



THE PHARMACEUTICAL OPERATIONS GUIDE

Right material. Right record. Released by a person.

From approved supplier to distributed, traceable batch

A capability and evaluation guide for finished-dose and API manufacturers, contract manufacturers and packagers who want every material, step, result and decision to reach the quality unit as one connected batch record.



GMP

BATCH RECORD

DISPOSITION

Global edition / October 2026

v5ultimate.com

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

INSIDE THE GUIDE

One batch. Every hand. One disposition.

A batch passes through purchasing, goods-in, sampling, the warehouse, dispensing, manufacture, the laboratory, packaging and the quality unit. This guide follows it, and shows what each handover must leave behind.

01 / FRAME

pp. 03–05

The rules and who decides

U.S. CGMP, EU GMP and PIC/S, WHO, ICH; the quality unit and Qualified Person; a batch week.

02 / FLOW

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Supplier to finished bulk

Supplier approval, sampling, status and retest dates, master records, dispensing and execution.

03 / DECIDE

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Test, review, investigate

Laboratory results, batch record review and disposition, deviations and OOS, CAPA and change, people.

04 / SUSTAIN

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Equipment, packs, supply chain

Cleaning and calibration, yield and review, labels, serialisation and distribution, recall, portals, data integrity.

05 / APPLY

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Evidence map and working tools

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

06 / SOURCES

pp. 31–33

What this guide rests on

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

Who it is for. Heads of quality and QA, Qualified Persons, production and warehouse managers, QC laboratory leads, validation and IT, and anyone choosing or reviewing a production and quality system for medicinal products or APIs.

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; guidelines and ICH documents apply as your regulators adopt them. Check the current text for your products and markets.

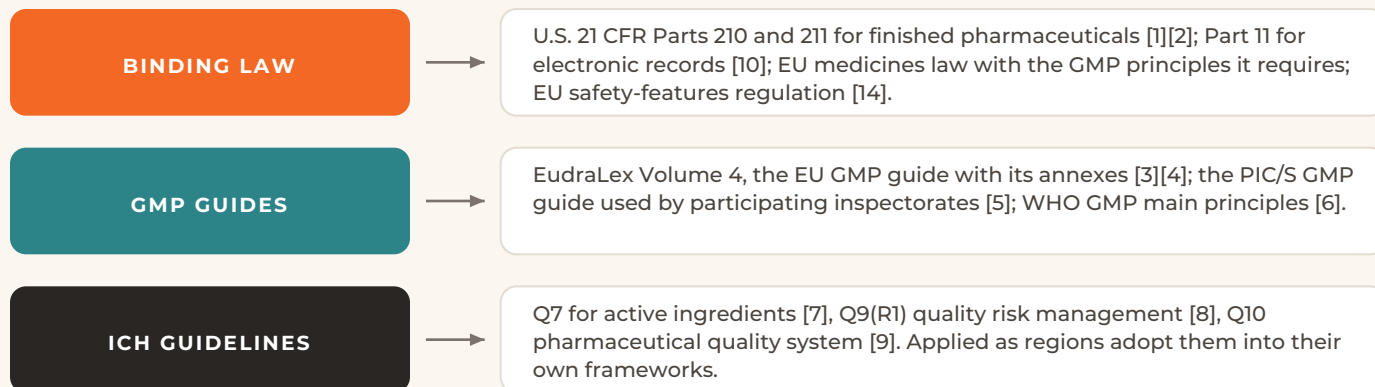
WHERE V5 FITS

V5 records the production, laboratory and quality work your procedures define. It does not write your marketing authorisation, set specifications, decide batch disposition or certify batches, or generate and upload serial numbers to national verification systems. Those stay with your people and your regulatory process.

FRAME / 01

Start with where you supply.

The same tablet may be made once and released into several markets. Each has its own law and inspectors, but the core GMP expectations are closely aligned.



Describe the operation

Finished dosage forms, APIs, sterile products, packaging only or contract testing? Part 211 covers finished pharmaceuticals [2]; ICH Q7 covers API manufacture [7]; sterile work adds its own annex in EU GMP [3].

Minimum, not maximum

Part 210 describes CGMP as minimum requirements for methods, facilities and controls [1]. Your marketing authorisation and specifications add product-specific obligations.

Write it down once

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

WHERE V5 FITS

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

Sources: [1], [2], [3], [4], [5], [6], [7], [8], [9], [10], [14] (linked on pages 31–32)

FRAME / 02

Who decides, and who may not.

Pharmaceutical GMP gives release authority to named, independent people. Systems should make that independence visible, not blur it.

WHO	WHAT THE TEXT SAYS	PRACTICAL NOTE
U.S. quality unit	21 CFR 211.22 gives a quality control unit responsibility and authority to approve or reject components, containers, in-process materials, packaging, labelling and drug products, and to review production records [2].	Configure roles so production cannot approve its own batch.
EU Qualified Person	Each batch is certified by a Qualified Person before release for sale or supply; EU GMP Annex 16 describes certification and batch release [3].	The QP certifies; the system shows the evidence and records the certification.
Pharmaceutical quality system	ICH Q10 describes management responsibility, process performance monitoring, CAPA, change management and management review across the lifecycle [9].	Use one set of records for daily decisions and periodic review.
Risk management	ICH Q9(R1) expects the level of effort, formality and documentation to match the level of risk, and addresses subjectivity in risk assessments [8].	Record why a control is lighter or heavier.

Elsewhere. PIC/S participating authorities inspect against the PIC/S GMP guide, which closely mirrors EU GMP [5]. WHO GMP describes an authorised person responsible for release in comparable terms [6]. Check your national law for the exact title and duties.

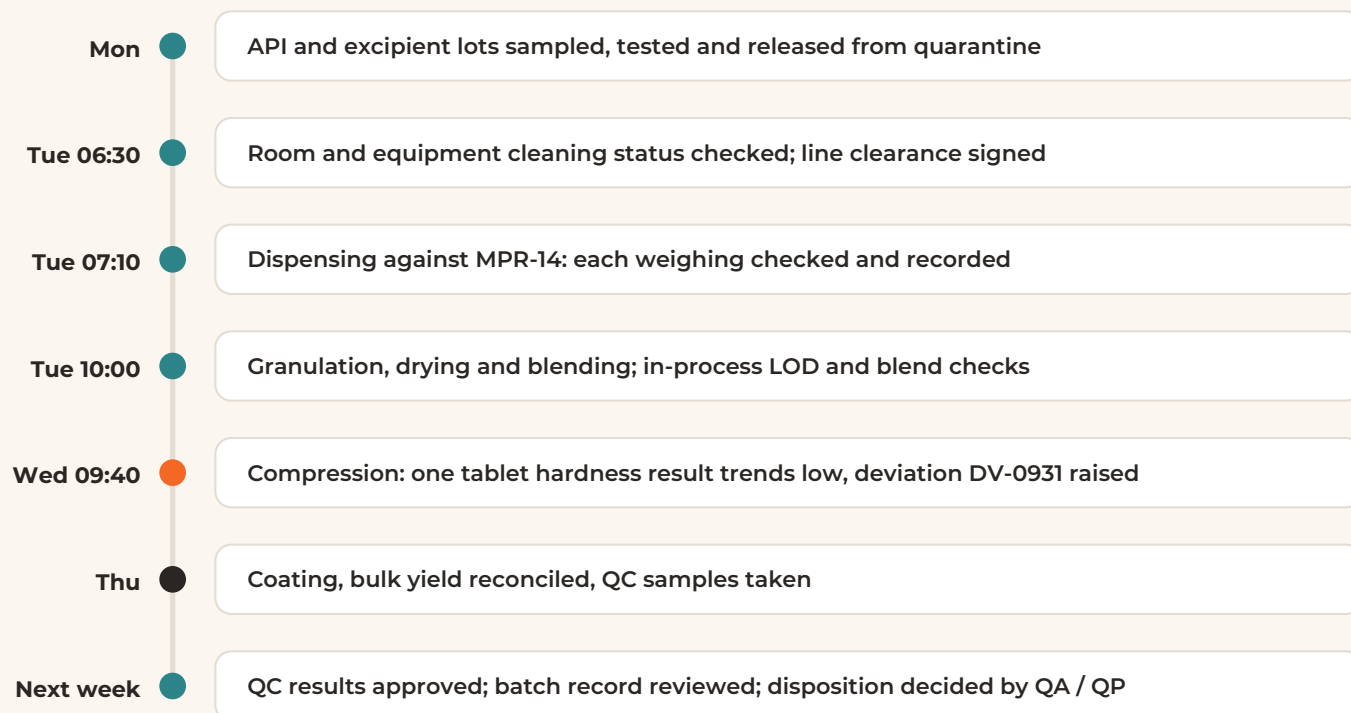
WHERE V5 FITS

The QA release queue shows each batch record with open items first. Role permissions decide who can record, review, approve or reject, and electronic signatures capture name, meaning and time. V5 never releases or certifies a batch by itself.

FRAME / 03

One batch, start to release.

A worked example: a 200 mg film-coated tablet, batch B-2207, made to master record MPR-14 rev 6. Times and steps are an example, not a recommendation.



One record grows

Every event adds lots, people, equipment, results and decisions to the same batch record, so review starts from a complete picture.

Deviations stay attached

DV-0931 is not a footnote. Its investigation, impact on B-2207 and any other batches, and its CAPA link to the record.

Testing is part of the batch

Laboratory results, their review and any OOS investigation belong with the batch before disposition.

WHERE V5 FITS

Work orders sit on the production schedule with their formula, materials and rooms. Kiosk steps capture who did what, with which lots, equipment and values, and the electronic batch record is assembled as the batch runs.

Sources: [2] (linked on pages 31–32)

FLOW / 01

Approve the supplier and the material.

An API, an excipient, a capsule shell and a printed carton all change the medicine. Approval covers who makes them, to which specification, and how you will confirm each delivery.



Identity every lot

21 CFR 211.84 requires at least one identity test on each component lot; a supplier's certificate may be accepted for other attributes if you establish its reliability and verify it at intervals [2].

APIs have their own GMP

ICH Q7 sets GMP expectations for API manufacture, including supplier approval and material controls [7]. EU GMP Part II applies it in Europe [3].

Agreements and change

Quality agreements define who tests, who notifies changes and which records come with each lot. A changed synthetic route or site can need regulatory action before use.

WHERE V5 FITS

Approved supplier lists, supplier qualification and scorecards sit with purchasing and receiving, so an unapproved manufacturer is visible at goods-in. Audits can route findings to SCAR, NCR or CAPA, and suppliers can submit documents against your specification through the supplier portal where configured.

Sources: [2], [3], [7] (linked on pages 31–32)

FLOW / 02

Quarantine first. Sample with care.

Goods-in turns a supplier lot into your lot. Identity, condition, quarantine and sampling captured here make every later trace and release possible.



Check the delivery

Purchase order, approved manufacturer, material code, supplier lot, quantity, container condition and seals, recorded once.

Quarantine by default

21 CFR 211.82 asks that components are stored under quarantine until tested or examined and released [2].

Sample to a plan

Number of containers, method, protection from contamination and identification of sampled containers, as 211.84 describes [2].

Certificates are claims

Decide which certificate values you test, which you accept on demonstrated reliability, and how often you confirm that reliance is still earned [2].

Containers, not just lots

A lot can arrive in many containers. Identify which were sampled and keep each container's status visible.

Reject cleanly

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

WHERE V5 FITS

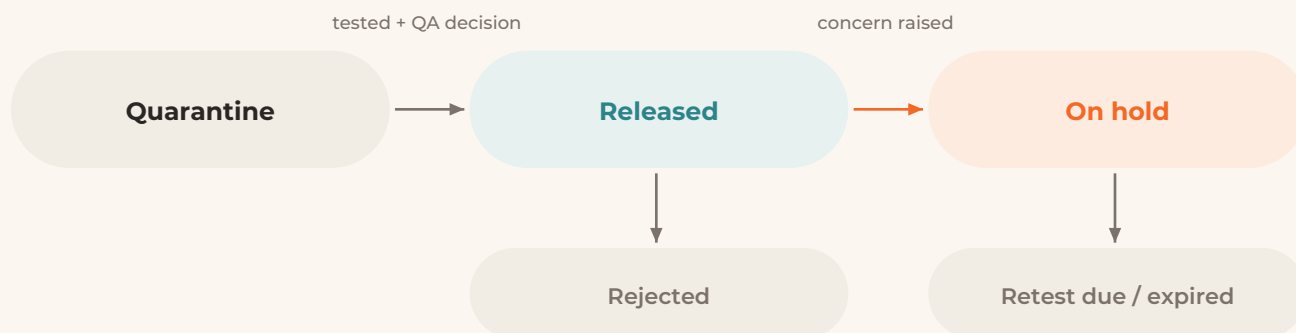
Receiving records lot, expiry and status against the purchase order, and lots start in quarantine where configured. Lab & QC creates sampling and test requests. Certificate values can be read from a PDF or photo and shown for a person to confirm; AI extraction never releases a lot.

Sources: [2] (linked on pages 31–32)

FLOW / 03

Status, retest and expiry.

Only released, in-date material of the right grade should reach a dispensary. Getting status wrong builds the error into every tablet.



Status is a decision

Only the quality unit approves or rejects materials [2]. The record should say who changed status, when and why.

Retest when due

211.87 asks that approved components are retested as appropriate after long storage or exposure to conditions that might affect them [2]. Track retest dates, not just expiry.

Store to condition

211.142 covers quarantine before release and storage under appropriate conditions [2]. Keep system locations and conditions matching the shelf.

WHERE V5 FITS

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

Sources: [2] (linked on pages 31–32)

FLOW / 04

The master record is the plan.

The master production and control record says what the batch should be. The batch record proves what it was. Both must be the right revision.

MPR-14 · REV 6 (IN FORCE)

- Formula, quantities and theoretical yield
- Materials by code and grade
- Equipment and room requirements
- Steps, limits and in-process checks
- Sampling, packaging and labelling

**PROPOSED REV 7 · IMPACT**

New granulation endpoint. Assess: validation status, registered details, risk, cleaning, training, stability, open batches. Approve before effective date; B-2207 stays on rev 6.

Two signatures

211.186 asks that master records are prepared, dated and signed by one person and independently checked, dated and signed by a second person of the quality unit [2].

Follow it, or record why

211.100 requires written procedures for production and process control, followed and documented; any deviation recorded and justified [2].

Change under control

ICH Q10 describes a change management system that evaluates, approves and reviews changes [9]. Some changes need regulatory approval before use.

WHERE V5 FITS

Formulas, master records and instructions are kept under revision with two-signature approval where configured, and change control with impact assessment is available where your plan includes it. An existing batch book or MMR can be uploaded and drafted into V5 for your team to check and approve; nothing goes live until approved.

Sources: [2], [9] (linked on pages 31–32)

FLOW / 05

Weigh once. Check it properly.

Dispensing is where the right quantity of the right lot meets the batch. Most errors here are invisible later, so the record must catch them now.

Released material only

Scan each container; block quarantined, expired, wrong-grade or wrong-material lots before anything is weighed.

Weigh to the record

Target, tolerance and actual weight with the balance used, its calibration status and the container label.

Second check or validated system

211.101 asks that each weighing is checked by a second person, or that automated equipment verifies it under 211.68 [2].

Label what you dispense

Containers identified with name, lot, weight and the batch they are for, so nothing travels unlabelled.



Potency and assay adjustments. Where your master record adjusts API quantity for assay or water content, the calculation and the inputs used belong on the record, checked like any other value.

WHERE V5 FITS

Weigh and dispense guides each material against the master record with scanning, target and tolerance, and stage sign-off. Supported scales such as Mettler SICS can be paired so weights are captured, not typed. Balances past calibration can be blocked at the kiosk where configured.

Sources: [2] (linked on pages 31–32)

FLOW / 06

Record the batch while it happens.

Granulation, drying, blending, compression and coating each leave evidence: settings, checks, times, yields and who did the work.



Batch production record

211.188 requires the batch record to include each significant step, with dates, equipment, lots, weights, in-process results, actual yield and identity of the people who performed and checked each step [2].

In-process controls

211.110 calls for in-process tests and controls to monitor output and validate processes that may cause variability [2].

Yield at each phase

211.103 asks that actual yields and percentages of theoretical yield are determined at appropriate phases [2]. Unexplained differences need investigation.

Cleaning and contamination

211.67 covers cleaning and maintenance of equipment; EU GMP chapters on premises and production address cross-contamination [2][3].

WHERE V5 FITS

Operators follow approved steps on the kiosk with scanning, values against limits, photos and signatures. Equipment cleaning status and room readings can be checked at the step, and yield reconciliation is part of the batch report. Readings from supported, configured devices are captured directly.

Sources: [2], [3] (linked on pages 31–32)

DECIDE / 01

Results you can stand behind.

The laboratory turns samples into evidence. A result counts when the sample, method, instrument, analyst and review are all traceable.



B-2207 · FINISHED PRODUCT · WORKED EXAMPLE

Description · visual	Complies
Identification · HPLC-03	Complies
Assay · HPLC-03	99.1%
Dissolution · DS-02	Complies
Uniformity of dosage units	Awaiting review
Related substances	In progress

Test before release

211.165 requires appropriate laboratory testing of each batch for conformance to final specifications, including identity and strength of each active ingredient, before release [2].

Complete lab records

211.194 asks for complete data from all tests, including the sample, method, results, calculations and the people who tested and reviewed [2].

WHERE V5 FITS

LIMS and Lab & QC cover sample lifecycle, methods, instruments, results against specification and certificates where your plan includes them. SPC and stability add Westgard rules and stability schedules, and an out-of-specification result escalates to an OOS workflow. Analysts and reviewers sign; V5 does not approve results.

Sources: [2] (linked on pages 31–32)

DECIDE / 02

A person decides. The record shows why.

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



Review before release

211.192 requires production and control records, including packaging and labelling, to be reviewed and approved by the quality unit before a batch is released or distributed [2].

Review by exception

Highlighting out-of-limit values, open deviations and missing signatures focuses review. It does not replace the review your procedures require.

Open means open

An unfinished investigation or pending result should be visible on the record and stop release unless a documented, approved procedure allows otherwise.



WHERE V5 FITS

The QA release queue shows each electronic batch record with exceptions first: out-of-limit values, open deviations, pending results and missing signatures. Part 11 electronic signatures are available where your plan includes them. V5 never releases or certifies a batch by itself.

Sources: [2], [3], [10] (linked on pages 31–32)

DECIDE / 03

When something does not go to plan.

Tablet hardness trends low during compression of B-2207. What happens next decides whether one batch, or several, are in question.

1

Record and contain

Record the event at the step, protect product and hold affected material.

2

Investigate

Find the cause with evidence: settings, materials, equipment, people, environment, method.

3

Extend the scope

Ask which other batches or products could share the cause, as 211.192 requires [2].

4

Decide and link

Document conclusions and follow-up; link to the batch, CAPA and any change.

What the regulation says. 21 CFR 211.192 requires that any unexplained discrepancy, or failure of a batch or its components to meet specifications, is thoroughly investigated whether or not the batch has already been distributed, that the investigation extends to other batches that may have been associated, and that a written record includes conclusions and follow-up [2]. Out-of-specification laboratory results follow the same principle: investigate before deciding, do not keep retesting until a passing result appears.

WHERE V5 FITS

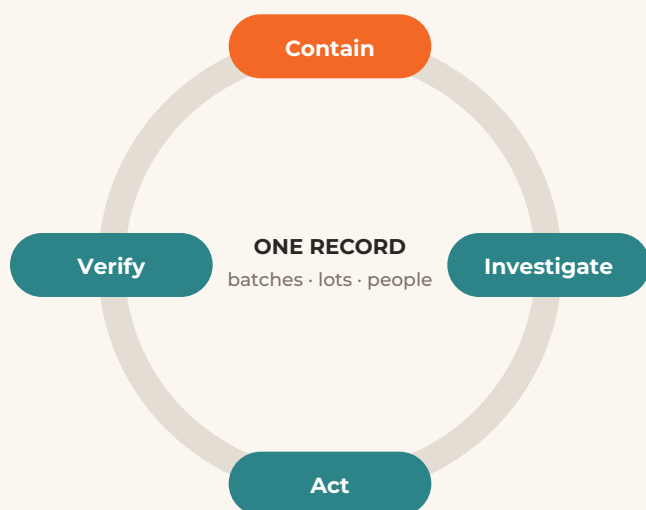
Deviations can be raised from the step and linked to the batch, materials, equipment and people. AI can suggest a classification and draft an investigation summary for a person to review and edit. OOS results follow a defined workflow. A person approves every conclusion.

Sources: [2] (linked on pages 31–32)

DECIDE / 04

Fix the cause. Control the change.

Deviations, OOS results, complaints, audit findings and trends are inputs. A connected CAPA and change loop turns them into fewer repeats without breaking validated processes.

**CAPA across sources**

ICH Q10 describes a CAPA system fed by complaints, rejections, nonconformances, recalls, deviations, audits, inspections and trends [9].

Act through change control

Changes to the process, equipment, method, supplier or master record go through change management, with risk assessment and approval [8][9].

Check it worked

Agree in advance what evidence will show the action was effective, and review it.

Review the product

211.180(e) requires at least annual evaluation of quality standards for each product, from a representative number of batches, complaints, recalls and investigations [2].

In the EU, the product quality review in EU GMP Chapter 1 has a similar purpose [3]. Using the same records for daily decisions and periodic review avoids a second, disconnected spreadsheet.

WHERE V5 FITS

CAPA links to deviations, OOS results, complaints and audits, with root-cause workflow, effectiveness checks and change control with impact assessment. Risk management aligned to ICH Q9 is available where your plan includes it. AI may suggest CAPA wording; people approve and close.

Sources: [2], [3], [8], [9] (linked on pages 31–32)

DECIDE / 05

Trained on the current revision.

Training is evidence. If an operator signed a step on MPR-14 rev 6 without training on rev 6, the batch record needs explaining.

Education, training, experience

211.25 requires that people have the education, training and experience to do their jobs, including training in CGMP and the procedures they follow, conducted often enough to stay familiar [2].

Train before the change

When a master record or SOP changes, train before the effective date. Read-and-understood is a start; practical sign-off may be needed for critical steps.

Separate the roles

Decide which roles may dispense, check, test, review and release, and have the system enforce it rather than relying on memory.

WORKED EXAMPLE: COMPETENCE AND PERMISSION MATRIX

	MPR-14 rev 6	Weigh check	Assay method	Batch release
Dispensary op.	Trained	Trained	—	Not permitted
Compression op.	Trained	Retraining due	—	Not permitted
QC analyst	—	—	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, check, test, review or approve.

SUSTAIN / 01

Clean, calibrated, ready.

Granulators, dryers, presses, balances and analytical instruments are part of every batch's story. Their state on the day belongs in the record.



Clean and log

211.67 requires written cleaning and maintenance procedures; 211.182 requires an equipment cleaning and use log showing date, product and batch for each piece of major equipment [2].

Calibrate on schedule

211.68 covers calibration and checking of automatic, mechanical and electronic equipment; 211.160(b)(4) covers calibration of laboratory instruments [2].

Look back when it fails

An out-of-tolerance probe or balance raises a question about every batch it touched since its last good check. The record should answer it fast.

WHERE V5 FITS

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

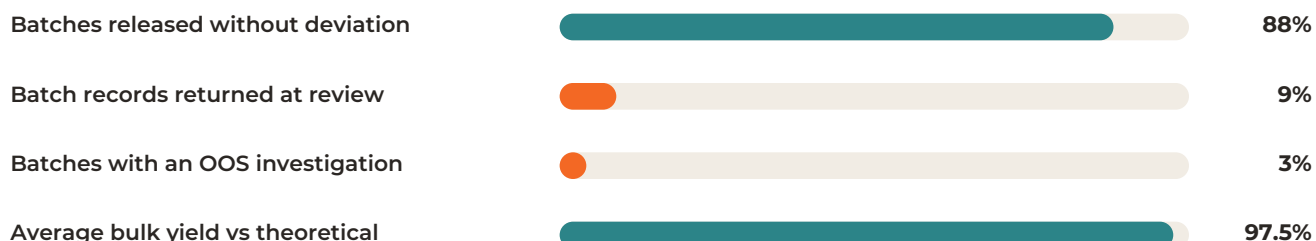
Sources: [2] (linked on pages 31–32)

SUSTAIN / 02

Measure right first time, not just output.

In pharmaceutical manufacturing the costliest batch is one that is made, tested and packed, then held. Measure where time and quality are lost.

WORKED EXAMPLE QUARTER · ONE PRODUCT



Time to disposition

Days from batch end to release tie up stock and capacity. Find which step of review or testing holds them.

Count review rework

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

Equipment losses

Downtime reasons, changeovers and cleaning time on shared equipment show where capacity goes. OEE helps where it fits your process.

WHERE V5 FITS

Reports and dashboards can show right-first-time, review returns, yield, deviations, downtime and OEE from the events your team records, where your plan includes them. AI demand and yield forecasting and process anomaly detection are coming soon, not available today.

SUSTAIN / 03

Right pack, right label, reconciled.

Mix-ups and labelling errors are classic causes of recalls. Pharmaceutical GMP treats labels as controlled materials, counted in and out.



Labels are controlled

211.122 covers receipt, examination, storage and access to labelling; 211.125 requires strict control of issuance and reconciliation of labels issued, used and returned, with investigation of discrepancies [2].

Line clearance

211.130 requires inspection of packaging and labelling facilities before use to confirm materials from previous operations are removed, and identification of each line with the product and batch [2].

Print from the record

Print batch number and expiry from the released record rather than retyping, and check them against the approved artwork revision.

Packaging is part of the batch record. 211.192 includes packaging and labelling records in the quality unit's review before release [2]. Keep reconciliation, line clearance and print checks on the same record as manufacture.

WHERE V5 FITS

Packaging work orders record line clearance, component lots and checks. Label design and printing use data from the record, with GS1-128 barcodes on configured printers. The barcode scheme set on the recipe is checked at pack-out and the approved artwork revision is printed on the batch record.

Sources: [2] (linked on pages 31–32)

SUSTAIN / 04

Serialised packs, controlled distribution.

Many markets now require a unique identifier on each pack and controlled records as product moves. Know which rules apply, and which system does what.



U.S. DSCSA

The Drug Supply Chain Security Act requires product identifiers and interoperable, electronic tracing at the package level [12]. FDA has issued time-limited exemptions; small business dispensers have exemptions from certain requirements until 27 Nov 2027 [13].

EU safety features

Delegated Regulation (EU) 2016/161 sets the unique identifier and anti-tampering device on packs of many prescription medicines, verified through the repositories system [14].

Good distribution practice

EU GDP guidelines cover storage, transport, temperature control, returns, falsified medicines and recalls in the distribution chain [15].

Distribution records

211.150 requires written procedures for distribution, including oldest approved stock first where suitable and a system to readily recall each lot [2].

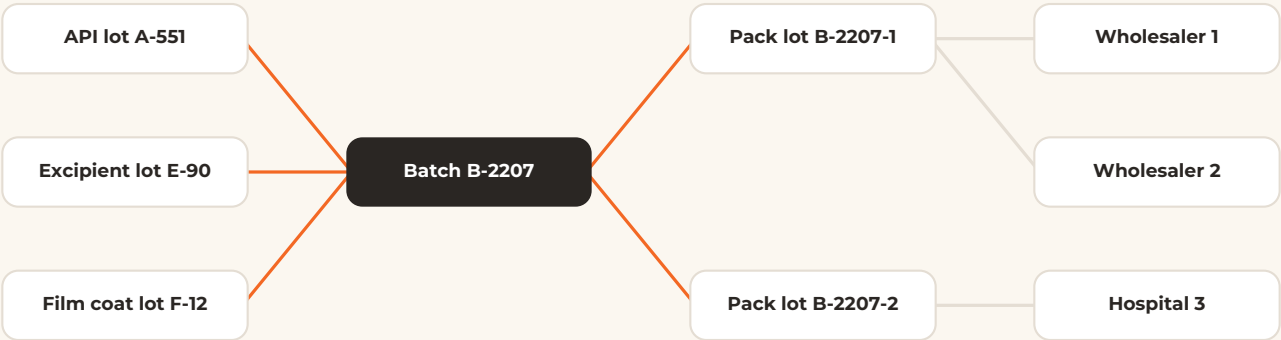
WHERE V5 FITS

V5 records which batches and lots shipped to which customer, with GS1-128 and SSCC labels and EDI/ASN where configured. It does not generate or commission DSCSA or EU serial numbers, aggregate packs, or upload data to EMVS or verification routers; keep a dedicated serialisation system for those.

Sources: [2], [12], [13], [14], [15] (linked on pages 31–32)

Trace both ways, in minutes.

A complaint arrives, or an API lot is suspect. The questions are the same: which batches, which packs, which customers, which records.



Complaints

211.198 requires written procedures for complaints, review by the quality unit, investigation where indicated and records kept [2].

Recalls

21 CFR Part 7 Subpart C sets FDA's recall policy, including strategy and effectiveness checks [16]. EU GMP and GDP expect a recall procedure tested regularly [3][15].

Rehearse it

Run a mock recall from a supplier lot to every customer and back from a complaint. Time it, and fix what slowed you.

WORKED EXAMPLE: MOCK RECALL · API LOT A-551 · TIMED STEPS

00:00

Question logged

Suspect API lot named; owner and clock started.

00:06

Forward trace

Batches, pack lots and shipments listed from the links.

00:18

Stock check

On-site quantities by status and location confirmed.

00:35

Customer list

Recipients and quantities exported for the recall team.

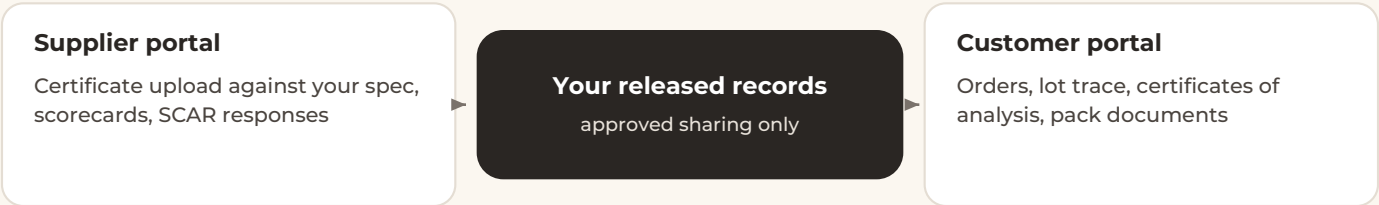
Times are a worked example for planning a rehearsal, not a target. What matters is that every answer comes from records, and that gaps found in rehearsal are fixed.

WHERE V5 FITS

Lots and batches link at receipt, dispensing, manufacture, packaging and shipment, so genealogy can be followed forward from an API lot or backward from a complaint, and recall scope listed from those links. Complaints can be logged and linked to the batch. Recall and reporting decisions stay with your quality team.

Share the right records, safely.

Marketing-authorisation holders want certificates, batch data and change notices from their contract manufacturer. Suppliers send certificates and answer SCARs. Each should see only what you approve.



Contract manufacture

EU GMP Chapter 7 expects a written contract defining responsibilities between contract giver and acceptor [3]. Agree which records the client receives, how fast, and who handles complaints.

Certification chains

Where a QP certifies a batch made elsewhere, agree how batch documentation and confirmations reach them.

Supplier evidence

Let suppliers upload certificates and change notices to the right material, then review them before they count.

A SHARING POLICY TO AGREE BEFORE ANYONE LOGS IN

Certificate of analysis	After batch disposition	Customer
Batch documentation summary	As the quality agreement defines	MAH / QP
Lot trace for their shipments	On request or always on	Customer
Open deviations and investigations	Not by portal; through agreed notification	Quality contacts
Supplier certificates and SCAR replies	Reviewed before they count	Your QA

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.

Sources: [3] (linked on pages 31–32)

SUSTAIN / 07

Trustworthy records. Honest AI.

Electronic batch records only help if they are attributable, legible, contemporaneous, original and accurate, and if AI stays a helper under human control.

Electronic records

21 CFR Part 11 sets criteria for electronic records and signatures in the U.S. [10]; EU GMP Annex 11 covers computerised systems, including validation, audit trails and signatures [4].

Data integrity

FDA's data integrity Q&A; explains expectations such as audit trail review, controlled access and keeping original records [11].

Validate for intended use

Annex 11 expects validation proportionate to risk across the system's life [4]; ICH Q9(R1) guides how much effort to apply [8].

AI CAN HELP

- Read certificate values from a PDF for a person to confirm
- Draft a master record from an uploaded batch book for approval
- Suggest a deviation classification or draft a summary
- Explain a batch's audit trail in plain language
- Find records and screens faster

AI NEVER

- Releases, certifies or rejects a batch
- Signs a record or approves a result
- Closes a deviation, OOS or CAPA
- 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], [8], [10], [11] (linked on pages 31–32)

APPLY / 01

Evidence map.

A one-page check that every theme an inspector may ask about has an owner and a record. Section numbers refer to 21 CFR Part 211 [2]; EU GMP chapters cover the same themes [3].

THEME	TYPICAL EVIDENCE	WHERE IT LIVES IN V5	OWNER
Quality unit (211.22)	Roles, approvals, independence	Roles, release queue	QA
Training (211.25)	Training records, effectiveness	Skills matrix, documents	Managers
Equipment (211.67/.68)	Cleaning, calibration, use logs	Equipment, calibration	Engineering
Components (211.82–.87)	Quarantine, sampling, testing, retest	Lots, status, Lab & QC	Warehouse + QC
Master records (211.186)	Signed, checked MPR revisions	Formulas, instructions	QA + production
Dispensing (211.101)	Weights, checks, labelled containers	Weigh and dispense	Production
Batch record (211.188)	Steps, lots, results, signatures	Kiosk, eBMR	Production
Yield (211.103)	Actual vs theoretical, explained	Batch report	Production
Labelling (211.122–.130)	Issuance, reconciliation, clearance	Packaging, labels	Packaging
Lab (211.160–.194)	Tests, methods, lab records	LIMS, Lab & QC	QC
Review (211.192)	Record review, investigations	Release queue, deviations	QA
Product review (211.180)	Annual review data	Reports, CAPA	QA
Distribution (211.150)	Shipments, recall ability	Genealogy, shipments	Logistics
Complaints (211.198)	Complaint files, investigation	Complaints	QA
Computer systems	Validation, audit trail, e-signatures	Validation pack, audit log	QA + 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 batch record ready for review?

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

	YES	PARTLY	NO
Master record revision The batch record shows which master record and revision it was made to.	☐	☐	☐
Materials traced Every component lot, its status at use and its quantity is recorded.	☐	☐	☐
Weighings checked Each weighing shows the balance, the result and the second check or validated system.	☐	☐	☐
Steps signed Significant steps show who did and who checked them, with times and values.	☐	☐	☐
Equipment valid Equipment was clean, calibrated and logged for this batch.	☐	☐	☐
Yield reconciled Actual yields at each phase are recorded and any difference explained.	☐	☐	☐
Labels reconciled Labels issued, used and returned balance, or the discrepancy is investigated.	☐	☐	☐
Lab results complete All specified tests are complete, reviewed and linked.	☐	☐	☐
Exceptions linked Deviations, OOS investigations and changes are linked and closed or explicitly open.	☐	☐	☐
Decision identity The record shows who reviewed and who decided disposition, with meaning and date.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Dispensing and line readiness.

A pre-start check for the room lead and QA. Adapt it to your products and keep it short enough to use every batch.

	DONE	N/A
Work order Product, master record revision, batch size and batch number confirmed.	☐	☐
Room status Room cleaned and released; previous product and documents removed.	☐	☐
Equipment status Equipment clean, in calibration, logged and labelled for this product.	☐	☐
Materials All lots released, in date or retest date, correct grade, staged to the batch.	☐	☐
Balances Daily checks done; balances suited to the quantities weighed.	☐	☐
People Operators trained on this revision; checker available.	☐	☐
Environment Temperature, humidity and pressure differentials in limits where required.	☐	☐
Labels and containers Dispensing labels and clean containers ready.	☐	☐
Exceptions Who to call and what to record if something is out of limits.	☐	☐

NOTES AND OWNERS

WORKSHEET 03

Ask to see it work.

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

	SHOWN	PARTLY	NOT SHOWN
Quarantined lot Scan a quarantined or past-retest lot at dispensing and show what happens.	☐	☐	☐
Out of tolerance Weigh outside tolerance and show how the step responds and what is recorded.	☐	☐	☐
Untrained operator Show an operator not trained on the revision being stopped, if configured.	☐	☐	☐
Out of calibration Show a balance or probe past its due date flagged before use, and the batches it touched.	☐	☐	☐
Deviation Raise a deviation from a step and show its link to the batch record.	☐	☐	☐
OOS result Enter a result outside specification and show the investigation workflow.	☐	☐	☐
Revision change Approve a new master record revision; show batches in progress keep the old one.	☐	☐	☐
Review by exception Show a batch record with exceptions first, then sign it.	☐	☐	☐
Trace From an API lot, list every batch, pack lot and customer; then the reverse.	☐	☐	☐
Export Export a complete batch record and its audit trail for an inspector.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

Roll out in phases.

Start where value is visible and risk is contained. Validate as you go, as Annex 11 and your procedures expect [4].

PHASE 1
Foundations

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

PHASE 2
Materials

Approved suppliers and specifications, receiving with quarantine and sampling, status, retest and expiry.

PHASE 3
Batch record

Master records, dispensing and kiosk execution for one product, run in parallel with the current record.

PHASE 4
Decide

Lab results, deviations, OOS, CAPA, review and disposition signatures, after validation of intended use.

PHASE 5
Connect

Packaging and labels, genealogy and distribution, mock recalls, portals, right-first-time review.

Validation runs through every phase. Agree intended use, risk and test evidence before each phase goes live, following Annex 11 and, for U.S. electronic records, Part 11 [4][10]. V5 offers a validation pack where your plan includes it; your validation remains yours.

Sources: [4], [10] (linked on pages 31–32)

WORKSHEET 04

Find your first improvement.

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

	E	P	G
Supplier approval Qualified manufacturers, agreements, monitoring	☐	☐	☐
Goods-in and sampling Quarantine, sampling plan, identity testing	☐	☐	☐
Status and retest Blocking at the scan, retest dates tracked	☐	☐	☐
Master records Two signatures, one current revision	☐	☐	☐
Dispensing Checked weighings, labelled containers	☐	☐	☐
Batch execution Steps, values, yields recorded as they happen	☐	☐	☐
Laboratory Complete records, OOS handled properly	☐	☐	☐
Review and disposition Exceptions first, decision identity	☐	☐	☐
Deviations and CAPA Scope extended, effectiveness checked	☐	☐	☐
Packaging and labels Clearance, issuance, reconciliation	☐	☐	☐
Distribution and recall Both ways, mock recall timed	☐	☐	☐
Computer systems Validated use, audit trail reviewed	☐	☐	☐

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, without touching released records.

WEEK 1

Agree the product, the batch record you want and the five questions that matter most. Load one formula, master record and specification.

WEEK 2

Run a batch end to end with test data: receipt, sampling, dispensing, steps, lab results, review and label.

WEEK 3

Break it on purpose: quarantined lot, weight out of tolerance, untrained operator, overdue balance, OOS result.

WEEK 4

Review with production, QC, QA and IT. Decide what to validate, what to change and what not to do.

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

ASK V5

“We make [dosage form] for [markets] under [21 CFR 211 / EU GMP / both]. Our hardest moment is [e.g. batch record review 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.

- | | | |
|-----|---|-------------------------|
| [1] | <u>U.S. eCFR, 21 CFR Part 210: CGMP for drugs, general</u> | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210 | |
| [2] | <u>U.S. eCFR, 21 CFR Part 211: CGMP for finished pharmaceuticals</u> | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211 | |
| [3] | <u>European Commission, EudraLex Volume 4: EU GMP guidelines, incl. Annex 16</u> | EU GMP GUIDELINES |
| | https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en | |
| [4] | <u>EudraLex Volume 4, Annex 11: Computerised Systems (2011)</u> | EU GMP ANNEX |
| | https://health.ec.europa.eu/system/files/2016-11/annex11_01-2011_en_0.pdf | |
| [5] | <u>PIC/S, GMP Guide for Medicinal Products (PE 009-18, in force 24 Sep 2026)</u> | INSPECTORATE GMP GUIDE |
| | https://picscheme.org/en/publications | |
| [6] | <u>WHO TRS 986 Annex 2: WHO GMP main principles (2014)</u> | WHO GUIDANCE |
| | https://www.who.int/publications/m/item/trs986-annex2 | |
| [7] | <u>ICH Q7: GMP Guide for Active Pharmaceutical Ingredients</u> | ICH GUIDELINE |
| | https://database.ich.org/sites/default/files/Q7%20Guideline.pdf | |
| [8] | <u>ICH Q9(R1): Quality Risk Management (2023; FDA final guidance May 2023)</u> | ICH GUIDELINE |
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| [9] | <u>ICH Q10: Pharmaceutical Quality System</u> | ICH GUIDELINE |
| | https://database.ich.org/sites/default/files/Q10%20Guideline.pdf | |

SOURCES

Sources, continued.

- | | | |
|------|--|----------------------------|
| [10] | <u>U.S. eCFR, 21 CFR Part 11: Electronic Records; Electronic Signatures</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11 | BINDING U.S. REGULATION |
| [11] | <u>U.S. FDA, Data Integrity and Compliance With Drug CGMP: Q&A (2018)</u>
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-i... | FDA GUIDANCE (NON-BINDING) |
| [12] | <u>U.S. FDA, Drug Supply Chain Security Act (DSCSA) overview</u>
https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-securit... | FDA OVERVIEW |
| [13] | <u>U.S. FDA, DSCSA small business dispenser exemptions to 27 Nov 2027 (Aug 2026)</u>
https://www.fda.gov/media/194424/download | FDA EXEMPTION LETTER |
| [14] | <u>Delegated Regulation (EU) 2016/161: safety features on medicine packs</u>
https://eur-lex.europa.eu/eli/reg_del/2016/161/oj | BINDING EU REGULATION |
| [15] | <u>EU Good Distribution Practice guidelines (2013/C 343/01)</u>
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013XC1123(01) | EU GUIDELINES |
| [16] | <u>U.S. eCFR, 21 CFR Part 7: Enforcement Policy (recalls, Subpart C)</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7 | U.S. REGULATION / POLICY |
| [17] | <u>U.S. FDA, Current Good Manufacturing Practice (CGMP) regulations hub</u>
https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufac... | FDA REGULATIONS HUB |
| [18] | <u>PIC/S, Revision of the PIC/S GMP Guide (PE 009-18, revised Annex 19)</u>
https://picscheme.org/en/news/revision-of-pic-s-gmp-guide | PIC/S NOTICE |
| [19] | <u>TGA, Complying with the PIC/S Guide to GMP (PE 009-17 adopted 1 Sep 2025)</u>
https://www.tga.gov.au/products/medicines/manufacturing/manufacture-medicine/go... | TGA ADOPTION NOTICE |

How to read the status labels. Binding regulation is law in its jurisdiction. EU GMP guidelines and annexes are the standard EU inspectors apply under EU medicines law. PIC/S and WHO guides are adopted by participating authorities. ICH guidelines apply as regions adopt them. FDA overviews and Q&A documents explain the agency's thinking but do not bind.

SCOPE AND LIMITS

What this guide is, and is not.

This guide is practical orientation for evaluating pharmaceutical production, laboratory, 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 product type, sterile or non-sterile manufacture, markets, marketing authorisations and your role as manufacturer, contract manufacturer, packager, testing site 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 set specifications, author regulatory submissions, generate or upload DSCSA or EU serial numbers, decide batch disposition, certify batches or release product by itself, and does not by itself make you compliant or validated.

Versions and scope, checked 1 October 2026. In the U.S., Parts 210 and 211 apply to drug manufacture; Part 212 covers PET drugs only, and product type can add other parts [17]. FDA's data integrity Q&A and ICH Q9(R1) are guidance, not law [11][8]. EU Annex 1 applies to sterile products and has been fully applicable since 25 Aug 2024; the revised Annex 19 on reference and retention samples applied from 24 Sep 2026, so this guide prints no retention periods [3]. PIC/S PE 009-18 entered into force on 24 Sep 2026 [18], but Australia legally adopted PE 009-17 [19]; check your authority's adopted version. Draft revisions, including EU Chapter 1 drafts, are not effective GMP.

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



Right material. Right record. Released by a person.

See pharmaceutical workflows at v5ultimate.com

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