



THE MEDICAL DEVICE PRODUCTION GUIDE

Built to revision. Inspected. On record.

From component supplier to shipped, traceable device

A capability and evaluation guide for finished-device and IVD manufacturers, contract manufacturers and sterile packers who want every build, inspection and label to reach its reviewer as one connected record.



QUALITY

TRACEABILITY

RELEASE

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Diagrams show control concepts, not V5 screenshots. Scope and limits are on the final page.

INSIDE THE GUIDE

One device. Many hands. One record.

A finished device passes through purchasing, receiving, stores, assembly, inspection, packaging, labelling and quality review. This guide follows it, and shows what each handover must leave behind.

01 / FRAME

pp. 03–05

The rules that apply to you

QMSR and ISO 13485, EU MDR/IVDR, UK rules, the vocabulary change, a build day.

02 / FLOW

pp. 06–11

Supplier to finished build

Purchasing controls, receiving, status and shelf life, revisions, assembly, cleanroom and sterile barrier.

03 / DECIDE

pp. 12–16

Inspect, review, correct

Measurement, device record review and release, nonconforming product, CAPA, competence.

04 / SUSTAIN

pp. 17–22

Equipment, labels, trace, portals

Calibration and maintenance, yield, UDI labels, traceability and recall, portals, data integrity and AI.

05 / APPLY

pp. 23–29

Evidence map and working tools

Evidence map, four worksheets, a phased roadmap and a fair four-week evaluation.

06 / SOURCES

pp. 30–32

What this guide rests on

Fifteen linked primary sources with status and scope, plus limits of this guide.

Who it is for. Quality and regulatory leads, operations and manufacturing engineers, supplier quality, and anyone choosing or reviewing a production and quality system for medical devices or IVDs.

How to read it. Every operational page ends with a teal Where V5 fits panel. Everything above it is practice and regulation, useful whether or not you ever use V5. Regulatory statements cite numbered sources; standards are voluntary unless a regulation or contract makes them binding. Check the current text for your devices and markets.

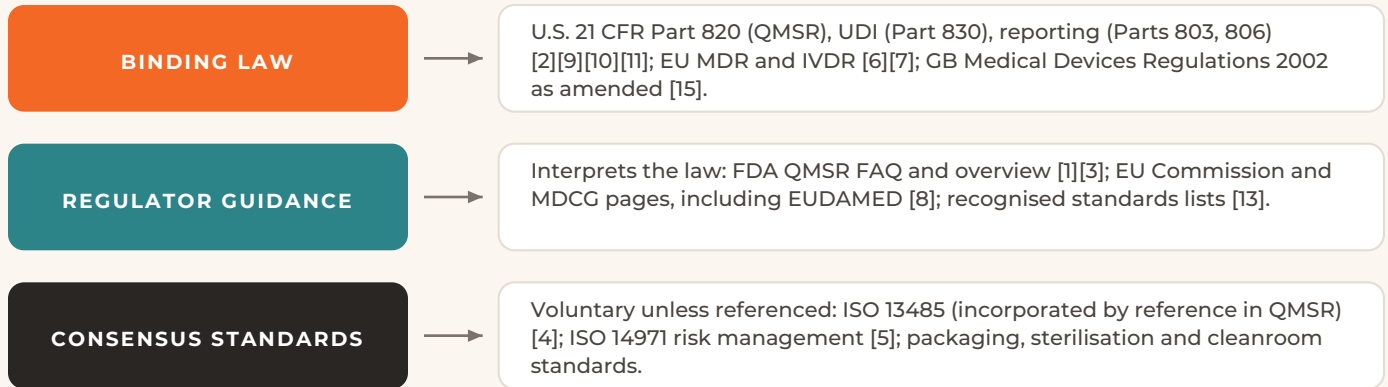
WHERE V5 FITS

V5 records the production and quality work your procedures define. It does not design your device, classify it, write your technical documentation, submit UDI data to GUDID or EUDAMED, or release product by itself. Those stay with your people and your regulatory process.

FRAME / 01

Start with where you sell.

The same infusion set may be built once and sold under several regimes. Each has its own law, its own route to market and its own inspectors, but they increasingly share one quality-system standard.



Describe the operation

Finished devices, IVDs, components, contract manufacture, sterilisation, packaging or relabelling? QMSR applies to manufacturers of finished devices, including contract sterilisers, relabellers and repackagers, for the operations they perform [2].

One QMS, several audits

MDSAP lets one audit serve several participating regulators, including the FDA, Health Canada, TGA, ANVISA and Japan's MHLW/PMDA [14]. EU notified bodies audit against MDR/IVDR.

Write it down once

Record which regulations, markets and standards apply, and why, in a controlled document your quality unit owns. Revisit it when products, markets or suppliers change.

WHERE V5 FITS

Keep the regulatory scope, device list and procedures as controlled documents with revisions, owners and review dates. V5 industry packs adjust wording and screens; they do not decide which rules apply to you.

Sources: [2], [4], [5], [6], [7], [8], [9], [10], [11], [13], [14], [15] (linked on pages 30–31)

New words for an old job, since February 2026.

The FDA's QMSR took effect on 2 February 2026. It incorporates ISO 13485:2016 by reference and retires some familiar U.S. terms. The evidence still matters; the names and structure changed.

TOPIC	WHAT THE QMSR DOES	PRACTICAL NOTE
Quality system	21 CFR 820 now incorporates ISO 13485:2016 by reference, with added FDA requirements and definitions [1][2]. FDA inspections use compliance programme 7382.850 rather than QSIT [3].	Map procedures to ISO 13485 clauses, then to the added Part 820 sections, not the other way round.
DMR, DHR, DHF	These terms are no longer used in the regulation. ISO 13485 asks for a medical device file (4.2.3) and a record for each device or batch giving traceability and the amount made and approved for distribution (7.5.1) [3][4].	If your SOPs still say DHR, decide whether to rename or cross-reference. Inspectors read content, not labels.
Labels, records	Part 820 keeps specific labelling and packaging controls (820.45) and adds record requirements, such as for complaints and servicing (820.35) [2].	Treat these as additions to ISO 13485, not as replaced by it.

Outside the U.S. EU MDR and IVDR require a quality management system proportionate to risk class (Article 10) and are enforced through notified bodies and competent authorities [6][7]. Great Britain continues under the Medical Devices Regulations 2002, with strengthened post-market surveillance requirements in force from 16 June 2025 [15].

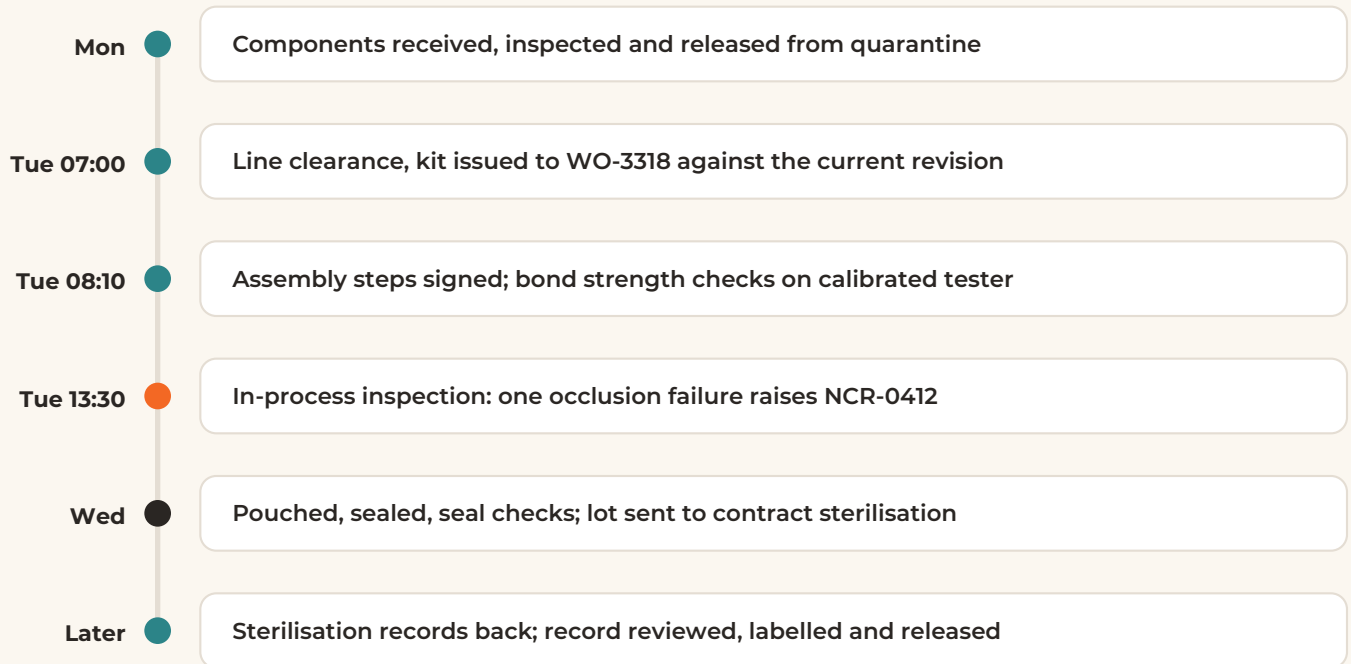
WHERE V5 FITS

V5 calls the per-build record a device production record (eDHR). Whatever your procedures call it, the record links work order, revision, component lots, signed steps, inspections, nonconformances and labels, so it can serve as the ISO 13485 7.5.1 record for each device or batch where you configure it that way.

FRAME / 03

One build, start to shipment.

A worked example: a work order for a sterile infusion set, WO-3318, built to work instruction WI-220. Times and steps are an example, not a recommendation.



The record grows with the build

Each event adds to the same record: lots, people, instruments, results and decisions. Review starts from a complete picture, not a pile of travellers.

Exceptions stay attached

The occlusion failure is not a side note. Its NCR, disposition and any rework are linked to the units and to the build.

Outsourced steps still count

Contract sterilisation is your process too. Its certificates and cycle records belong with the lot before release.

WHERE V5 FITS

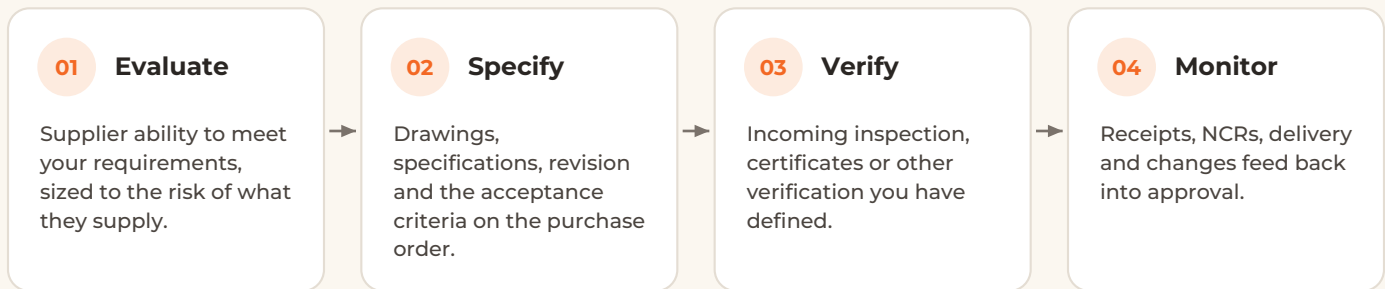
Work orders sit on the production schedule with their materials and stations. Kiosk steps capture who did what, with which lots and instruments, and the work order's record is assembled as the build runs.

Sources: [4] (linked on pages 30–31)

FLOW / 01

Control what you buy as tightly as what you make.

Moulded parts, tubing, adhesives, electronics, sterile barrier materials and outsourced processes such as sterilisation all shape the finished device.



Risk-based controls

ISO 13485 7.4 asks you to establish criteria for evaluating and selecting suppliers, proportionate to the risk the purchased product poses, and to keep records of evaluation and monitoring [4].

Change notification

Purchasing information should, where applicable, include a written agreement that the supplier tells you about changes before they affect your product [4]. A new resin grade can change a validated process.

Outsourced processes

Sterilisation, cleaning, coating and testing done by others stay under your QMS. Agree what records come back with each lot and how you check them.

WHERE V5 FITS

Approved supplier lists, supplier qualification and scorecards sit with purchasing and receiving, so an unapproved supplier or part is visible at the point of use. Supplier findings can route to SCARs and CAPA, and suppliers can submit documents through the supplier portal where configured.

Sources: [4], [5] (linked on pages 30–31)

FLOW / 02

Receiving decides what the line can trust.

Goods-in is where a supplier lot becomes your lot. Identity, revision, status and inspection evidence captured here make every later trace possible.



Match the delivery

Purchase order, part number and revision, supplier lot, quantity and shelf life, recorded once.

Quarantine by default

New lots stay unusable until the verification your procedure requires is done and a person releases them.

Inspect to a plan

Sampling plan, characteristics and acceptance criteria tied to the part revision; results recorded with the instrument used.

Certificates are claims

Decide which certificate values you verify on receipt, which you accept on supplier approval, and how often you confirm that trust is still earned.

Revision at the dock

A correct part at the wrong revision is a nonconformance. Check revision against the purchase order and the bill of materials in force.

Reject cleanly

Segregate physically and in the record, raise an NCR against the supplier lot and feed it into supplier monitoring.

WHERE V5 FITS

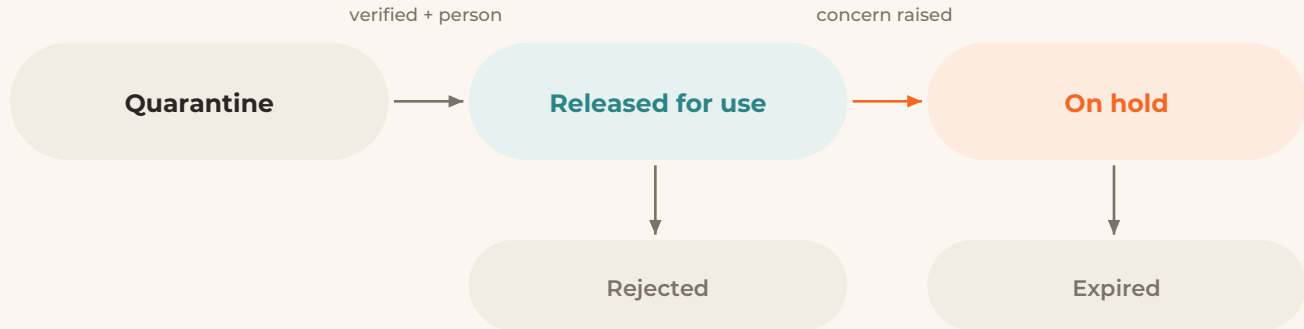
Receiving records lot, expiry and status against the purchase order, and lots can start in quarantine. Certificate values can be read from a photo or PDF and presented for a person to confirm before anything changes; AI extraction never releases a lot.

Sources: [4] (linked on pages 30–31)

FLOW / 03

Know what you can use, right now.

Status, revision, location and shelf life decide whether a component can go into a build. Get it wrong and the error is built into every unit.



Status is a decision

Only named roles change status, and the record says who, when and why. ISO 13485 asks that product status is identified throughout production [4].

Store by need

Adhesives with shelf life, ESD-sensitive electronics, humidity-sensitive polymers and sterile barrier stock may need their own conditions. Keep system locations matching the shelf.

Block at the scan

Issue earliest-expiry-first where it fits, and stop a held, rejected, expired or wrong-revision lot when it is scanned to a work order.

WHERE V5 FITS

Lots carry status, location and expiry, with FEFO/FIFO issue and storage zones. Scanning a held, rejected or expired lot at the kiosk stops the step according to your workspace rules. Storage readings can stream in with alerts through a supported, configured sensor connection.

Sources: [4] (linked on pages 30–31)

FLOW / 04

Build to the revision that is in force.

Drawings, bills of materials, work instructions, inspection plans and label artwork are all revisions. A build is only right if every one of them was current.

WI-220 · REV C (IN FORCE)

- Bill of materials and revisions
- Steps, torque and bond limits
- Fixtures and instruments
- In-process inspections
- Pouch, label and IFU revision



PROPOSED REV D · IMPACT

New tubing supplier. Assess: risk file, verification and validation, process settings, inspection plan, training, labels, open work orders. Approve before the effective date; WO-3318 stays on rev C.

Control documents

ISO 13485 4.2.4 asks that documents are reviewed and approved before issue, that current revisions are available at the point of use and that obsolete ones are prevented from unintended use [4].

Change with evidence

Design and process changes are reviewed for their effect on the device, verified or validated as appropriate and approved before implementation (7.3.9) [4]. Update the ISO 14971 risk file where risk changes [5].

Fix the revision at issue

A work order should carry the revisions it was released with, so its record compares actual work to the instruction that was in force at the time.

WHERE V5 FITS

Work instructions, bills of materials and inspection plans are kept under revision with approval signatures, and change control with impact assessment is available where your plan includes it. Existing SOPs can be uploaded and drafted into instructions for your team to check and approve.

Sources: [4], [5] (linked on pages 30–31)

FLOW / 05

Record the build while it happens.

Most device errors are small: a wrong part, a skipped step, an untrained hand, an out-of-calibration tool. The record should catch them at the bench, not at review.

Line clearance

Previous parts, labels and documents removed and checked before the new work order starts.

Components verified at use

Scan each component lot to the work order, so the record shows exactly what went into which units.

Steps signed as done

Each step signed by a trained operator, with values recorded against limits, not ticked afterwards.

Special processes

Bonding, welding and sealing whose results cannot be fully verified afterwards need validated parameters and monitoring (ISO 13485 7.5.6) [4].



Units, lots or both. Decide what you trace: individual serial numbers for implantables and active devices, lot or batch for most disposables. The choice shapes labels, inspection sampling and how fast you can scope a recall.

WHERE V5 FITS

Operators follow approved steps on the kiosk with scanning, photos, values against limits and signatures. Instrument readings can be attached or captured through supported, configured connections. V5 records lots and units as you configure them; it does not generate serial numbers by itself.

Sources: [4] (linked on pages 30–31)

FLOW / 06

The package is part of the device.

For sterile devices, the environment, the sterile barrier and the sterilisation process are evidence about every unit, and some of it arrives after the build is finished.



Work environment

ISO 13485 6.4 asks for documented requirements for the work environment and contamination control where they affect product, including sterile devices [4].

Sterile barrier

Seal parameters, seal checks and packaging validation show the barrier will hold until use.

Sterilisation records

Cycle records, load configuration and release evidence from in-house or contract sterilisation belong with the lot (ISO 13485 7.5.7) [4].

Recognised standards

Packaging, sterilisation and cleanroom standards are voluntary; check which editions the FDA recognises [13] and which are harmonised under the MDR.

WHERE V5 FITS

Room readings, seal checks, integrity results and sterilisation certificates can be recorded against the work order or lot and kept visible to the reviewer. Sensor streams need supported, configured devices. Training records can gate who performs packaging steps where configured.

Sources: [4], [13] (linked on pages 30–31)

DECIDE / 01

Measure with tools you can trust.

Inspection is only evidence if the method, the sample, the limits and the instrument are all right. The record should show each one.



WO-3318 · IN-PROCESS · WORKED EXAMPLE

Bond pull strength · TT-07	Pass
Flow rate · FR-02	Pass
Visual, 2.5x	Pass
Occlusion test	1 fail · NCR-0412
Seal width · CAL-118	Pass
Sterility release	Awaiting certificate

Calibrated, at the time

ISO 13485 7.6 asks that measuring equipment is calibrated or verified, identified, and that you assess earlier results when it is found out of calibration [4].

Acceptance is recorded

Record evidence of conformity to acceptance criteria and the identity of the person authorising release (8.2.6) [4].

WHERE V5 FITS

Inspection plans record results against limits with the instrument used, and the instrument's calibration status is shown at the step. Lab & QC adds sample plans, result queues and SPC for trend review. A failed result can raise a nonconformance from the step.

DECIDE / 02

A person releases. The record shows why.

Release is an authorised decision, not a calculation. The system's job is to put a complete record, with its open items, in front of the right person.



Planned arrangements first

ISO 13485 8.2.6 says product is not released until planned arrangements are satisfactorily completed, and the record identifies who authorised release [4].

Labels checked too

Part 820 keeps labelling and packaging controls, including examining labels for accuracy before release, with the record of who did it [2].

Open means open

A pending sterilisation certificate or an unclosed NCR should be visible on the record and stop release unless your procedure allows a documented exception.



WHERE V5 FITS

The review queue shows each device production record with open items first. Electronic signatures with meaning and time are designed for 21 CFR Part 11 where your plan includes them. V5 never releases product by itself; your procedures and role permissions decide who can approve.

Sources: [2], [4], [12] (linked on pages 30–31)

DECIDE / 03

When a unit does not conform.

A failed occlusion test on one unit of WO-3318. What happens next decides whether the nonconformance stays small.

1

Identify and segregate

Tag the unit or lot, record the failure on the step, prevent unintended use.

2

Evaluate

Is it isolated or systemic? Which other units, lots or work orders could share the cause?

3

Disposition

Rework, scrap, return to supplier, or accept by concession with justification and authorisation.

4

Verify and link

Re-inspect reworked units; link the NCR to the build record, supplier lot and any CAPA.

What the standard expects. ISO 13485 8.3 asks that nonconforming product is identified, documented, segregated, evaluated and dispositioned by authorised people; that concessions are justified and only granted where regulatory requirements are met; that reworked product is re-verified; and that nonconforming product found after delivery is acted on appropriately [4].

WHERE V5 FITS

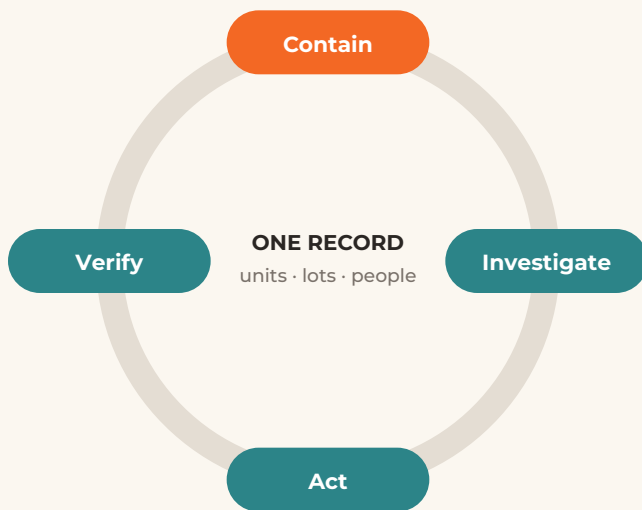
Nonconformances can be raised from the failed step and linked to units, lots, the supplier and the work order. Disposition decisions record who authorised them and why. A material review board can work from one shared record rather than email threads.

Sources: [4] (linked on pages 30–31)

DECIDE / 04

Fix the cause, not just the unit.

NCRs, complaints, audit findings, service records and trends are all inputs. A connected CAPA loop turns them into fewer repeats and a risk file that stays honest.



Contain fast

Hold affected lots and open work orders; record the immediate decision and who made it.

Investigate with evidence

Build records, inspections, instruments, operators and supplier lots, all reachable from the NCR.

Act on the system

Change the instruction, fixture, training, supplier approval or design, through change control.

Verify effectiveness

Agree what evidence will show the fix held, and check it. ISO 13485 8.5.2 asks you to verify that the action does not adversely affect the device [4].

Keep risk in the loop. ISO 14971 expects production and post-production information to be collected and reviewed, and the risk management file updated when it reveals new or changed risks [5]. A CAPA that changes nothing in the risk file deserves a second look.

WHERE V5 FITS

Deviations, NCRs and CAPA link to the work order, lot, equipment and people involved, with root-cause workflow, effectiveness checks and change control. AI can suggest a classification or draft an investigation summary for a person to review and edit; it never closes or approves one.

Sources: [4], [5] (linked on pages 30–31)

DECIDE / 05

The right people, on the current revision.

Competence is evidence. If an operator was not trained on rev C, the units they built on rev C need explaining.

Competence, not attendance

ISO 13485 6.2 asks you to determine necessary competence, provide training, evaluate its effectiveness and keep records [4].

Train before the change

When a revision changes, operators should be trained on it before they build to it. Read-and-understood is a start; practical sign-off may be needed for special processes.

Separate the roles

Decide which roles may build, inspect, disposition and release, and make the system enforce it rather than relying on memory.

WORKED EXAMPLE: COMPETENCE AND PERMISSION MATRIX

	WI-220 rev C	Pouch sealing	Final inspection	Record release
Operator A	Trained	Trained	—	Not permitted
Operator B	Trained	Retraining due	—	Not permitted
Inspector	—	—	Trained	Not permitted
QA reviewer	—	—	—	Trained

WHERE V5 FITS

Document control keeps SOPs and instructions under revision with read-and-understood training. The skills matrix can block untrained operators at the kiosk where configured, and role permissions control who can record, inspect, disposition or approve.

Sources: [4] (linked on pages 30–31)

SUSTAIN / 01

Ready equipment is evidence too.

Fixtures, sealers, testers, gauges and automated assembly cells are part of every unit's story. Their state on the day belongs in the record.



Calibrate and verify

Identify each measuring instrument, calibrate it at defined intervals against traceable standards, protect it from invalidating adjustment and record results (ISO 13485 7.6) [4].

Maintain on a plan

Document maintenance requirements, including intervals, where lack of maintenance could affect product quality, and keep records (6.3) [4].

Look back when it fails

An out-of-tolerance gauge raises a question about every result it produced since its last good check. The record should answer it fast.

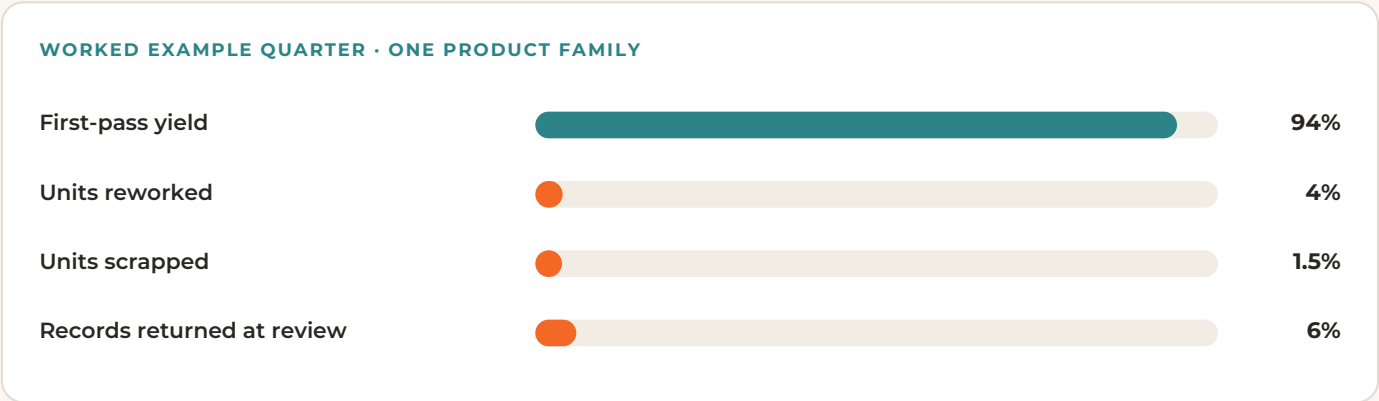
WHERE V5 FITS

Each instrument, fixture and machine can have an equipment record with calibration schedules, tolerance checks, certificates and planned maintenance. Out-of-calibration instruments can be blocked at the kiosk, and the work orders that used them can be found. Predictive failure analytics are not offered today.

Sources: [4] (linked on pages 30–31)

Measure right first time, not just output.

In device manufacturing the most expensive unit is the one that fails after it has been built, inspected and packed. Measure where quality is lost.



Rank the losses

NCRs by reason, step and supplier show where to start. A Pareto from records beats one from memory.

Count review rework

Records sent back at review are hidden cost. Track why, and fix the step that produced the gap.

Bring it to review

ISO 13485 5.6 management review includes process and product monitoring, CAPA and feedback [4]. Use the same data, not a separate spreadsheet.

WHERE V5 FITS

Reports and dashboards can show yield, NCRs by reason, rework, downtime and OEE from the events your team records, where your plan includes them. AI forecasting and anomaly detection are coming soon, not available today.

SUSTAIN / 03

Right label, right identifier, every time.

Labelling errors are among the most avoidable causes of device recalls. UDI adds a machine-readable identity that must match the record behind it.



U.S. UDI

21 CFR Part 830 sets the UDI system; labelers submit device data to the FDA's GUDID. The UDI carries a device identifier and production identifiers such as lot, serial, expiry or manufacture date. Exceptions, alternatives and direct-marking duties vary by device [9].

EU UDI and EUDAMED

MDR Article 27 sets the EU UDI system [6]. EUDAMED's actor, UDI/device, certificate and market-surveillance modules became mandatory from 28 May 2026; vigilance follows later [8].

Print from the record

Print lot, expiry and serial from the released record rather than retyping, check labels against the approved artwork revision, and reconcile labels issued, used and destroyed.

What software should not pretend to do. Issuing agency, device identifier allocation, GUDID and EUDAMED submissions and labelling content decisions belong to your regulatory process. A production system should print what was approved and prove it was checked.

WHERE V5 FITS

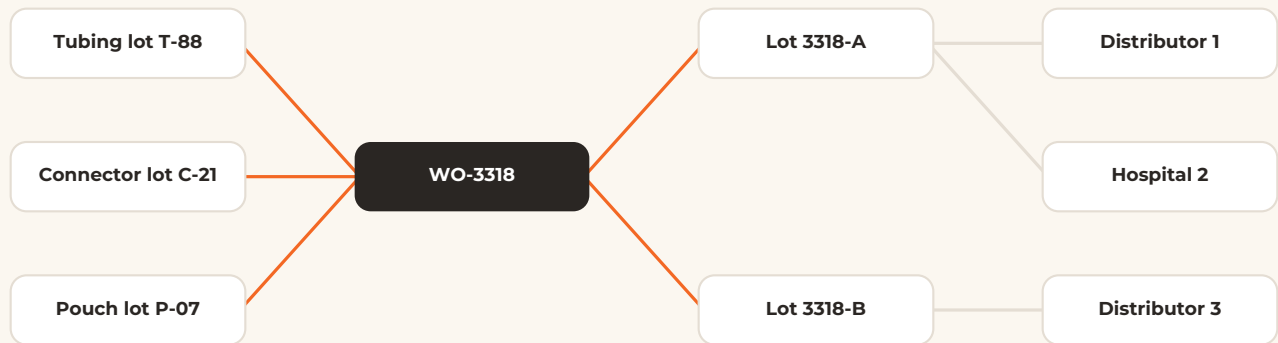
Label design and printing use data from the record, including GS1-128 barcodes, on configured printers, with label checks recorded. V5 does not allocate UDIs or submit data to GUDID or EUDAMED; keep those in your regulatory process.

Sources: [6], [8], [9] (linked on pages 30–31)

SUSTAIN / 04

Trace both ways, in minutes.

When a complaint arrives or a supplier lot is suspect, the question is the same: which units, which customers, which records. The answer should come from the record.



Distribution records

Keep who received which lots or serials. ISO 13485 7.5.9 sets traceability requirements, stricter for implantable devices [4].

Complaints and reports

Complaints feed investigation and, where criteria are met, regulatory reports: FDA Part 803 [10], EU MDR vigilance [6], GB post-market surveillance [15].

Corrections and removals

U.S. Part 806 requires reports of certain corrections and removals [11]. Rehearse a mock recall and time it.

WHERE V5 FITS

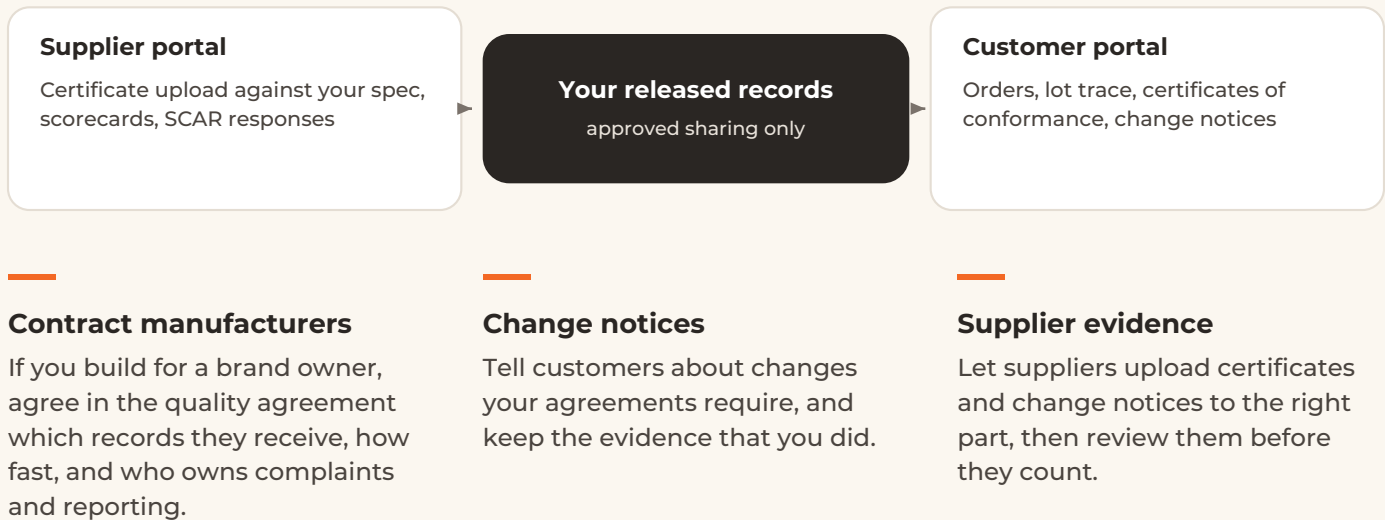
Lots and units link at receipt, build and shipment, so genealogy can be followed forward from a supplier lot or backward from a complaint, and recall scope listed from those links. Complaints can be logged and linked to the device record. Reporting decisions and submissions stay with your regulatory team.

Sources: [4], [6], [10], [11], [15] (linked on pages 30–31)

SUSTAIN / 05

Share the right records, safely.

OEM customers want certificates of conformance, lot data and change notices. Suppliers need to send certificates and respond to SCARs. Both should see only what you choose.



WHERE V5 FITS

A portal foundation gives customers and suppliers branded, read-only access to what you approve. Portal scope and permissions depend on configuration; check the current plan comparison for inclusion. Nothing is shared automatically from an open record.

SUSTAIN / 06

Trustworthy records. Honest AI.

Electronic records and signatures need controls, and AI is useful only where a person stays accountable for the result.

Electronic records

21 CFR Part 11 sets criteria for electronic records and signatures in the U.S. [12]. Other markets have their own expectations; your procedures should name them.

Validate QMS software

ISO 13485 4.1.6 asks you to validate computer software used in the quality management system, proportionate to risk, before first use and after changes [4].

Audit trail you read

Review audit trails as part of routine record review where risk warrants, not only after an incident.

AI CAN HELP

- Read certificate values from a photo for a person to confirm
- Draft work instructions from an uploaded SOP for approval
- Suggest an NCR classification or draft a summary
- Explain a record's audit trail in plain language
- Find records and screens faster

AI NEVER

- Releases a unit, lot or record
- Signs a record or closes an NCR or CAPA
- Decides reportability or classifies your device
- Decides which regulations apply to you
- Predicts failures today (forecasting is coming soon)

WHERE V5 FITS

Electronic signatures designed for 21 CFR Part 11, a tamper-evident audit trail and an IQ/OQ/PQ validation pack are available where your plan includes them; every plan can view the audit log. AI features require configured provider access and their outputs need human review.

Sources: [4], [12] (linked on pages 30–31)

APPLY / 01

Evidence map.

A one-page way to check that every theme an auditor or inspector may ask about has an owner and a record. Clause numbers refer to ISO 13485:2016 [4].

THEME	TYPICAL EVIDENCE	WHERE IT LIVES IN V5	OWNER
Scope (4.1, 4.2)	Regulatory scope, device list, medical device files	Controlled documents	Quality + regulatory
Documents (4.2.4)	Approved revisions, obsolete control	Document control	Quality
Suppliers (7.4)	Evaluation, purchase specs, monitoring	Supplier qualification, receiving	Supplier quality
Receiving (7.4.3)	Incoming inspection, quarantine, release	Lots, status, inspection plans	Receiving + QC
Production (7.5.1)	Build record per device or batch	Work order, kiosk steps, eDHR	Production
Special processes (7.5.6)	Validated parameters, monitoring	Instructions, readings, equipment	Engineering
Sterile (7.5.7)	Sterilisation and barrier records	Lot records, certificates	Quality
Measurement (7.6)	Calibration, out-of-tolerance review	Equipment, calibration	Metrology
Release (8.2.6)	Acceptance evidence, authoriser	Review queue, e-signatures	Quality
Nonconforming (8.3)	NCR, disposition, concession	Nonconformances	MRB
CAPA (8.5)	Investigation, action, effectiveness	CAPA, change control	Quality
Competence (6.2)	Training, effectiveness, roles	Skills matrix, roles	Managers
Labels and UDI	Artwork revision, label checks, UDI data	Label design, print checks	Regulatory + production
Traceability (7.5.9)	Genealogy, distribution records	Lot genealogy, shipments	Quality
Software (4.1.6)	QMS software validation, audit trail	Validation pack, audit trail	Quality + IT

Plan inclusion varies; some areas need Professional or Enterprise. Confirm against the current plan comparison before you scope a project.

WORKSHEET 01

Is your device record ready for review?

Pick one recent work order and check its record. Mark Yes, Partly or No, then note the gap.

	YES	PARTLY	NO
Revisions shown The record shows the drawing, BOM, instruction, inspection plan and label revisions in force.	☐	☐	☐
Components traced Every critical component lot or serial is linked to the units or batch.	☐	☐	☐
Steps signed Each step shows who did it, when and with recorded values against limits.	☐	☐	☐
Trained operators Every signer was trained on that revision at the time.	☐	☐	☐
Instruments valid Every measuring instrument used was in calibration on the day.	☐	☐	☐
Inspections complete In-process and final inspections recorded with acceptance criteria.	☐	☐	☐
Exceptions linked NCRs, rework and concessions are linked and closed or explicitly open.	☐	☐	☐
Outsourced records Sterilisation or other outsourced-process records are attached.	☐	☐	☐
Labels checked Label check recorded against the approved artwork, with UDI data matching.	☐	☐	☐
Release identity The record identifies who authorised release, with meaning and date.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Build readiness.

A pre-build check for the line lead and quality. Adapt it to your products; keep it short enough to be used every shift.

	DONE	N/A
Work order Product, revision, quantity and planned completion confirmed.	☐	☐
Line clearance Previous parts, labels and documents removed and signed.	☐	☐
Components All lots released, in date, correct revision and kitted to the work order.	☐	☐
Instructions Current revision at the station; obsolete copies removed.	☐	☐
People Operators trained on this revision and special processes.	☐	☐
Equipment Fixtures, sealers and testers calibrated and maintained.	☐	☐
Environment Room readings in limits where the product requires it.	☐	☐
Labels Approved artwork revision and label stock ready; printer checked.	☐	☐
Exceptions Who to call and what to record if a unit or step fails.	☐	☐

NOTES AND OWNERS

WORKSHEET 03

Ask to see it work.

Questions for any software demonstration. Ask the vendor to show each one with your device, not a slide.

	SHOWN	PARTLY	NOT SHOWN
Wrong revision Scan a component at the wrong revision to a work order and show what happens.	☐	☐	☐
Held lot Scan a quarantined or expired lot at the step.	☐	☐	☐
Untrained operator Show an operator not trained on the revision being stopped, if configured.	☐	☐	☐
Out of calibration Show a tester past its due date flagged before use, and the work orders it touched.	☐	☐	☐
Failed unit Raise an NCR from a failed inspection and show its link to the record.	☐	☐	☐
Revision change Approve a new revision; show work orders in progress keep the old one.	☐	☐	☐
Record review Show a complete device record with open items first, then sign it.	☐	☐	☐
Trace From a supplier lot, list every unit and customer; then the reverse.	☐	☐	☐
AI limits Show certificate extraction waiting for a person to confirm.	☐	☐	☐
Export Export a complete device record and its audit trail for an auditor.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

Roll out in phases.

Start where the value is visible and the risk is contained. Validate as you go, as ISO 13485 4.1.6 expects for QMS software [4].

PHASE 1
Foundations

Scope, roles, document control, training records, equipment register with calibration and maintenance.

PHASE 2
Materials

Approved suppliers, part revisions, receiving with inspection and quarantine, status and shelf life.

PHASE 3
Build record

Work instructions and kiosk execution for one product family, in parallel with the current record.

PHASE 4
Decide

Inspection plans, NCR and CAPA, record review and release signatures, after validation of intended use.

PHASE 5
Connect

Labels, genealogy and distribution, mock recalls, portals, yield and performance review.

Validation runs through every phase. Agree intended use, risk and test evidence before each phase goes live, following your procedures and, for U.S. electronic records, Part 11 [4][12]. V5 offers a validation pack where your plan includes it; your validation remains yours.

WORKSHEET 04

Find your first improvement.

Score each area today: E evidenced, P partial, G gap. Start with the gap that costs you rework, review time or audit findings.

	E	P	G
Supplier controls Evaluation, purchase specs, change notification	☐	☐	☐
Receiving and status Inspection plans, quarantine, blocking at the scan	☐	☐	☐
Revision control One current revision at the point of use	☐	☐	☐
Build record Lots, signed steps, values against limits	☐	☐	☐
Special processes Validated parameters, monitoring	☐	☐	☐
Inspection and calibration Instrument status at the step	☐	☐	☐
Record review and release Open items first, identity of authoriser	☐	☐	☐
Nonconforming product Linked NCRs, authorised disposition	☐	☐	☐
CAPA and risk Effectiveness checked, risk file updated	☐	☐	☐
Labels and UDI Printed from record, checked against artwork	☐	☐	☐
Traceability and recall Both ways, mock recall timed	☐	☐	☐
Software and audit trail Validated use, routine review	☐	☐	☐

NOTES AND OWNERS

APPLY / 03

A fair evaluation in four weeks.

A practical way to test any system with your own people and one real product family, without touching your released records.

WEEK 1

Agree the product, the record you want and the five questions that matter most. Load one BOM, instruction and inspection plan.

WEEK 2

Run a build end to end with test data: receipt, kitting, steps, inspections, review and label.

WEEK 3

Break it on purpose: wrong revision, held lot, untrained operator, out-of-calibration tester, failed unit.

WEEK 4

Review with production, quality and regulatory. Decide what to validate, what to change and what not to do.

Rules for the evaluation. Use test data only. Keep your current record and release process live until a validated change is approved. Record what was shown, not what was promised.

ASK V5

“We build [device type] for [markets] under [QMSR / MDR / both]. Our hardest moment is [e.g. reviewing device records before release]. Which workflows should we evaluate first?”

Start a 7-day free trial, no card required, or ask V5 on v5ultimate.com.

WHERE V5 FITS

Try V5 with your own product in a trial workspace using test data. The assistant can answer questions about features and plans; it does not give regulatory advice.

SOURCES

Keep the evidence close.

Primary sources behind this guide, checked October 2026. Click a title to open the publisher's page. Standards are sold by ISO and national bodies; links go to their catalogue pages.

- | | | |
|-----|---|--------------------------------|
| [1] | <u>U.S. FDA, Quality Management System Regulation (QMSR) overview (updated 2 Feb 2026)</u> | FDA OVERVIEW |
| [2] | <u>U.S. eCFR, 21 CFR Part 820: Quality Management System Regulation (effective 2 Feb 2026)</u> | BINDING U.S. REGULATION |
| [3] | <u>U.S. FDA, QMSR Frequently Asked Questions (updated 2 Feb 2026)</u> | FDA FAQ (NON-BINDING) |
| [4] | <u>ISO 13485:2016, Medical devices: Quality management systems, requirements for regulatory purposes</u> | STANDARD; INCORPORATED IN QMSR |
| [5] | <u>ISO 14971:2019, Medical devices: Application of risk management to medical devices</u> | VOLUNTARY STANDARD |
| [6] | <u>Regulation (EU) 2017/745 on medical devices (MDR), consolidated text on EUR-Lex</u> | BINDING EU REGULATION |
| [7] | <u>Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), EUR-Lex</u> | BINDING EU REGULATION |
| [8] | <u>European Commission, EUDAMED overview (first four modules mandatory from 28 May 2026)</u> | EU COMMISSION PAGE |

SOURCES

Sources, continued.

- | | | |
|------|--|-----------------------------|
| [9] | U.S. eCFR, 21 CFR Part 830: Unique Device Identification | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-830 | |
| [10] | U.S. eCFR, 21 CFR Part 803: Medical Device Reporting | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803 | |
| [11] | U.S. eCFR, 21 CFR Part 806: Reports of Corrections and Removals | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-806 | |
| [12] | U.S. eCFR, 21 CFR Part 11: Electronic Records; Electronic Signatures | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11 | |
| [13] | U.S. FDA, Recognized Consensus Standards database | FDA DATABASE |
| | https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm | |
| [14] | U.S. FDA, Medical Device Single Audit Program (MDSAP) | AUDIT PROGRAMME |
| | https://www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-s... | |
| [15] | UK SI 2024/1368, Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 | BINDING GB REGULATION |
| | https://www.legislation.gov.uk/uksi/2024/1368/made | |
| [16] | European Commission, Getting ready for the new regulations (MDR/IVDR transition conditions) | EU COMMISSION PAGE |
| | https://health.ec.europa.eu/medical-devices-new-regulations/getting-ready-new-r... | |
| [17] | Canada, Medical Devices Regulations SOR/98-282 (Justice Laws, current text) | BINDING CANADIAN REGULATION |
| | https://www.laws-lois.justice.gc.ca/eng/regulations/sor-98-282/FullText.html | |
| [18] | TGA, Quality management and medical devices (conformity assessment evidence) | TGA GUIDANCE |
| | https://www.tga.gov.au/products/medical-devices/manufacturing/quality-managemen... | |

How to read the status labels. Binding regulation is law in its jurisdiction. FDA overviews and FAQs explain how the agency reads its rules but do not bind. ISO standards are voluntary unless a regulation incorporates them, as the QMSR does for ISO 13485, or a contract requires them. EU harmonised standards give a presumption of conformity for the requirements they cover.

SCOPE AND LIMITS

What this guide is, and is not.

This guide is practical orientation for evaluating production, quality and traceability operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you. Requirements depend on device type, risk class, markets and your role as manufacturer, contract manufacturer, steriliser or distributor. Your quality, regulatory and legal advisers decide what applies.

V5 capability statements reflect the V5 product reference reviewed on 1 October 2026. Some capabilities depend on plan, configuration, devices and permissions. AI demand and yield forecasting and process anomaly detection are coming soon and are not available today. V5 does not cover design controls or technical documentation authoring, does not allocate UDIs or submit to GUDID or EUDAMED, does not decide reportability, does not release product by itself, and does not by itself make you compliant or validated.

Regional scope. EU legacy-device transition deadlines depend on class and conditions, not one date [16]; MDCG documents are guidance, and later EUDAMED modules follow their own timelines [8]. Great Britain remains under the Medical Devices Regulations 2002 with Part 4A post-market surveillance from 16 June 2025; proposed future measures are not yet law [15]. In Canada, Class II–IV devices need a Medical Device Licence before sale or import [17]. In Australia, quality-system evidence depends on class and evidence route; ISO 13485 certification is not a market authorisation [18]. The legal role of ISO 13485 differs by market.

Photography is staged; everyone shown wears protective clothing. Work orders, lots, results and charts are worked examples, not customer data or results.



Built to revision. Inspected. On record.

See medical device workflows at v5ultimate.com

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