trace from a receipt
Which materials went into this finished lot?	Investigate a complaint	Backward trace from a finished lot
Where did this lot ship?	Notify customers	Shipments by lot
Which records relate to this lot?	Investigation and audit	Batch record, deviations, results, holds in one place
CHECK	WHAT GOOD LOOKS LIKE	OK
Complaint to lot	A complaint can be linked to the lot and its production record in a few clicks.	☐
Finding to action	An audit finding becomes a tracked action with an owner, not a note.	☐
Supplier status at receiving	Material from an unapproved or suspended supplier is visible at goods-in.	☐
Holds	Placing a lot on hold prevents its use until quality releases it.	☐

Requirement, workflow or lab system?

Three different things often get blurred in QMS evaluations. Keep them apart to avoid buying the wrong thing — or assuming software satisfies a rule by itself.

Regulatory requirement
What applicable law or standard expects — e.g. investigating unexplained discrepancies, handling complaints, CAPA in a device QMS. Set by the regulator; interpreted by you.

Configured workflow
How your procedure carries it out in software: states, approvals, fields, owners, due dates. Product capability plus your configuration.

Specialist laboratory features
Sample lifecycle, instrument integration, method management, stability studies, statistical rules. Often a LIMS — confirm scope and plan separately.

TOPIC	REQUIREMENT EXAMPLES	WORKFLOW YOU CONFIGURE	MAY NEED LAB FEATURES
Deviations	21 CFR 211.192; EU GMP Ch. 1	Triage, investigation, approval route	—
OOS results	FDA OOS guidance (drugs)	Phase I / II investigation records	Results capture, instrument data
CAPA	21 CFR 820 via ISO 13485 §8.5; ICH Q10	Actions, owners, effectiveness	—
Complaints	21 CFR 211.198; EU GMP Ch. 8	Intake, investigation, trending	—
Documents & training	21 CFR 211.25, 211.100; ISO 13485 §4.2, 6.2	Revision, approval, training routes	—
Stability	21 CFR 211.166	Schedules, review	Stability studies, pull schedules

Citations are examples, not a complete legal list, and vary by product and market. Your regulatory team decides which apply.

7 • EVALUATION WORKFLOW

Risk-based evaluation and validation

Spend testing effort where an error could harm a patient, consumer or product — not evenly across every screen. ICH Q9(R1) and EU GMP Annex 11 both describe a risk-based approach.

STEP	WHAT YOU DO	OUTPUT
1. Intended use	Write what the QMS must do, for which products, sites and processes.	Intended-use statement
2. Risk assessment	Rank functions by impact: release, holds, CAPA closure, document effectivity rank high.	Risk-ranked function list
3. Supplier assessment	Review the supplier's quality system, development and testing evidence.	Supplier assessment record
4. Configure	Set workflows, roles, approvals and fields to your procedures.	Configuration specification
5. Test	Test high-risk functions with real scenarios, including negative tests.	Test evidence
6. Release for use	Approve with a summary; train users.	Validation summary
7. Keep it controlled	Assess supplier updates and your configuration changes before use.	Change records

TEST	WHAT GOOD LOOKS LIKE	OK
Negative tests	A held lot cannot be released; an untrained user cannot sign; a CAPA cannot close without an effectiveness result.	☐
Audit trail	Changes to quality records show old and new values, who, when and why.	☐
Signatures	Signature meaning and the signed record are linked.	☐
Updates	You know when the supplier changes the software and can assess impact.	☐

Decision checklists and RFP questions

DECISION	WHO SHOULD OWN IT	WHAT THE SYSTEM SHOULD RECORD
Is this a deviation, and how serious?	Quality	Classification and rationale
What is the root cause?	Investigator, reviewed by quality	Method, evidence, conclusion
What happens to the product?	Authorised quality person	Disposition with signature
Is CAPA needed?	Quality	Decision and reason
Did the action work?	Quality	Effectiveness result against criteria
Can this be closed?	Authorised quality person	Closure signature with meaning

Links and evidence

- Show an issue linked to the batch record, lot, step and document.
- How are attachments and source records protected from change?
- Can quality records be retrieved with their audit trail for an inspection?

Owners and closure

- How are owners, due dates and escalations set?
- Can a CAPA close without an effectiveness check? Who decides?

Documents and training

- Does a new revision assign training automatically?
- Is training checked before people work to the procedure?

Scope and deployment

- Which lab features (sampling, OOS, stability, instruments) are included, and on which plan?
- Supplier audits and scorecards: included or separate?
- Deployment options, update cadence and validation support?

9 • SCORING

Scored evaluation

Score each system 0–3 during demonstrations (0 = not shown, 3 = shown with your own event and data).

AREA	WHAT TO SEE DEMONSTRATED	SYSTEM A	SYSTEM B
Your event, rebuilt	A real deviation or complaint from raise to closure.	_____	_____
Evidence links	Issue linked to lot, record, step, document, supplier.	_____	_____
Owners	Named owners, due dates, overdue visibility.	_____	_____
Effectiveness	Criteria set at planning; checked before closure.	_____	_____
Human closure	Signed decision with meaning; no automatic closure.	_____	_____
Documents	Revision approved, training assigned, old revision retired.	_____	_____
Training gate	Untrained person blocked or flagged.	_____	_____
Audits & suppliers	Finding routed to action; supplier status visible.	_____	_____
Complaints	Complaint linked to lot; trend by cause.	_____	_____
Traceability	Forward and backward trace from a lot.	_____	_____
Lab scope	OOS and lab features in scope, or clearly not.	_____	_____
Total (0–3 each)		_____	_____

Tip. Ask for the audit trail of the record you just watched being created. Real systems show it immediately.

Where V5 fits, and sources

- **Quality events:** deviations, CAPA with a root-cause workflow, customer complaints intake and investigation, change control with impact assessment and approvals, and risk management. Quality management is included from Professional; confirm plan inclusion for each feature.
- **Documents and training:** controlled SOPs and work instructions with revisions; training records per revision and a skills matrix (Enterprise). Whether training status restricts a task depends on your set-up; confirm it in evaluation.
- **Audits and suppliers:** internal and supplier audits whose findings route to nonconformance, CAPA, hold or training; supplier qualification and monitoring; scorecards.
- **Records:** audit trail and electronic signatures; linked lots and production records for traceability; a QA release queue where a person decides.
- **Laboratory:** basic lab and QC (sampling, methods, results, OOS workflow) and fuller laboratory features (LIMS, stability) are listed; confirm which plan includes them — specialist lab scope is often Enterprise.
- **Validation:** IQ/OQ and validation support is offered with Enterprise. Your own validation decides your validated state.

Primary sources, reviewed 1 October 2026. Rules apply by product and market; check the current version.

Laws and regulations (binding where they apply)

- **US 21 CFR Part 11 — electronic records and signatures** — www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11
- **US 21 CFR Part 211 — drug CGMP (incl. 211.192 investigations, 211.198 complaints)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211
- **US 21 CFR Part 820 — device Quality Management System Regulation (incorporates ISO 13485)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820
- **US 21 CFR Part 117 — human food preventive controls (incl. corrective actions)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117

Guidance

- **FDA Part 11 Scope and Application guidance** — www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application
- **EudraLex Volume 4 — EU GMP Part I (incl. Ch. 1, 4, 8) and Annex 11** — health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
- **ICH quality guidelines (Q9(R1) risk management, Q10 pharmaceutical quality system)** — www.ich.org/page/quality-guidelines
- **FDA Investigating Out-of-Specification (OOS) Test Results guidance** — www.fda.gov/regulatory-information/search-fda-guidance-documents/investigating-out-specification-oos-test-results-pharmaceutical-production-level-2-revision
- **FDA Quality Management System Regulation (QMSR) overview** — www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr

Voluntary standards (binding only when adopted by a regulator or customer)

- **ISO 13485:2016 — medical device quality management** — www.iso.org/standard/59752.html
- **ISO 9001:2015 — quality management systems** — www.iso.org/standard/62085.html

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