

A clear next step for operators. A review-ready record at the end.

The Manufacturing Execution Buyer Guide is for operations, quality and IT teams choosing manufacturing execution software (MES): what it should control on the floor, what evidence it should leave, and how to test it with your own jobs — batch, assembly or packaging.



An operator-to-review map

What each stage of a job should record, and who decides — from approved instruction to human release.

Evidence and exception tests

An electronic-record checklist, readiness checks, and how deviations and rework should flow.

Tools to compare suppliers

Implementation plan, RFP questions, a scored evaluation worksheet and primary sources by region.

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Who this is for

Production managers, quality and compliance leads, continuous-improvement and IT teams replacing paper travellers, spreadsheets or an older execution system — in food, supplements, pharma, devices, chemicals, cosmetics and other regulated manufacturing.

How to use it

- Read pages 3–9 to agree what controlled execution should look like on your site.
- Pick one real job — ideally one that went wrong once — and use it for every demonstration.
- Send the RFP questions on page 11 and score what suppliers *show*, not what they say.

Important. Software supports your procedures; it does not make you compliant or validated. Which rules apply depends on your products and markets. This guide is not legal or regulatory advice.

1 • THE PROBLEM

Why execution control matters

Most production problems are not exotic. They are the right step done from the wrong revision, a check written up afterwards, or an exception nobody noticed until review.

FAILURE	TYPICAL CAUSE ON PAPER OR SPREADSHEETS	CONTROL EXECUTION SOFTWARE SHOULD PROVIDE
Wrong instruction used	Old printout at the line; revision not checked	Only the approved revision is issued to the job
Step skipped or out of order	Long traveller; steps ticked in a batch at the end	Steps presented in sequence; skipped steps visible
Value recorded late or guessed	Readings copied from scraps or memory	Values captured at the step with who and when
Wrong material or lot	Visual check only	Material and lot confirmed by scan against the job
Untrained person or out-of-date equipment	Training and calibration held in other files	Readiness checked before the step can be signed
Exception found at review, days later	No signal when a limit is missed	Out-of-limit result raised at the step for a decision
Review takes hours	Reviewer reads every page to find problems	Record complete by design; review starts with exceptions

The outcome to buy. Operators always know the next action. Reviewers receive a complete record and a short list of exceptions. People still make the decisions.

Avoid buying a dashboard. A screen that shows status is not execution control. Ask to see a step blocked, an exception raised, and the record that results.

2 • THE RECORD MAP

From operator to reviewer

Every stage of a job should leave evidence the next person can trust. Use this map to ask each supplier where the evidence comes from.

1	Approved instructions Master instruction / formula / routing at its approved revision	RECORDED Revision, approver, effective date	WHO DECIDES Author + approver under change control
2	Job released to the floor Work order created from the approved master	RECORDED Quantity, materials required, revision used	WHO DECIDES Planner / supervisor
3	Readiness Materials, people, equipment and documents ready	RECORDED Material status, training, calibration, line clearance	WHO DECIDES System checks; supervisor confirms
4	Step execution One step at a time on a tablet or kiosk	RECORDED Actions, scans, weights, times, operator identity	WHO DECIDES Operator, within the approved method
5	In-process checks Readings against limits defined in the master	RECORDED Value, limit, pass / out-of-limit, instrument	WHO DECIDES Operator; second person where required
6	Exceptions Out-of-limit, missed or changed steps	RECORDED Deviation linked to job, step and lot	WHO DECIDES Quality decides disposition
7	Completed record Batch / device / production record assembled	RECORDED Everything above, with audit trail and signatures	WHO DECIDES Generated from the captured data
8	Human review and release Reviewer sees completeness and open exceptions first	RECORDED Review decision, signature with meaning	WHO DECIDES Authorised quality person — never automatic

Ask: "Show me where the value on line 4 of the final record was captured, by whom, and what limit it was checked against." A good system answers in one click.

3 • EVIDENCE

Electronic record evidence checklist

Regulators and auditors expect records that are attributable, legible, contemporaneous, original and accurate, and that stay complete and available. These expectations are often summarised as ALCOA+.

PRINCIPLE	WHAT TO SEE DEMONSTRATED	OK
Attributable	Every entry shows the individual user (no shared logins) and their role.	☐
Contemporaneous	Time stamps come from the system clock at the moment of capture.	☐
Original values	Device readings (scales, instruments) are captured directly where connected, not retyped.	☐
Corrections	A change keeps the old value, the new value, who, when and why.	☐
Signatures	Signatures show the signer, date/time and meaning (e.g. performed, verified, approved), linked to the record.	☐
Second-person checks	Where your procedure needs a witness, the system enforces a different user.	☐
Completeness	A record cannot be marked complete with mandatory steps or values missing.	☐
Retention and retrieval	Records can be retrieved in readable form for the retention period you set, including the audit trail.	☐
Access control	Who can execute, verify, approve and edit masters are separate permissions.	☐
Audit trail review	Reviewers can see relevant audit-trail entries as part of record review, not in a separate tool.	☐
REFERENCE	WHAT IT ASKS FOR (SUMMARY ONLY)	
21 CFR Part 11 (US)	Trustworthy electronic records and signatures: audit trails, unique users, signature manifestation and linking.	
EU GMP Annex 11	Computerised systems: risk management, validation, data integrity, audit trails, change and configuration control.	
21 CFR 211.186–192 (US drugs)	Master and batch production records, and their review before release.	

4 • READINESS & REVIEW

Readiness, procedures and human review

Good execution software checks the obvious before work starts, so operators spend their attention on the product.

READINESS CHECK	QUESTION TO ANSWER BEFORE THE STEP	EVIDENCE
Material status	Is every lot released for use, in date and the right item?	Lot status and scan confirmation
Instruction revision	Is the instruction the approved revision for this product?	Revision on the record
People	Is the operator trained on the current revision of this procedure?	Training record at time of signing
Equipment and instruments	Is the scale or instrument in calibration and the equipment available?	Calibration status, equipment ID
Line clearance	Is the line clear of the previous product, labels and materials?	Clearance check with signature
Environment (where relevant)	Are room or storage conditions within limits?	Reading or linked monitoring record

What the system should do

- Present the approved procedure, not a copy.
- Stop or flag a step when a readiness check fails — as configured by you.
- Record each check with the person and time.
- Assemble the record as the job runs.

What people still decide

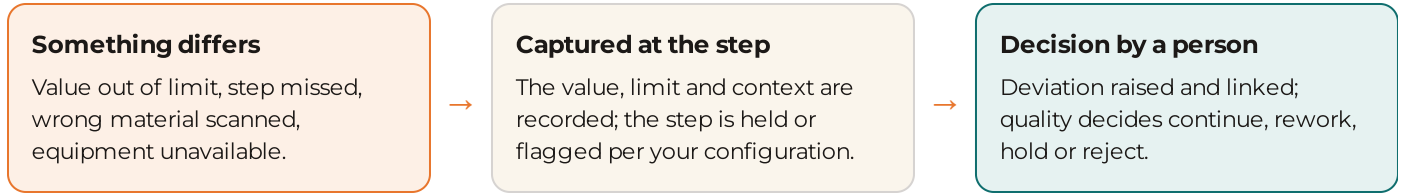
- Whether an exception is acceptable.
- Disposition of material: use, rework, hold or reject.
- Approval of master instructions and changes.
- Release of the finished lot.

Review by exception, not review without reading. Exception-first review means a complete record arrives with problems at the top. The reviewer still owns the release decision and the procedure for what must be read.

5 • EXCEPTIONS

Exceptions, deviations and rework

Exceptions are where execution systems earn their keep — or quietly fail. Test them on purpose.



SCENARIO TO TEST	WHAT GOOD LOOKS LIKE
Weight outside tolerance	Operator cannot sign the step as in-limit; exception recorded with the actual value.
Wrong lot scanned	Scan rejected with a clear reason; the attempt is visible in the audit trail.
Step needs to be repeated	Repeat recorded as a new entry with reason; original kept.
Rework	Rework follows an approved instruction; the reworked material keeps its genealogy.
Job paused across shifts	Hand-over shows where the job stopped and what is open.
Deviation raised	Deviation links to the work order, step and lot; open deviations show on the record at review.
Material placed on hold	Held material cannot be issued to another job until released.

Look for honesty, not perfection. A system that makes it easy to record what really happened produces better records than one that only accepts the happy path.

Batch, assembly or packaging: fit the vocabulary

Batching is optional. The same control ideas apply whether you mix, assemble, fill or pack — only the words and evidence change.

	BATCH / PROCESS	DISCRETE ASSEMBLY	PACKAGING / FILL
Master	Formula + process instructions	Bill of materials + routing + work instructions	Packaging specification + line set-up
Key step	Weigh, add, mix, hold, test	Pick components, assemble, inspect, test	Fill, seal, label, check weight
Identity	Batch / lot	Serial or lot; component lots	Finished lot, often per pallet or case
Typical checks	Weights, temperatures, times, in-process tests	Torque, dimensions, functional test	Fill weight, seal, label and barcode
Record	Batch record	Device history / production record	Packaging record
Typical exceptions	Out-of-spec addition, hold time exceeded	Failed test, rework, non-conforming part	Wrong label, weight out of range

Food, supplements, chemicals

Formulas, scaling, allergen or hazard changeovers, lot genealogy from raw material to pack.

Pharma, vet, radiopharma

Approved master records, second-person verification, record review before disposition.

Devices, consumer goods

Component traceability, inspection and test evidence, revision-controlled assembly instructions.

Ask the supplier to run your vocabulary. If a demonstration only works when you rename your assembly line a "batch", the fit is weaker than it looks.

7 • CONTROL & CONNECTIONS

Change control and connected records

A master instruction is a controlled document. Changing it should be as deliberate as changing a label.



CHECK	WHAT GOOD LOOKS LIKE	OK
Revision on every job	Each work order records the master revision it ran.	☐
Change reason and impact	Changes record why, what is affected and who approved.	☐
In-flight jobs	Your rule for jobs started on the old revision is applied and visible.	☐
Training follows change	People are re-trained before they can sign steps under a new procedure revision, where you require it.	☐

CONNECTED RECORD	WHAT EXECUTION SHOULD READ OR WRITE	ASK
Inventory / WMS	Lot status, issue to job, finished goods receipt	Can a held lot still be issued?
Quality / QMS	Deviations, holds, release decisions	Do open deviations show at review?
Training	Who is qualified on which procedure revision	Is training checked at the step?
Assets & calibration	Equipment availability, calibration status	Is an out-of-calibration instrument flagged?
Devices	Scales, printers, sensors	Are readings captured directly?
ERP	Orders, items, costs, completions	Which system is master for each field?
Laboratory	Test results for in-process or release	Are results approved before they count?

8 • IMPLEMENTATION

Implementation plan and common pitfalls

Start with one product family on one line. Prove the record, then widen.

PHASE	WHAT HAPPENS	EXIT EVIDENCE
1. Scope	Choose one product family, line and record type; list the decisions people keep.	Written scope and owners
2. Masters	Rebuild the approved instructions, checks and limits; agree units and rounding.	Masters approved under change control
3. Readiness data	Load materials and lot status, training, equipment and calibration.	Readiness checks pass on test jobs
4. Test	Run normal jobs and deliberate exceptions; review the records produced.	Test records reviewed and signed
5. Validate	Risk-based testing to your validation procedure for regulated use.	Validation summary approved by you
6. Parallel run	Run electronic and paper for a defined period or number of jobs.	Differences explained and closed
7. Go live and widen	Retire paper for that scope; add the next line or family.	Paper retired; lessons recorded

Common pitfalls

- Copying the paper traveller screen-for-screen instead of simplifying it.
- Masters not cleaned before go-live — the system exposes every inconsistency.
- No decision on who reviews what, and when.
- Exceptions tested last, or not at all.
- Shop-floor hardware (tablets, scanners, scales) left until the week before go-live.

What to measure

- Records needing correction at review.
- Time from job end to review decision.
- Exceptions caught at the step vs found at review.
- Steps signed late (after the work).

Set your own baseline first. Any improvement depends on your process — this guide makes no promise of savings.

RFP questions and scored evaluation

Execution

- How is the approved revision issued to a job, and how is an old one blocked?
- Which readiness checks can stop a step, and which only warn?
- How are device readings captured, and what happens if a device is offline?

Records

- Show a correction: what is kept, who, when and why?
- How are signatures and their meaning shown on the record?
- Which records can be produced (batch, device history, packaging)?

Exceptions and review

- How is a deviation raised from a step, and what does the reviewer see?
- Can release happen with an open exception? Who decides?

Fit and deployment

- Run one of our jobs in our vocabulary (batch, assembly or packing).
- Which deployment options exist, and how are updates validated?
- What validation support is offered, and on which plan?

AREA	WHAT TO SEE DEMONSTRATED	SYSTEM A	SYSTEM B
Your job, rebuilt	One of your real jobs from approved master to record.	_____	_____
Readiness	A failed check (training, calibration, lot status) stops or flags the step.	_____	_____
Step evidence	Values, scans and signatures captured at the step.	_____	_____
Exceptions	Out-of-limit value raised and linked to a deviation.	_____	_____
Corrections	Change kept with reason in the audit trail.	_____	_____
Record review	Complete record, exceptions first, signed decision.	_____	_____
Change control	Master revised, approved; old revision blocked.	_____	_____
Connections	Lot status, training, equipment and ERP in one flow.	_____	_____
Total (0–3 each)		_____	_____

Where V5 fits, and sources

- **Execution:** formulas, work orders and production instructions; an industry-aware operator kiosk for blending, packaging and other steps; materials confirmed by scan; scales and printers paired as devices.
- **Readiness:** kiosk access can be gated on training (skills matrix and controlled documents) and on out-of-calibration instruments, as you configure it.
- **Records:** audit trail, 21 CFR Part 11-style electronic signatures and regulated reports such as batch record, device history record, master record and certificate of analysis (Professional and above). Two-signature formula approvals.
- **Exceptions and review:** deviations raised from the step and linked to the work order and lot; a QA release queue where a person decides.
- **Validation:** IQ/OQ and validation support is offered with Enterprise. Your own validation decides your validated state.
- **Confirm in evaluation:** exactly which checks block versus warn in your configuration, equipment interlocks with your machines, and plan inclusion for each feature.

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. 211.186–192 production records and review)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211
- **US 21 CFR Part 111 — dietary supplement CGMP (master manufacturing and batch production records)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-111
- **US 21 CFR Part 117 — human food CGMP and preventive controls (records)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117
- **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

Guidance and standards

- **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 Quality Management System Regulation (QMSR) overview** — www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr

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