

# Records you can stand behind when someone asks to see them.

For quality, regulatory, operations and IT teams choosing software for signed electronic records, batch and device history records, audits and inspection requests.



## What a trustworthy record holds

Attribution, signatures, corrections, audit trail and retrieval.

## Where the rules really apply

Predicate rules, Part 11 scope, Annex 11 today and the 2025 draft.

## How to test it

Request drills, demo scenarios, RFP questions and a scored sheet.

## CONTENTS

# What's inside

|    |                                                    |    |
|----|----------------------------------------------------|----|
| 1  | Why record questions go badly                      | 3  |
| 2  | Which rules apply to which records                 | 4  |
| 3  | The record lifecycle                               | 5  |
| 4  | Attribution, access and authority checks           | 6  |
| 5  | Electronic signatures: identity, meaning, link     | 7  |
| 6  | Corrections and the audit trail                    | 8  |
| 7  | Batch and device history records                   | 9  |
| 8  | Review by exception and controlled release         | 10 |
| 9  | Validation: risk-based, and what Enterprise adds   | 11 |
| 10 | Audit readiness: an evidence map, not a score      | 12 |
| 11 | Inspection requests: from ask to approved response | 13 |
| 12 | Floor audits: findings to owned actions            | 14 |
| 13 | Sharing records outside the company                | 15 |
| 14 | Evidence matrix, RACI and migration                | 16 |
| 15 | Demo scenarios and RFP questions                   | 17 |
| 16 | Where V5 fits, plans and sources                   | 18 |

## Who this is for

Quality and regulatory leads, QA reviewers, operations managers, validation and IT teams in pharmaceuticals, devices, supplements, food, cosmetics, chemicals and other regulated manufacturing.

**Important.** This guide supports software evaluation. It is not legal advice and does not decide which regulations apply to you. Software can keep records, signatures and history; it does not by itself make you compliant, validated or ready for any particular inspection. People review records and make quality decisions.

## 1 • THE PROBLEM

## Why record questions go badly

Most teams did the work. Trouble starts when they must show it quickly, completely and without anyone wondering whether it was changed.

| WHAT HAPPENS                                  | USUAL CAUSE                                           | WHAT GOOD LOOKS LIKE                                      |
|-----------------------------------------------|-------------------------------------------------------|-----------------------------------------------------------|
| <b>Twenty minutes to find one signed step</b> | Records spread across paper, spreadsheets and systems | One record per lot or unit, with links to the evidence    |
| <b>A correction looks like a cover-up</b>     | Overwritten value, no reason, no history              | Original kept, new value, reason, who and when            |
| <b>Nobody can say what a signature meant</b>  | Initials without meaning                              | Name, date and time, and meaning shown with the signature |
| <b>Old revision used on the floor</b>         | Printed copies outlive changes                        | Revision in force shown at the step                       |
| <b>Review takes days</b>                      | Reviewer reads everything                             | Review starts from exceptions                             |
| <b>Response pack sent before checking</b>     | No one owns the request                               | Each request has an owner and an approver                 |

**The outcome to buy.** For any lot, unit or event, show who did what, when, against which instruction, what changed afterwards and who decided.

**Beware feature lists.** "Part 11 compliant" on a brochure is not evidence. Ask to see signatures, corrections and the audit trail on a record like yours.

### A five-minute test before any demo

| CHECK                      | WHAT GOOD LOOKS LIKE                                            | OK                       |
|----------------------------|-----------------------------------------------------------------|--------------------------|
| <b>One lot, one record</b> | Can you open one complete record for last week's busiest lot?   | <input type="checkbox"/> |
| <b>One correction</b>      | Can you explain the last correction from history alone?         | <input type="checkbox"/> |
| <b>One signature</b>       | Can you show what the reviewer's signature meant?               | <input type="checkbox"/> |
| <b>One revision</b>        | Can you prove which instruction revision was in force that day? | <input type="checkbox"/> |

## 2 • SCOPE

## Which rules apply to which records

Electronic-record rules sit on top of the rules that say which records you must keep. Start with those, then decide what the software must do.

| CONTEXT                                     | WHAT IT COVERS                                                 | PRACTICAL MEANING                                                           |
|---------------------------------------------|----------------------------------------------------------------|-----------------------------------------------------------------------------|
| <b>Predicate rules (US)</b>                 | e.g. 21 CFR 211 drugs, 111 supplements, 117 food, 820 devices  | Say which records and signatures are required at all                        |
| <b>21 CFR Part 11 (US)</b>                  | Electronic records and signatures used to meet predicate rules | Controls for those records: access, audit trail, signatures                 |
| <b>FDA Part 11 scope guidance</b>           | FDA's current enforcement approach                             | Narrow, risk-based interpretation; predicate rules still apply in full      |
| <b>EU GMP Chapter 4 and Annex 11</b>        | Documentation and computerised systems for medicines           | Risk management, validation, audit trails, signatures, periodic review      |
| <b>Annex 11 and Chapter 4 drafts (2025)</b> | Consultation drafts plus new Annex 22 on AI                    | Not in force; signal direction on identity, audit-trail review and security |
| <b>21 CFR 820 QMSR (US devices)</b>         | Current device quality rule, effective 2 February 2026         | Incorporates ISO 13485:2016 by reference; device records follow it          |

**Rule of thumb.** List each record you must keep, the rule that requires it and whether it is kept electronically. That list scopes the evaluation.

**Historical clauses.** Older device documents cite the previous Quality System Regulation section numbers. Use them only when describing historical records.

### Build your record inventory

| RECORD                               | RULE THAT REQUIRES IT   | KEPT ELECTRONICALLY? | SIGNED? |
|--------------------------------------|-------------------------|----------------------|---------|
| <b>Batch / device history record</b> | e.g. 211.188 / Part 820 | Yes / hybrid         | Yes     |
| <b>Training record</b>               | Your predicate rule     |                      |         |
| <b>Calibration record</b>            | Your predicate rule     |                      |         |
| <b>Complaint file</b>                | Your predicate rule     |                      |         |

### 3 · LIFECYCLE

## The record lifecycle

Data-integrity guidance asks that records stay attributable, legible, contemporaneous, original and accurate, complete and available, for as long as they must be kept.

|                                                                                                                                                                                                                                                                             |                                                                     |                                                                   |                                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------|-------------------------------------------------|
| 1                                                                                                                                                                                                                                                                           | <b>Create</b><br>Entered at the step or captured from a device      | <b>RECORDED</b><br>Who, when, where, against which instruction    | <b>WHO DECIDES</b><br>The person doing the work |
| 2                                                                                                                                                                                                                                                                           | <b>Check</b><br>Limits, required fields and second person where set | <b>RECORDED</b><br>Result, flags, verifier                        | <b>WHO DECIDES</b><br>Per your procedure        |
| 3                                                                                                                                                                                                                                                                           | <b>Correct</b><br>A change with a reason                            | <b>RECORDED</b><br>Original, new value, reason, who, when         | <b>WHO DECIDES</b><br>Authorised person         |
| 4                                                                                                                                                                                                                                                                           | <b>Sign</b><br>Signature with its meaning                           | <b>RECORDED</b><br>Name, date-time, meaning, linked to the record | <b>WHO DECIDES</b><br>The signer                |
| 5                                                                                                                                                                                                                                                                           | <b>Review</b><br>From exceptions first                              | <b>RECORDED</b><br>Review notes and decisions                     | <b>WHO DECIDES</b><br>Quality reviewer          |
| 6                                                                                                                                                                                                                                                                           | <b>Retain and retrieve</b><br>Kept for the retention period         | <b>RECORDED</b><br>Readable copy, history intact                  | <b>WHO DECIDES</b><br>Records owner             |
| <div> <div> <b>Original</b><br/>The first capture, kept even when corrected. </div> <div> <b>Complete</b><br/>Including exceptions, corrections and failed attempts. </div> <div> <b>Available</b><br/>Retrievable in readable form for the retention period. </div> </div> |                                                                     |                                                                   |                                                 |
| <b>Hybrid records.</b> Where paper and electronic records coexist, decide which is the original and how the two are linked. Inspectors look hardest at the joins.                                                                                                           |                                                                     |                                                                   |                                                 |

## 4 • ACCESS

## Attribution, access and authority checks

A record is only as trustworthy as the log-in behind it. Every entry should belong to one person, acting within what their role allows.

| CONTROL                      | WHAT TO LOOK FOR                           | ASK TO SEE                                                             |
|------------------------------|--------------------------------------------|------------------------------------------------------------------------|
| <b>Unique accounts</b>       | No shared log-ins at stations              | How a kiosk switches between operators                                 |
| <b>Role permissions</b>      | Who may enter, correct, approve or release | A user trying an action outside their role                             |
| <b>Authority at signing</b>  | Signer's role checked when they sign       | A reviewer signing a step they also performed, if your rules forbid it |
| <b>Training and revision</b> | Trained on the revision in force           | What happens for an untrained person, on your set-up                   |
| <b>Account lifecycle</b>     | Leavers disabled; history kept             | A disabled user's past entries still attributed                        |
| <b>Administrator actions</b> | Configuration changes recorded             | The audit trail for a permission change                                |

**Plain test.** Pick one entry at random. Can you say who made it, from which station, in what role, and whether they were allowed to?

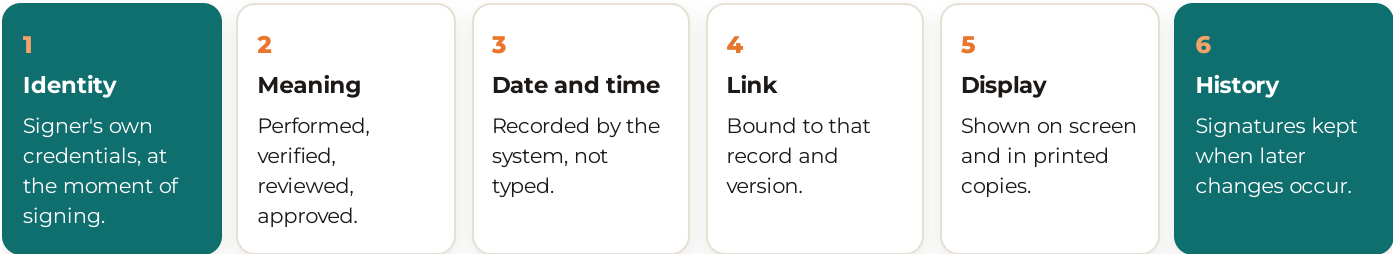
**Your procedures decide.** Software enforces the roles and rules you configure. Deciding segregation of duties is your quality system's job.

### Worked check: one kiosk, three people

| EVENT                                              | GOOD RESULT                                                         |
|----------------------------------------------------|---------------------------------------------------------------------|
| <b>Operator A logs in, performs step 4</b>         | Entry attributed to A, station K-2                                  |
| <b>Operator B takes over without logging out A</b> | Not possible; B must sign in                                        |
| <b>Supervisor corrects A's entry</b>               | Correction attributed to supervisor, with reason; A's original kept |
| <b>Untrained operator opens step 6</b>             | Handled as your configured rule says; recorded                      |

# Electronic signatures: identity, meaning, link

Part 11 asks that a signed record show the signer's printed name, the date and time, and the meaning of the signature, and that the signature stays linked to its record.



## Questions that separate real controls from labels

| CHECK                       | WHAT GOOD LOOKS LIKE                                               | OK                       |
|-----------------------------|--------------------------------------------------------------------|--------------------------|
| <b>Re-authentication</b>    | Password (or equivalent) entered at signing, not just a session    | <input type="checkbox"/> |
| <b>Meaning</b>              | Signer chooses or sees the meaning, and it prints with the record  | <input type="checkbox"/> |
| <b>Second person</b>        | Second signature required where your rules say so                  | <input type="checkbox"/> |
| <b>Change after signing</b> | Record shows the change and the earlier signature stays in history | <input type="checkbox"/> |
| <b>AI and automation</b>    | No signature is applied by software on someone's behalf            | <input type="checkbox"/> |

**Organisation duties.** Part 11 also expects you to certify to FDA that electronic signatures are binding, and to control accounts. Those are your actions, not the software's.

**Hybrid signatures.** If a handwritten signature is applied to an electronic record, Part 11 expects it to be linked to that record. Ask how the system handles this if you plan to use it.

## Corrections and the audit trail

Corrections are normal. What matters is that the original stays visible and the reason is recorded by the person who made the change.

| FIELD                                 | BEFORE                     | AFTER            | RECORDED                               |
|---------------------------------------|----------------------------|------------------|----------------------------------------|
| <b>Assay result, sample S-3307-02</b> | 98.1%                      | 99.1%            | Transcription error · K. Patel · 14:12 |
| <b>Reviewer note</b>                  | —                          | Raw data checked | QA · M. Ortiz · 14:30                  |
| <b>Signature</b>                      | Performed · K. Patel 13:58 | Kept in history  | Re-signed after correction 14:13       |

### What a useful audit trail shows

- Who, when, old value, new value and reason.
- Created, changed and deleted actions, including configuration.
- Readable without a database query.
- Filtered to one record, lot or user.

### Audit-trail review

- Decide which trails are reviewed, when and by whom, based on risk.
- Review at batch review for critical data; periodically for system activity.
- Record that review happened and what was found.

**Plain-English help.** Some systems explain recorded history in plain language. Treat that as a reading aid; the audit trail itself remains the evidence.

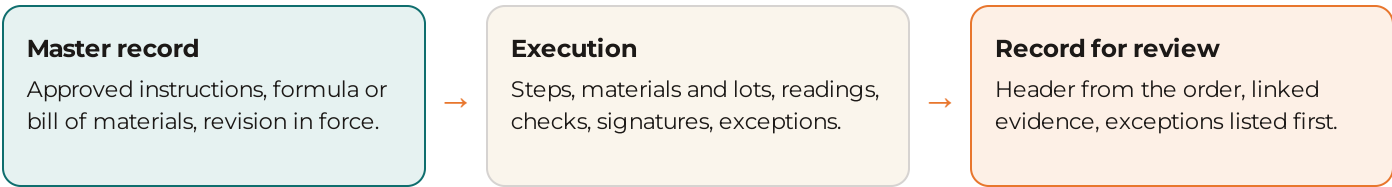
### What reviewers should flag in an audit trail

| PATTERN                                     | WHY LOOK CLOSER                        |
|---------------------------------------------|----------------------------------------|
| <b>Repeated edits to the same result</b>    | Possible testing into compliance       |
| <b>Changes after signing</b>                | Should carry a reason and fresh review |
| <b>Entries outside shift times</b>          | Check the record was contemporaneous   |
| <b>Configuration changes before a batch</b> | Confirm change control covered them    |

## 7 · PRODUCTION RECORDS

# Batch and device history records

An electronic batch record (eBMR) or device history record (eDHR) should be built from the work as it happens, not typed up afterwards.



| SECTION             | BATCH (EBMR)                       | UNIT OR LOT (EDHR)                                       |
|---------------------|------------------------------------|----------------------------------------------------------|
| <b>Identity</b>     | Product, batch number, size, dates | Device, lot or serial, quantity, dates                   |
| <b>Instructions</b> | Master batch record revision       | Medical device file and production instructions revision |
| <b>Materials</b>    | Components, lots, quantities       | Components and sub-assemblies, lots or serials           |
| <b>Evidence</b>     | Readings, checks, signatures       | Inspection and test results, acceptance                  |
| <b>Exceptions</b>   | Deviations, corrections, holds     | Nonconformances, rework, holds                           |
| <b>Labelling</b>    | Labels issued and reconciled       | Labelling and UDI where applicable                       |

**Words differ by sector.** Since the QMSR took effect, FDA uses ISO 13485 terms; "DHR" and "DMR" remain common shorthand. Use your own record names in the evaluation; the structure, not the label, is what matters.

**Ask for one real record.** In evaluation, run one of your products end to end and print the resulting record. Compare it line by line with your current paper record.

## Review by exception and controlled release

Reviewers should start with what went differently, then confirm the rest is complete. The release decision stays with a person.

|          |                                                                    |                                                 |                                                       |
|----------|--------------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------|
| <b>1</b> | <b>Completeness</b><br>All steps done, required entries present    | <b>RECORDED</b><br>Missing items listed         | <b>WHO DECIDES</b><br>System shows; reviewer confirms |
| <b>2</b> | <b>Exceptions</b><br>Out-of-limit readings, corrections, overrides | <b>RECORDED</b><br>Each with reason and who     | <b>WHO DECIDES</b><br>Reviewer                        |
| <b>3</b> | <b>Linked events</b><br>Deviations, CAPA, lab results              | <b>RECORDED</b><br>Status of each               | <b>WHO DECIDES</b><br>Reviewer and owners             |
| <b>4</b> | <b>Decision</b><br>Release, reject or hold                         | <b>RECORDED</b><br>Signed decision with meaning | <b>WHO DECIDES</b><br>Authorised person               |

**What software can do.** Assemble the record, list exceptions first, show linked events and hold the signed decision.

**What it should not do.** Release or reject product on its own, or hide a resolved exception from the reviewer.

| CHECK                   | WHAT GOOD LOOKS LIKE                         | OK                       |
|-------------------------|----------------------------------------------|--------------------------|
| <b>Exceptions first</b> | List of every flagged entry with reason      | <input type="checkbox"/> |
| <b>Pending lab work</b> | Open results visible before decision         | <input type="checkbox"/> |
| <b>Hold</b>             | Product stays on hold until a person decides | <input type="checkbox"/> |

### Typical exception list for one batch

| EXCEPTION                                    | OWNER               | STATE                 |
|----------------------------------------------|---------------------|-----------------------|
| <b>Reading 0.12 kg over band, re-weighed</b> | Operator / reviewer | Explained             |
| <b>Lot correction at step 2</b>              | Supervisor          | Reason recorded       |
| <b>Micro result pending</b>                  | Lab                 | Open: blocks decision |
| <b>DEV-1104 linked</b>                       | Quality             | Closed                |

## Validation: risk-based, and what Enterprise adds

You validate your use of the system for its intended purpose. The supplier can make that easier with documentation and test evidence; it cannot do it for you.

| ACTIVITY                                | WHO USUALLY DOES IT                             | EVIDENCE                                                |
|-----------------------------------------|-------------------------------------------------|---------------------------------------------------------|
| <b>Intended use and risk assessment</b> | Customer, with supplier input                   | Requirements and risk register                          |
| <b>Supplier assessment</b>              | Customer                                        | Audit or questionnaire, quality documentation           |
| <b>Installation qualification (IQ)</b>  | Supplier support, customer approval             | Environment and configuration recorded                  |
| <b>Operational qualification (OQ)</b>   | Supplier scripts, customer execution or witness | Executed tests against requirements                     |
| <b>Performance / user acceptance</b>    | Customer                                        | Tests with your products and procedures                 |
| <b>Change and periodic review</b>       | Customer                                        | Release notes reviewed, regression scope, review record |

**In V5:** IQ/OQ and validation support are Enterprise only. Every plan still needs your own intended-use assessment and acceptance testing.

**Risk-based effort.** Focus testing on functions that affect product quality and data integrity: signatures, audit trail, limits, holds and release.

### Plan your acceptance tests around risk

| FUNCTION                     | RISK   | TEST DEPTH                   |
|------------------------------|--------|------------------------------|
| <b>Electronic signatures</b> | High   | Full scripted tests          |
| <b>Audit trail</b>           | High   | Scripted, plus review sample |
| <b>Limits and holds</b>      | High   | Scripted with your limits    |
| <b>Reports and printouts</b> | Medium | Compare against source data  |
| <b>Dashboards</b>            | Low    | Fit-for-purpose check        |

## Audit readiness: an evidence map, not a score

Readiness means you can find and explain evidence for each area an auditor is likely to look at. A self-check helps; it does not predict an outcome.

| AREA                          | EVIDENCE TO LOCATE                                  | FOUND?                   |
|-------------------------------|-----------------------------------------------------|--------------------------|
| <b>Documents and training</b> | Revision in force on a date; who was trained        | <input type="checkbox"/> |
| <b>Production records</b>     | One complete record, with exceptions                | <input type="checkbox"/> |
| <b>Deviations and CAPA</b>    | Open items, investigations, effectiveness checks    | <input type="checkbox"/> |
| <b>Suppliers</b>              | Approval status and evidence for a key supplier     | <input type="checkbox"/> |
| <b>Equipment</b>              | Calibration status on the date of use               | <input type="checkbox"/> |
| <b>Complaints and recalls</b> | Last complaint trend; last trace exercise           | <input type="checkbox"/> |
| <b>Computer systems</b>       | Access list, audit-trail review, validation summary | <input type="checkbox"/> |

**Self-check method.** Your team marks each item found, partly found or not found, and turns gaps into owned actions with due dates.

**Scores are not verdicts.** Any readiness index reflects your inputs and set-up. Auditors judge evidence, not dashboards.

### Turn gaps into actions

| GAP FOUND                                           | ACTION             | OWNER         | DUE     |
|-----------------------------------------------------|--------------------|---------------|---------|
| <b>Training record missing for one SOP revision</b> | Retrain and record | Training lead | 2 weeks |
| <b>Calibration certificate not attached</b>         | Attach and verify  | Engineering   | 1 week  |
| <b>CAPA effectiveness check overdue</b>             | Complete check     | CAPA owner    | 1 week  |

# Inspection requests: from ask to approved response

During an inspection, speed matters, but sending the wrong or unchecked record costs more. Every request needs an owner, a check and an approver.

|   |                                                                     |                                                |                                       |
|---|---------------------------------------------------------------------|------------------------------------------------|---------------------------------------|
| 1 | <b>Log the request</b><br>Exactly what was asked, by whom, when     | <b>RECORDED</b><br>Request ID, wording, time   | <b>WHO DECIDES</b><br>Front-room lead |
| 2 | <b>Assign</b><br>One owner per request                              | <b>RECORDED</b><br>Owner, due time             | <b>WHO DECIDES</b><br>Front-room lead |
| 3 | <b>Retrieve</b><br>Find the record and its history                  | <b>RECORDED</b><br>Record IDs, versions        | <b>WHO DECIDES</b><br>Owner           |
| 4 | <b>Check</b><br>Right record, complete, readable, no unrelated data | <b>RECORDED</b><br>Check notes                 | <b>WHO DECIDES</b><br>Subject expert  |
| 5 | <b>Approve and hand over</b><br>Approved copy given, log updated    | <b>RECORDED</b><br>Approver, copy handed, time | <b>WHO DECIDES</b><br>Quality lead    |

| PRACTICE DRILL           | TARGET                                                  |
|--------------------------|---------------------------------------------------------|
| Pick three random lots   | Retrieve each full record with history                  |
| Pick a training question | Show who was trained on the revision in force on a date |
| Pick a correction        | Explain it from the audit trail alone                   |

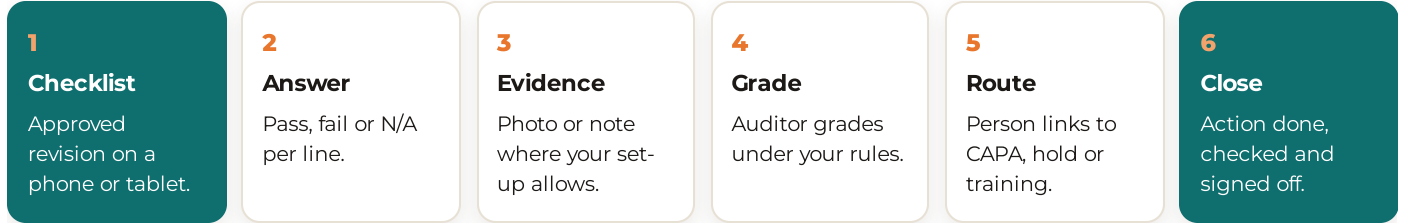
**Plan it with people.** Name back-room retrievers per area and rehearse before inspections. Software keeps the records findable; it does not replace the plan.

**Front room and back room.** One person talks to the inspector; a small team retrieves and checks. A shared request log keeps both sides aligned.

## 12 • FLOOR AUDITS

# Floor audits: findings to owned actions

Walk-round audits work when the checklist is controlled, findings are captured on the spot with evidence and each one ends with an owner.



| QUESTION                                  | WHY IT MATTERS                                          |
|-------------------------------------------|---------------------------------------------------------|
| Which devices and browsers are supported? | Phones on the floor vary; confirm with your own devices |
| What happens with no connection?          | Offline capture is not universal; ask, do not assume    |
| Who grades and routes findings?           | A person should decide severity and the follow-up       |
| Are repeat findings visible?              | Trends across audits show whether fixes work            |

**Good sign.** A finding raised on a phone appears with its photo, area and auditor in the action list the same day.

## Example finding, end to end

| STAGE         | RECORDED                                                          |
|---------------|-------------------------------------------------------------------|
| <b>Raised</b> | AUD-2702 · Packing hall · Hand-wash station empty · photo · 09:14 |
| <b>Graded</b> | Minor, by auditor, under site rule                                |
| <b>Routed</b> | Linked to CAPA-0412 by the auditor                                |
| <b>Closed</b> | Dispenser restocked, checked next walk · signed off               |

## 13 • SHARING

# Sharing records outside the company

Customers, auditors and regulators ask for records. Decide what each recipient may see, approve the exact version and log what left.

|   |                                                                 |                                                    |                                     |
|---|-----------------------------------------------------------------|----------------------------------------------------|-------------------------------------|
| 1 | <b>Choose records</b><br>Approved versions only                 | <b>RECORDED</b><br>Record IDs and versions         | <b>WHO DECIDES</b><br>Requester     |
| 2 | <b>Scope the recipient</b><br>Only what they asked for          | <b>RECORDED</b><br>Recipient, purpose              | <b>WHO DECIDES</b><br>Quality owner |
| 3 | <b>Review the pack</b><br>Remove unrelated or confidential data | <b>RECORDED</b><br>Review notes                    | <b>WHO DECIDES</b><br>Reviewer      |
| 4 | <b>Approve and release</b><br>Approved copy sent or shared      | <b>RECORDED</b><br>Approver, date, what was shared | <b>WHO DECIDES</b><br>Quality lead  |

| ASK THE SUPPLIER                                           | WHY                                                          |
|------------------------------------------------------------|--------------------------------------------------------------|
| <b>How is sharing done: export, portal or both?</b>        | Methods differ by plan and set-up                            |
| <b>Can a recipient see only their own lots?</b>            | Customers must not see each other's records                  |
| <b>Is there a log of what was shared, with whom, when?</b> | You must be able to answer later                             |
| <b>What security controls apply to shared copies?</b>      | Get specifics in writing; do not assume expiry or watermarks |

**Nothing should leave automatically.** A person approves each external release.

**Keep a release log.** Recipient, purpose, records and versions, approver, date. It answers "what did we send?" months later.

## Evidence matrix, RACI and migration

| REQUIREMENT                 | EVIDENCE IN EVALUATION                       |  |  |  | OWNER      |
|-----------------------------|----------------------------------------------|--|--|--|------------|
| <b>Attributable entries</b> | Random entry traced to person, role, station |  |  |  | QA         |
| <b>Signatures</b>           | Signed record shows name, date-time, meaning |  |  |  | QA / IT    |
| <b>Corrections</b>          | Original kept with reason                    |  |  |  | QA         |
| <b>Audit-trail review</b>   | Filtered trail for one lot                   |  |  |  | QA         |
| <b>Retention</b>            | Archived record retrieved readable           |  |  |  | IT         |
| <b>Validation</b>           | Supplier pack and your acceptance tests      |  |  |  | Validation |

| ACTIVITY                              | QUALITY | OPERATIONS | IT | SUPPLIER              |
|---------------------------------------|---------|------------|----|-----------------------|
| <b>Scope records and rules</b>        | A/R     | C          | C  | I                     |
| <b>Configure roles and signatures</b> | A       | C          | R  | C                     |
| <b>Validation and acceptance</b>      | A       | C          | R  | C (IQ/OQ, Enterprise) |
| <b>Migrate legacy records</b>         | A       | I          | R  | C                     |
| <b>Inspection request plan</b>        | A/R     | C          | C  | —                     |

### Migration checklist

- Decide which legacy records move, which stay archived, and how they remain retrievable.
- Keep paper or legacy originals until you have verified the migrated copy.
- Record the migration as a controlled change with a verification sample.

**Retention.** Set retention by record type and rule, and test that a record from the oldest period you must keep can still be opened, read and printed.

## Demo scenarios and RFP questions

### Ask them to show

- A signed step, then a correction, with the full history.
- A batch or device record reviewed from exceptions.
- A training-gated step for an untrained user, on your set-up.
- An inspection request logged, owned, checked and approved.
- A floor-audit finding raised on a phone and routed by a person.
- A shared pack limited to one customer's lots.

### RFP questions

- Which plan includes electronic signatures and regulated reports?
- How is the audit trail protected and reviewed?
- What validation documentation do you provide, on which plan?
- How are configuration changes and releases communicated?
- What is the retention and export approach?

| AREA                       | WHAT TO SEE DEMONSTRATED                 | SYSTEM A | SYSTEM B |
|----------------------------|------------------------------------------|----------|----------|
| <b>Attribution</b>         | Random entry traced fully.               | _____    | _____    |
| <b>Signatures</b>          | Name, date-time, meaning, link.          | _____    | _____    |
| <b>Corrections</b>         | Original, reason, who, when.             | _____    | _____    |
| <b>Audit trail</b>         | Readable, filtered to one lot.           | _____    | _____    |
| <b>Batch/device record</b> | Built from execution; exceptions first.  | _____    | _____    |
| <b>Release</b>             | Person decides; product held until then. | _____    | _____    |
| <b>Requests</b>            | Logged, owned, approved.                 | _____    | _____    |
| <b>Floor audits</b>        | Finding to owned action.                 | _____    | _____    |
| <b>Sharing</b>             | Scoped, approved, logged.                | _____    | _____    |
| <b>Validation</b>          | Documents and support clear by plan.     | _____    | _____    |
| <b>Total (0–3 each)</b>    |                                          | _____    | _____    |

## Where V5 fits, plans and sources

- **Every plan:** work orders and shop-floor entry, lot records and traceability, audit log view, standard PDF reports, QA release queue, calibration due dates.
- **Professional and Enterprise:** electronic signatures with name, date-time and meaning; tamper-evident audit trail; document control and training; deviations and CAPA; audits; regulated reports (BMR, eDHR, MMR, CoA); customer portal.
- **Enterprise:** IQ/OQ and validation support; readiness scoring, kept separate from your own self-check.
- **Confirm in evaluation:** mobile devices and connection behaviour, external sharing method and controls, your deployment. V5 does not make you compliant or validated, and people make release decisions.

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; electronic signatures** — [www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11](http://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11)
- **US 21 CFR Part 211 — drug CGMP (records, review and release)** — [www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211](http://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](http://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820)

### Guidance

- **FDA — Part 11 Scope and Application** — [www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application)
- **FDA — Data Integrity and Compliance With Drug CGMP: Q&A** — [www.fda.gov/regulatory-information/search-fda-guidance-documents/data-integrity-and-compliance-drug-cgmp-questions-and-answers](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-integrity-and-compliance-drug-cgmp-questions-and-answers)
- **FDA — Quality Management System Regulation overview (effective 2 Feb 2026)** — [www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr](http://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr)
- **EudraLex Volume 4 — EU GMP Chapter 4 and Annex 11 (in force)** — [health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4\\_en](http://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en)
- **EU consultation (7 Jul–7 Oct 2025, drafts not in force) — Chapter 4, Annex 11, new Annex 22** — [health.ec.europa.eu/consultations/stakeholders-consultation-eudralex-volume-4-good-manufacturing-practice-guidelines-chapter-4-annex\\_en](http://health.ec.europa.eu/consultations/stakeholders-consultation-eudralex-volume-4-good-manufacturing-practice-guidelines-chapter-4-annex_en)
- **MHRA — GXP data integrity guidance and definitions** — [www.gov.uk/government/publications/guidance-on-gxp-data-integrity](http://www.gov.uk/government/publications/guidance-on-gxp-data-integrity)

**Try it with one of your own records.** 7-day free trial, no card required, at [v5ultimate.com](http://v5ultimate.com).