

Decisions you can show your evidence for.

For quality, operations and IT teams choosing software for management review, laboratory results, approved suppliers and controlled customer document sharing — and the evidence that connects them.



Four workflows, one evidence map

Review inputs, lab results, supplier approvals and shared documents, with who owns and who decides.

Worked examples you can replay

A quarterly review, an out-of-specification result, a lapsing certificate and a customer lookup.

Questions that expose gaps

RACI, implementation steps, RFP questions and a scored checklist for each area.

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Who this is for

Quality heads, laboratory managers, supplier quality and purchasing leads, customer service teams and IT. Use the sections you need; each area stands alone, and page 15 shows how they connect.

Important. This guide explains workflows and evidence for software evaluation. It is not legal or regulatory advice and does not say which rules apply to your products or markets. Software records evidence; qualified people make approval, laboratory and release decisions.

1 • THE PROBLEM

Why quality evidence goes missing

Most gaps found in audits are not missing work. The work happened; the evidence is scattered, late, or can't be tied to the decision it supported.

AREA	WHAT USUALLY GOES WRONG	WHAT GOOD EVIDENCE LOOKS LIKE
Management review	Slides rebuilt from spreadsheets; actions agreed but never followed	Inputs drawn from records, decisions minuted, actions with owners and due dates carried to next review
Lab results	Results typed late against the wrong limit; retests overwrite originals	Result against the approved specification, original kept, second-person review recorded
Out of specification	Investigation in email; outcome not linked to the lot	Result, investigation and decision linked to the same lot record
Approved suppliers	List approves a supplier, not a supplier for a material	Approval scoped to supplier × material, with evidence and validity dates
Supplier evidence	Certificates expire unnoticed	Expiry visible before it lapses; what happens next follows your procedure
Customer documents	Requests by email; wrong revision sent	Only approved, current documents shared; withdrawals and deliveries logged

The outcome to buy. Any decision — approve, release, accept, share — traceable in a few clicks to the evidence and the person who made it.

Avoid buying a dashboard. Charts summarise. Ask to open the record behind one number and see who entered it, when, against which version.

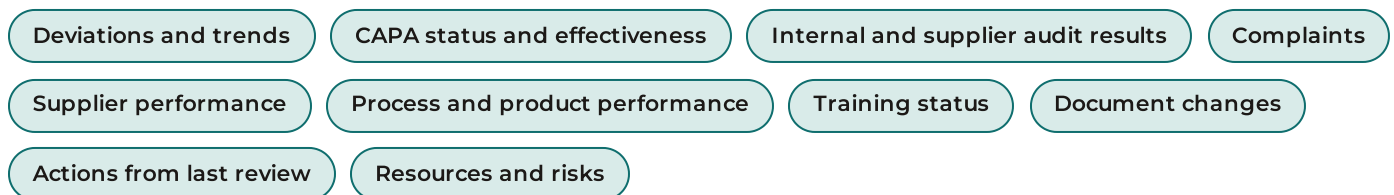
2 • MANAGEMENT REVIEW

From inputs to owned decisions

A management review is useful when it ends with decisions and actions that someone owns — not when it produces a deck.

1	Agenda set Standing items plus anything escalated	RECORDED Agenda, attendees, period covered	WHO DECIDES Review chair
2	Inputs gathered Deviations, CAPA status, audit results, complaints, supplier and process performance	RECORDED Linked records and figures for the period	WHO DECIDES Owners of each area
3	Prior actions checked Status of actions from the last review	RECORDED Open / closed / overdue, with evidence of closure	WHO DECIDES Action owners
4	Discussion Trends, risks, resource needs	RECORDED Notes against each input	WHO DECIDES Attendees
5	Decisions recorded What leadership decided and why	RECORDED Decision text, rationale, who approved	WHO DECIDES Management
6	Actions raised Each with an owner, due date and link to the decision	RECORDED Action records (CAPA where appropriate)	WHO DECIDES Management assigns
7	Follow-up Actions tracked to closure and reviewed next time	RECORDED Closure evidence, effectiveness where relevant	WHO DECIDES Action owners; chair checks

Typical inputs



Check your standard. The required inputs and outputs differ by framework (for example ISO 9001 clause 9.3, ISO 13485 clause 5.6, or ICH Q10 for pharmaceutical quality systems). Map your own list; no software template satisfies a standard by itself.

3 • WORKED EXAMPLE

A worked quarterly review

Fictional site, review MR-Q4. Figures are invented for illustration and are consistent across this page.

INPUT	FROM THE RECORDS	DISCUSSION POINT
Deviations	14 opened, 11 closed; 5 linked to one filling line	Recurring filler deviations
CAPA	9 open, 2 overdue	Overdue CAPA on label changeover
Audits	1 internal, 1 supplier; 6 findings, 1 major	Major finding: supplier certificate control
Complaints	3, all packaging	Linked to the same filler
Supplier performance	Supplier C: 2 late certificates	Approval scope review
Prior actions	7 from MR-Q3: 5 closed, 2 open	Both open actions re-dated with reason

Decisions and actions

DECISION	ACTION	OWNER	DUE	LINKED TO
Investigate filler as one problem, not five	Open CAPA for filler root cause	Engineering lead	15 Jan	5 deviations, 3 complaints
Tighten supplier certificate follow-up	Review Supplier C approval scope	Supplier quality	31 Dec	Audit finding, supplier record
Add capacity for CAPA closure	Assign second reviewer	Quality head	10 Dec	Overdue CAPA

What makes this auditable. Every figure opens to its records; every action links back to the decision and forward to its closure evidence.

Ask in a demo: "Show me last quarter's open action, who owns it, and the evidence that will close it."

4 • LAB RESULTS

Specifications, entry and review

A result is only as good as the specification, method and sample it was recorded against.

Specification			Sample and method			Result and review		
Approved limits per test and product or material, with revision and effective date.			Which lot, which sample plan, which approved method and instrument.			Value, unit, who entered it and when; a second person reviews before it is used.		
1	Sample plan triggered	From receipt, production step or schedule	RECORDED	Lot, plan, sample ID	WHO DECIDES	Configured by the lab		
2	Request queued	Tests listed against the approved method	RECORDED	Test list, method revision, due time	WHO DECIDES	Lab supervisor		
3	Result entered	Against the specification in force	RECORDED	Value, unit, analyst, time, instrument	WHO DECIDES	Analyst		
4	Compared with limits	Within / outside specification shown	RECORDED	Status against limit revision	WHO DECIDES	Displayed, not decided		
5	Second-person review	Check data, calculation and method	RECORDED	Reviewer, time, comments	WHO DECIDES	Reviewer		
6	Available to release review	Reviewed results as inputs	RECORDED	Linked to lot and CoA inputs	WHO DECIDES	Qualified release person decides		

CHECK	WHAT GOOD LOOKS LIKE	OK
Limits versioned	Specification revision visible on every result.	☐
Original values kept	Corrections and retests never overwrite the first result.	☐
Units explicit	Result unit matches the limit unit, or conversion is visible.	☐
Review separate from entry	The analyst cannot be the only reviewer, where your procedure requires.	☐

5 · OUT OF SPECIFICATION

When a result is out of specification

Software should make the out-of-specification result impossible to miss and easy to investigate. It should not decide the outcome.

Worked example: incoming lot RM-2290, assay

STEP	RECORD	WHO
First result	Assay 96.1% against 97.0–103.0% — outside specification; original value kept	Analyst
Laboratory check	Calculation, sample preparation, instrument and calibration status checked	Analyst + supervisor
Investigation opened	Linked to the lot and the result; reason and scope recorded	Lab supervisor
Retest (if your procedure allows)	Retest recorded as a new result with reason; first result still visible	Analyst, per procedure
Conclusion	Investigation outcome and rationale	Qualified reviewer
Lot disposition	Accept, reject or further action, as your procedure defines	Qualified person — never automatic
Follow-up	Deviation or CAPA where needed; supplier informed	Quality

Good practice to look for. The out-of-specification flag, the investigation and the decision live on the same lot. Retests add records; they never replace them.

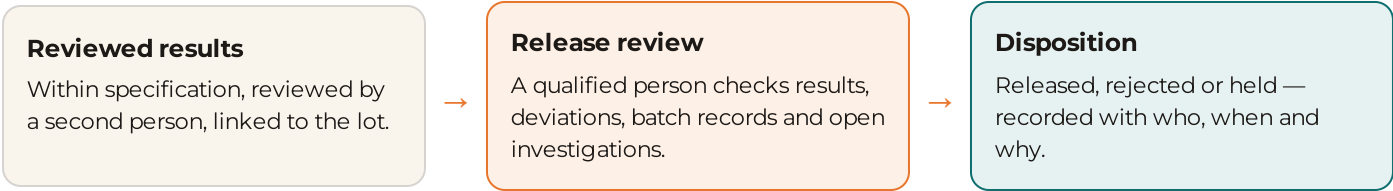
Context. Regulators publish expectations for investigating out-of-specification results in pharmaceutical settings (FDA OOS guidance, see sources). Other sectors set their own rules. Your lab procedure governs.

Questions for the demo

- Enter an out-of-specification value. What changes on screen, and who is notified?
- Record a retest. Can an auditor still see the first result, and why it was retested?
- Show the investigation linked to the lot and the deviation, if one was raised.

Release boundaries and certificates of analysis

Lab software supplies reviewed evidence to release. People release.



TOPIC	BUYER REQUIREMENT	CHECK IN EVALUATION
Release decision	Made and signed by an authorised person	Who can release; what they must see first
Open investigations	Visible at release review	How an open investigation appears to the reviewer
Certificate of analysis	Built from reviewed results and approved template	Which fields come from results; who approves before it is issued
Supplier CoA values	Captured for review, not trusted blindly	How supplier values are entered or extracted and checked
Electronic signatures	Meaning, date and signer recorded where required	Signature manifestation on reports
Trends and stability	Trends reviewed by qualified people	Which trend rules exist; who acts on a signal

Avoid any proposal where a system "releases automatically when results pass". Automatic comparison against limits is useful; disposition remains a human decision under your quality system.

7 • APPROVED SUPPLIERS

Scope of approval: supplier × material

"Approved" is meaningless without "for what". Approve a supplier for specific materials, sites and grades, against the evidence your procedure requires.

SUPPLIER	MATERIAL	SITE	STATUS	KEY EVIDENCE	VALID UNTIL
Supplier A	Sugar, granulated	Plant 1	Approved	Questionnaire, spec, audit	Mar 2027
Supplier A	Cocoa powder	Plant 1	Conditional	Spec agreed; audit pending	Jan 2027
Supplier C	Surfactant blend	Plant 2	Approved	Certificate, spec, CoA history	30 Nov 2026
Supplier C	Fragrance oil	—	Not approved	No evidence submitted	—
Supplier D	Corrugated cases	Plant 1	Approved	Spec, food-contact declaration	Jun 2027

Requirements by kind of supplier

Raw materials

Specification, questionnaire, certificates your procedure requires, CoA expectations, audit or assessment.

Packaging

Specification, declarations relevant to use (for example food contact), artwork control where applicable.

Services

Scope, qualifications, insurance or certifications your procedure lists.

Check. Whether an unapproved supplier can be selected on a purchase order or received at goods-in depends on the system and its configuration. Ask to see exactly what happens; don't assume a block.

8 • SUPPLIER EVIDENCE

Evidence, expiry and performance

Approval is a state that decays. Keep evidence dated, expiry visible and performance in front of the people who review it.

1	Requirements set Template per supplier category	RECORDED Required documents, checks, validity rules	WHO DECIDES Supplier quality
2	Evidence collected From supplier, by portal where configured, or uploaded	RECORDED Document, issuer, date, validity	WHO DECIDES Supplier / buyer
3	Assessment Evidence reviewed against requirements	RECORDED Reviewer, comments, risk rating	WHO DECIDES Supplier quality
4	Approval Scoped to supplier × material	RECORDED Status, scope, approver, date	WHO DECIDES Authorised approver
5	Monitoring Expiry dates, late documents, receipt issues, audit findings	RECORDED Due list, performance figures	WHO DECIDES Supplier quality
6	Re-review Periodic or triggered by an event	RECORDED Outcome; status change with reason	WHO DECIDES Authorised approver

PERFORMANCE SIGNAL	WHERE IT COMES FROM	TYPICAL USE
Late or missing documents	Evidence due dates	Prompt follow-up; review scope
Receipt issues	Goods-in checks, rejections	Supplier scorecard; SCAR where needed
CoA discrepancies	Lab comparison with supplier CoA	Testing frequency decisions
Audit findings	Supplier audits	Approval conditions; re-audit

9 • WORKED EXAMPLE

A lapsing certificate, worked through

Supplier C is approved for surfactant blend at Plant 2. Its certificate expires on 30 November.

WHEN	WHAT THE RECORD SHOWS	WHO ACTS
1 Nov (30 days before)	Certificate appears on the due list	Supplier quality requests renewal
15 Nov	Request outstanding; status unchanged	Buyer informed of upcoming lapse
30 Nov	Certificate expired; shown beside approval	Supplier quality applies your procedure
1 Dec	Approval set to conditional, with reason	Authorised approver
3 Dec	Purchase order raised; approval status visible beside the supplier	Buyer decides per procedure
8 Dec	New certificate received and reviewed	Supplier quality
8 Dec	Approval restored; history keeps both states	Authorised approver

What makes this defensible. The lapse was visible in advance, the status change has a reason and a person, and history shows every state.

Your procedure decides what a lapse means — conditional use, increased testing, hold, or no new orders. Configure the rule; don't let software invent one.

Ask in a demo

- Show me every approval with evidence expiring in the next 60 days.
- Open Supplier C's approval history. Who changed it, when and why?
- Raise a purchase order and receive a delivery from a conditional supplier. What does each person see?

Customer document sharing: what, who, when

Customers and their auditors ask for certificates, specifications and pack documents. Share only what has been approved for them, and know exactly what they saw.

DOCUMENT	SHARED WITH	APPROVED BY	TRIGGER
Certificate of analysis	Customer receiving the lot	Quality, after review	Lot shipped and CoA approved
Product specification	Customers buying the product	Quality / technical	On approval of revision
Pack documents	Customer receiving the shipment	Shipping / quality	At dispatch
Certificates (site/product)	Named customers	Quality head	On issue or renewal
Batch records	Normally not shared	—	Only by deliberate decision, outside routine sharing

Access principles to decide first

CHECK	WHAT GOOD LOOKS LIKE	OK
Who gets access	Named contacts per customer; access set and removed by your team.	☐
What each sees	Their own orders, shipments, lots and approved documents only.	☐
Read-only	Customers view and download; they cannot change records.	☐
Auditors	Given a read-only view where you choose, scoped like the customer.	☐
Notifications	Which events send an email, and whether deliveries are logged.	☐

Security. Ask how customer separation is implemented and tested, and request the supplier's security documentation. This guide does not describe or assess any product's internal architecture.

11 • REVISION AND EVALUATION

Revision, withdrawal and evaluating a portal

The riskiest moment in document sharing is a change: a new revision, a corrected certificate, or a document that must be withdrawn.



SITUATION	WHAT SHOULD HAPPEN	EVIDENCE TO KEEP
New specification revision	Old revision no longer offered; new one shared after approval	Who approved, when, which customers can see it
Corrected certificate	Original withdrawn with reason; corrected version shared	Both versions, reason, notification
Customer contact leaves	Access removed promptly	Who removed it, when
Document shared in error	Withdrawn; impact assessed	What was visible, to whom, for how long

Portal evaluation criteria

AREA	WHAT TO SEE DEMONSTRATED	SYSTEM A	SYSTEM B
Scope	Customer sees only own orders, lots and approved documents.	_____	_____
Approval gate	Nothing appears before approval.	_____	_____
Revisions	Superseded documents no longer offered.	_____	_____
Withdrawal	Withdraw with reason; history kept.	_____	_____
Access admin	Add/remove contacts; review who has access.	_____	_____
Notifications	Configurable events; delivery logged.	_____	_____
Branding	Your name and look.	_____	_____
Security evidence	Documentation on separation and testing provided.	_____	_____
Total (0–3 each)		_____	_____

12 • WORKED EXAMPLE

A customer lookup, worked through

A quality contact at Customer A needs the certificate for Tuesday's delivery.

1	Signs in Branded, read-only portal	RECORDED Contact, time	WHO DECIDES Your team set the access
2	Finds shipment SH-3302 Order SO-2187, 40 cases Product A	RECORDED From the shipping record	WHO DECIDES —
3	Opens lot L-5498 Lot recorded at shipping	RECORDED Lot link	WHO DECIDES —
4	Downloads the CoA Approved certificate, current revision	RECORDED Download logged	WHO DECIDES Quality approved it earlier
5	No email to your office Routine request answered without staff time	RECORDED —	WHO DECIDES —

What the customer cannot see

- Other customers' orders or lots
- Unapproved or draft documents
- Batch records, unless you deliberately decide otherwise
- Internal investigations and comments

What your team can see

- Who has access, per customer
- Which documents are shared, by revision
- Notification deliveries
- Withdrawals and their reasons

Only recorded lots appear. A portal can show only what was recorded at shipping. If lot capture at dispatch is incomplete, fix that first.

13 • CONNECTIONS

The connected evidence map

The four workflows feed each other. When they live in one system, the trail from decision to evidence stays intact.

FROM	FEEDS	EXAMPLE
Lab results	Release review, CoA, supplier performance	Out-of-specification assay on a supplier lot
OOS investigation	Deviation, CAPA, management review	Root cause at supplier → SCAR
Supplier approvals	Purchasing, receiving visibility, management review	Conditional status visible on PO
Audit findings	CAPA, supplier approval, management review	Major finding on certificate control
Approved documents	Customer portal	Current CoA and specification shared
CAPA status	Management review	Overdue CAPA discussed and re-assigned
Training and document control	All of the above	Only trained people review results

One thread, worked through: lot RM-2290 from Supplier C fails assay → investigation finds supplier cause → deviation and SCAR raised → Supplier C's approval set to conditional → discussed at MR-Q4 → action owned by supplier quality → closure evidence reviewed next quarter. Every step links to the last.

Roles and responsibilities (RACI)

R = does the work · A = accountable / decides · C = consulted · I = informed. Adapt to your organisation.

ACTIVITY	QUALITY HEAD	LAB	SUPPLIER QUALITY	PURCHASING	CUSTOMER SERVICE	SITE LEADERSHIP
Set management review agenda	R	C	C	I	I	A
Approve review decisions	C	I	I	I	I	A
Enter lab results	I	R	—	—	—	—
Review lab results	A	R	I	—	—	—
Decide OOS outcome	A	R	C	—	—	I
Release / disposition	A/R	C	I	—	I	I
Set supplier requirements	A	C	R	C	—	—
Approve supplier for material	A	C	R	I	—	—
Act on lapsed evidence	A	—	R	C	—	—
Approve documents for sharing	A	C	—	—	R	—
Grant/remove customer access	C	—	—	—	R	A
Withdraw a shared document	A	C	—	—	R	I

Implementation plan and data to prepare

Start where the evidence gap hurts most. Each area can go live separately.

PHASE	SCOPE	DATA TO PREPARE	DONE WHEN
1 • Foundations	Users, roles, sites, document control, training	Org chart, role matrix, controlled procedures	Reviewers trained on procedures in the system
2 • Suppliers	Categories, requirements, approvals	Supplier list, materials, current evidence and expiry dates	Every active supplier × material has a status
3 • Laboratory	Specifications, methods, sample plans	Approved specs and methods with revisions	One material and one product tested end to end
4 • Management review	Inputs, agenda, actions	Last two reviews' actions; KPI definitions	Next review run from records
5 • Customer sharing	Portal access, document approval, notifications	Customer contacts, document list per customer	One customer self-serves a CoA

Migration and validation responsibilities

- **You decide** which historical records to migrate and how to verify them; keep legacy records accessible for their retention period.
- **You validate** the system for your intended use where your regulations require it, using a risk-based approach. Ask the supplier what documentation and services they provide and in which plan.
- **Test with real cases:** a past OOS, a lapsed certificate, last quarter's review and a real customer request.

RFP questions and scored checklist

Management review

- Which inputs come from records, and which are typed in?
- How are decisions and actions linked and followed to closure?

Laboratory

- How are specification revisions applied to results?
- How are retests and corrections kept beside originals?
- What does a release reviewer see about open investigations?

Suppliers

- Is approval scoped to supplier × material × site?
- What exactly happens on PO and receipt when status is conditional or expired?

Customer sharing

- How is customer separation implemented and tested?
- How are superseded and withdrawn documents handled?
- Which plan includes each capability?

AREA	WHAT TO SEE DEMONSTRATED	SYSTEM A	SYSTEM B
Review from records	Our last review rebuilt from records, actions linked.	_____	_____
Result integrity	Original, retest and correction all visible.	_____	_____
OOS linkage	Result, investigation and decision on one lot.	_____	_____
Human release	Disposition signed by an authorised person.	_____	_____
Approval scope	Supplier × material × site with evidence.	_____	_____
Expiry	Due list and status change with reason.	_____	_____
Sharing control	Approved, current documents only; withdrawal logged.	_____	_____
Connected trail	Page-15 thread demonstrated end to end.	_____	_____
Total (0–3 each)		_____	_____

Where V5 fits, plans and sources

- **Management review:** reports and dashboards bring deviations, CAPA, audit, scorecard and operational information into the review; people prepare, run and approve it. Quality inputs, scorecards and e-signatures are Professional and Enterprise.
- **Laboratory:** sample plans, requests, queues, results, lab reports and CoA inputs, with approved methods and laboratory configuration required; OOS workflow, LIMS, SPC and stability are Enterprise. Supplier CoA extraction with AI for review is Professional and Enterprise. The OOS outcome follows your lab procedure; people decide disposition.
- **Approved suppliers:** requirement templates per category, approval status and validity dates in view, status beside purchase orders and receipts; supplier qualification and portal are Professional and Enterprise. Purchasing or receiving blocks: confirm for your configuration.
- **Customer portal:** branded, read-only access where each customer sees their own orders, shipped lots, approved CoAs and pack documents; notifications with delivery log. Professional and Enterprise.

Primary sources for context; applicability depends on your products and markets. Links reviewed 1 October 2026.

Law and regulation (where they apply to you)

- **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 — CGMP for finished pharmaceuticals (incl. 211.84, 211.192)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211
- **US 21 CFR Part 820 — Quality Management System Regulation (devices)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820
- **US 21 CFR Part 117 — food CGMP and preventive controls (incl. supply-chain program)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117

Guidance

- **FDA — Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production** — www.fda.gov/regulatory-information/search-fda-guidance-documents/investigating-out-specification-oos-test-results-pharmaceutical-production-level-2-revision
- **EudraLex Volume 4 — EU GMP (Ch. 1 management review, Ch. 6 QC, Ch. 7 outsourced activities)** — health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
- **ICH Q10 Pharmaceutical Quality System** — www.ich.org/page/quality-guidelines

Voluntary standards (certification is your choice)

- **ISO 9001:2015 Quality management systems** — www.iso.org/standard/62085.html
- **ISO 13485:2016 Medical devices — QMS** — www.iso.org/standard/59752.html
- **ISO/IEC 17025:2017 Testing and calibration laboratories** — www.iso.org/standard/66912.html

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