



THE VETERINARY MEDICINES GUIDE

The right product, strength and species. Every batch.

From approved supplier to released, labelled pack, and back again

A capability and evaluation guide for manufacturers of veterinary medicines: oral solutions, tablets and boluses, injectables and other dosage forms for companion and food-producing animals. Animal medicines are drugs, regulated under medicines law, not as pet food or feed.



MASTER RECORD TO RELEASE

SPECIES AND STRENGTH

TRACE AND RECALL

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v5ultimate.com

Photography is staged, with full protective clothing; worked examples and diagrams are illustrative, not V5 screenshots or customer data. Nothing here is legal, regulatory or veterinary advice.

INSIDE THE GUIDE

Approved record in, released pack out.

A veterinary medicine may be given to a dog at home or to a herd whose milk and meat enter the food chain. Getting the product, strength, species and withdrawal period right is a safety matter twice over. This guide follows one batch, VO-2217, a 100 mg/mL oral solution for cattle at master record revision 5.

01 / FRAME

pp. 03–06

Rules and one day

U.S. drug CGMP and animal drug reporting, EU Regulation 2019/6 and the new EU veterinary GMP rules, Great Britain and international context, one production day.

02 / MATERIAL

pp. 07–09

Supplier to shelf

Supplier and active substance evidence, receiving and sampling, quarantine, status, retest and expiry.

03 / MAKE

pp. 10–15

Master to filled product

Master records by product, strength and species, dispensing, cross-contamination and line clearance, dosage forms, sterile products, yield.

04 / RELEASE

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Test, review, label

Laboratory records, batch review and release, holds and out-of-specification results, labels and reconciliation.

05 / CONTROL

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Fix, report, change, train

Deviations and CAPA, complaints and adverse events, change control, roles and training.

06 / SUSTAIN + APPLY

pp. 25–37

Assets, trace, tools

Equipment and cleaning, calibration and OEE, trace and recall, portals and AI, evidence map, worksheets, roadmap, sources.

Who it is for. Quality heads and qualified persons, production and packaging managers, QC laboratory leads, regulatory and pharmacovigilance teams, engineering and warehouse teams at veterinary medicine sites and contract manufacturers, and anyone choosing a system for them.

How to read it. Requirements quoted from 21 CFR Part 211, 21 CFR 514.80 and EU Regulation 2019/6 were read in the current texts in October 2026. Other sources are described at framework level. Every operational page ends with a teal Where V5 fits panel.

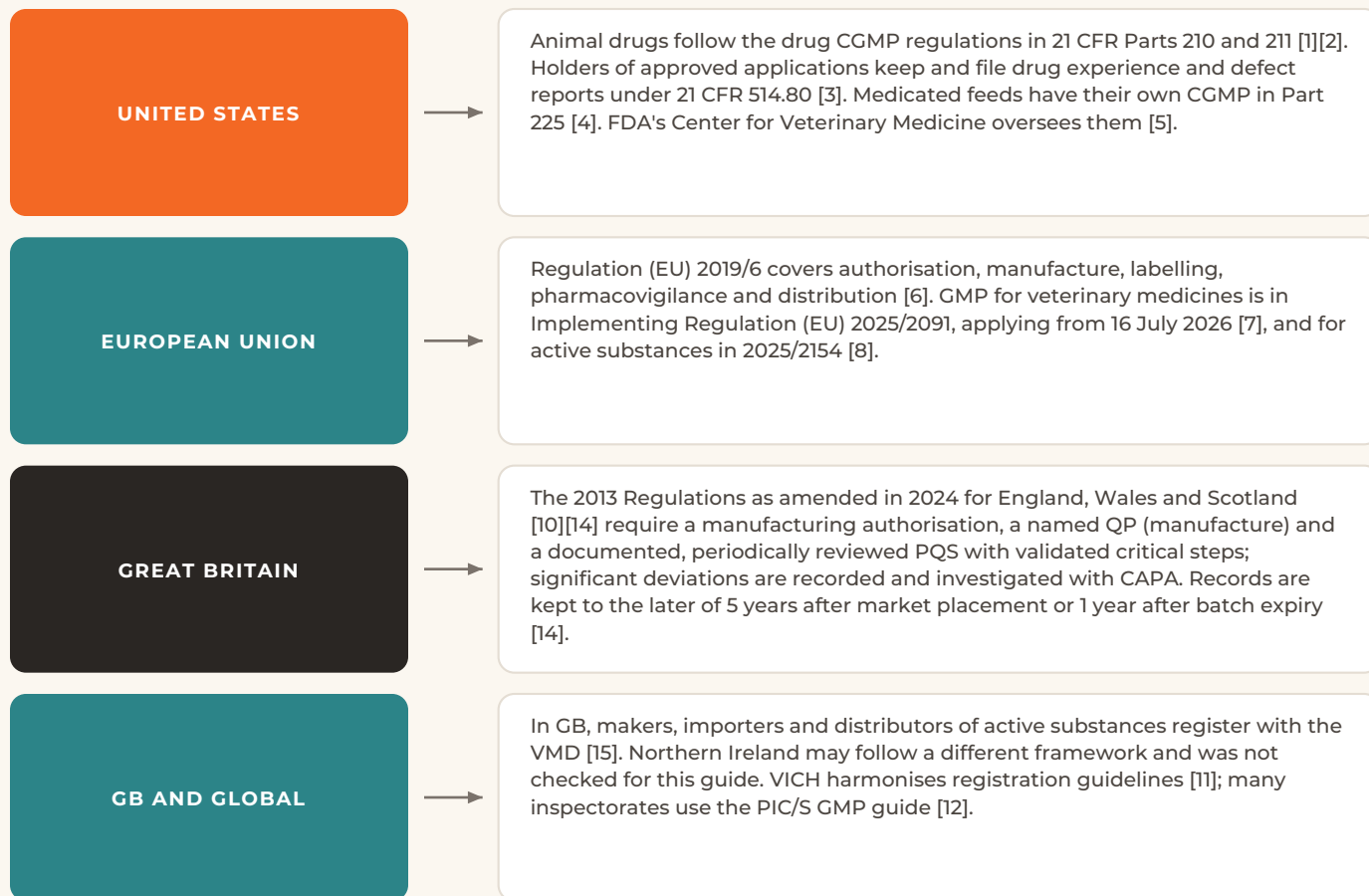
WHERE V5 FITS

V5 records the receiving, dispensing, manufacturing, testing, packaging and shipping work your procedures define, and links it to lots, batches and customers. It does not hold marketing authorisations, approve products, certify or release batches, or file regulatory reports. Your quality unit and qualified persons do.

FRAME / 01

Which rules reach your product?

Veterinary medicines are medicines. The site, the product type and the markets you supply decide which rules apply. These are the main frameworks this guide refers to.



Not pet food

A medicine for animals is not animal food. Pet food and feed rules do not replace drug GMP.

Medicated feed is its own case

Feeds containing drugs follow their own rules, such as Part 225 in the U.S. [4].

Labels changed in the EU

Transitional label rules apply to older authorisations until 29 January 2027 [9].

WHERE V5 FITS

Keep procedures, specifications, master records and certificates as controlled documents with revisions, owners and review dates. V5 does not decide which rules apply to a product or site; your regulatory and quality teams do.

Sources: [1], [2], [3], [4], [5], [6], [7], [8], [9], [10], [11], [12], [14], [15] (linked on pages 36–37)

FRAME / 02

U.S. drug CGMP: selected duties.

Part 211 applies to finished drugs for humans and animals. The lines below are short summaries of the current text [1]; read the full sections that apply to you.

SELECTED REQUIREMENTS, 21 CFR PART 211 [1]

211.22	Quality control unit approves or rejects materials, labelling and drug products
211.67	Written cleaning and maintenance procedures for equipment
211.84	Each lot of components withheld from use until sampled, tested and released
211.130	Procedures to prevent label mix-ups, incl. separation from other products
211.165	Lab testing of each batch, incl. identity and strength, before release
211.188	Batch record for each batch, incl. equipment and component lots used
211.192	QC unit reviews records; unexplained discrepancies investigated
211.180	Batch records kept at least 1 year after the batch's expiry date

ANIMAL DRUG REPORTS, 21 CFR 514.80 [3]

Applicants report product and manufacturing defects that may result in serious adverse drug events in a **3-day field alert**, within 3 working days of becoming aware a defect may exist. Serious, unexpected adverse drug events go in a **15-day alert**, within 15 working days. Records and reports are kept for **5 years** after submission. These duties add to CGMP.

WHERE V5 FITS

Batch records, lab results, cleaning and maintenance records, complaints and deviations sit in one place and stay searchable for the retention you set. V5 does not decide whether an event is reportable or submit reports to FDA.

FRAME / 03

EU: the qualified person and the new GMP rules.

Under Regulation 2019/6 every manufacturing authorisation holder must have a qualified person. Since 16 July 2026, veterinary GMP has its own EU regulation [6][7].

ARTICLE 97, QUALIFIED PERSON [6]

Each batch

Ensures each batch is made in compliance with GMP and tested in line with the marketing authorisation, and draws up a control report.

Imports

Imported batches need a full qualitative and quantitative analysis of at least all active substances in the Union.

Records

Kept for each released batch, up to date, for one year after expiry or at least five years from recording, whichever is longer.

ARTICLE 10, IMMEDIATE PACKAGING [6]

- Name, strength and pharmaceutical form
- Active substances, per unit or volume
- Batch number, preceded by 'Lot'
- Marketing authorisation holder
- Target species
- Expiry, 'Exp.' mm/yyyy
- Special storage precautions
- Route of administration
- Withdrawal period, even if zero

GMP regulation 2025/2091

Applies from 16 July 2026 [7]. Annex I adds sterile and aseptic rules, Annex II biologicals, Annex IV computerised systems.

Samples and supply

Article 93 requires samples of each batch and supply records, and GMP active substances as starting materials [6].

Pharmacovigilance

Marketing authorisation holders run a system for collecting and evaluating suspected adverse events (Art. 77) [6].

WHERE V5 FITS

Batch records, lab results and deviations come together for the QP's review, and the release decision is recorded with name, time and reason. V5 does not draw up QP control reports, certify batches or run your pharmacovigilance system.

Sources: [6], [7] (linked on pages 36–37)

FRAME / 04

One production day.

A worked example: batch VO-2217, a 100 mg/mL oral solution for cattle, master record revision 5, filled into 250 mL bottles. Times and values are examples only.

06:00	Line clearance after previous product checked and signed
06:30	Master record rev 5 issued as batch record VO-2217
07:00	Active and excipient lots dispensed and checked
08:30	Dissolved and mixed; pH and appearance recorded
10:00	Bulk sampled for assay; bulk held pending results
12:30	Filling: volume checks every 30 minutes
14:00	Labelling: species, strength, lot and expiry verified
16:30	Labels reconciled; batch record to QA review

Orange is where mix-ups live

Changeover, dispensing and labelling are where the wrong product, strength or species can enter a batch.

Bulk waits for the lab

Your procedures decide what must be known before filling and before release.

Release is a person

A named qualified person or quality unit decides, after review.

WHERE V5 FITS

Batches sit on the schedule with master record revision, line and materials. Kiosk steps capture lots, weights, checks and samples, and the batch record grows with them.

MATERIAL / 01

Qualified suppliers, specified materials.

Active substances, excipients, containers, closures and printed packaging each need a specification and an approved source. EU rules require active substances made under GMP [6]; U.S. CGMP requires components to be tested and released before use [1].

Active

Identity, assay, impurities, GMP evidence

Excipients

Grade and specification

Containers

Material, size, compatibility

Closures

Fit and integrity

Printed

Approved artwork and version

Know who really makes it

A broker is not a manufacturer. Record the actual site of manufacture for active substances.

Audit by risk

Plan supplier audits and questionnaires by material criticality and history.

Agreements

Quality agreements say who tests, who notifies changes and who decides.

WHERE V5 FITS

Approved supplier lists hold specifications, qualification documents, audits and scorecards, so receiving can see which supplier and site are approved. Suppliers can upload certificates through the supplier portal where configured; a person reviews each before it counts.

Sources: [1], [6], [8] (linked on pages 36–37)

MATERIAL / 02

Receive, sample, quarantine.

U.S. CGMP says each lot of components, containers and closures is withheld from use until sampled, tested or examined and released by the quality control unit [1]. Representative samples come from each shipment of each lot.



Match the paperwork

Supplier, site, material, lot, quantity and certificate match the order and approved list.

Inspect containers

Seals, labels, damage and cleanliness, before sampling under controlled conditions.

Quarantine first

Received material is not usable until QC releases it.

WORKED EXAMPLE: RECEIPT

Material	Active ingredient, 4 x 10 kg fibre drums
Supplier / lot	Approved supplier S-014, lot AP-55120
Internal lot	RM-4410
Certificate	Identity, assay, impurities, residual solvents
Status	Quarantine until QC tests and releases

WHERE V5 FITS

Receiving records supplier, lot, quantity, inspection and samples, and places material in quarantine until release. Certificate values can be read from an upload for a person to confirm; AI never releases a lot.

Sources: [1] (linked on pages 36–37)

MATERIAL / 03

Status, retest and expiry.

Medicines and their materials age. Status tells people what they may use; retest and expiry dates tell them for how long.



STATUS FLOW FOR A MATERIAL LOT

Quarantine

QC decision

Released

date reached

Retest due

retested: back or out

Rejected

Physical or system status

Whichever you use, people must not be able to pick quarantined or rejected material.

Storage conditions

Temperature-sensitive materials need monitored storage and records.

First expired, first out

Pick by date, not arrival, where shelf life matters.

WHERE V5 FITS

Warehouse locations, lot status and expiry or retest dates support FEFO picking and holds; a lot that is quarantined, rejected or past its date can be blocked at picking and dispensing.

One master record per product, strength, species.

A batch record starts as an accurate reproduction of the approved master record [1]. When one product comes in several strengths or for several species, each needs its own approved, revision-controlled master.

WORKED EXAMPLE: MASTER RECORD FAMILY · HIGHLIGHTED ROW IS THE ONE VO-2217 USES

PRODUCT	STRENGTH	SPECIES	PACK	REVISION
Oral solution A	100 mg/mL	Cattle	250 mL	rev 5
Oral solution A	100 mg/mL	Sheep	250 mL	rev 3
Oral solution A	25 mg/mL	Calves	100 mL	rev 2
Bolus B	2.5 g	Cattle	50 x 1	rev 7
Injection C	50 mg/mL	Dogs, cats	20 mL vial	rev 4

Close is dangerous

Same product, different species: the strength, withdrawal period and label differ. Selection must be deliberate.

Only approved revisions

Draft or superseded masters cannot be issued as batch records.

Match the authorisation

Your regulatory team keeps the master in line with what each market approved.

WHERE V5 FITS

Master formulas and master records are kept under revision control with approvals, and batches are issued from the approved revision only. Materials scanned at dispensing are checked against that master, so a lot for another product or strength is flagged.

Sources: [1] (linked on pages 36–37)

MAKE / 02

Dispense the right lot, in the right amount.

The batch record must show the specific lot of each component used and the weights and measures [1]. Dispensing is where both are fixed.



VO-2217 DISPENSING

MATERIAL	TARGET	ACTUAL	
Active RM-4410	4.000 kg	3.996 kg	OK
Co-solvent RM-4377	12.00 kg	12.02 kg	OK
Preservative RM-4391	0.072 kg	0.072 kg	OK
Buffer RM-4402	0.400 kg	0.401 kg	OK
Wrong lot RM-4398	scan	—	Block

Tolerance on the master: active ± 10 g. The 4 g shortfall is inside it. RM-4398 is an active lot released for a different product, so the scan blocks it.

Scan, then weigh

The lot is checked before the scale is used, not after.

Second check by risk

Your procedure says when a second person or device check is needed.

Clean scales and booths

Dispensing booths and scales need cleaning records between materials.

WHERE V5 FITS

Weigh and dispense steps run at the kiosk with lot scanning, target and tolerance checks, and blocks on wrong or unreleased materials. Supported connected scales send weights directly; the actual value and the person are recorded.

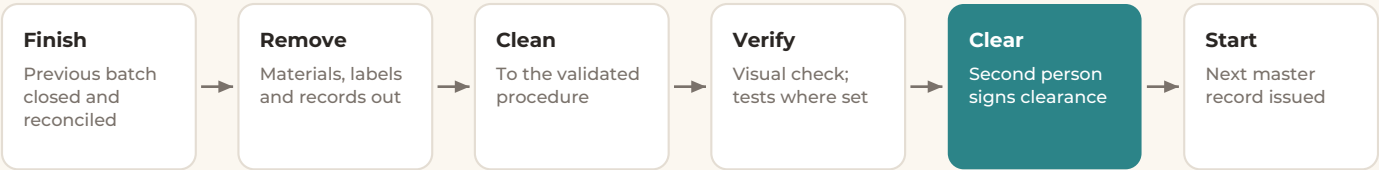
Sources: [1] (linked on pages 36–37)

MAKE / 03

Keep products apart.

U.S. CGMP calls for separation to prevent mix-ups and cross-contamination in packaging and labelling [1]. The EU veterinary GMP regulation sets out requirements for preventing cross-contamination [7]. Many sites make several products on shared equipment, so changeover is a control point.

A CHANGEOVER BETWEEN PRODUCTS



LINE CLEARANCE RECORD, FILLING LINE 2	
Previous product	Bolus B rev 7, batch BB-1180, closed
Cleaning	Procedure CL-12 rev 4, done by operator 214
Visual check	No residue, labels or containers from BB-1180
Cleared by	Supervisor 117, 06:12
Next	VO-2217 may start

Dedicated where needed

Some products need dedicated or segregated facilities; your risk assessment decides.

Clean hold times

Record when equipment was cleaned, so dirty and clean hold limits can be checked.

Labels leave too

Printed packaging from the last product is a mix-up waiting to happen.

WHERE V5 FITS

Line clearance and cleaning can be required as signed steps before the next batch starts, with equipment status and cleaning history kept on each equipment record.

MAKE / 04

Make it to the record, whatever the form.

Oral solutions, boluses, pastes, intramammaries, pour-ons and injectables each have their own steps and in-process checks. The batch record shows each significant step was done, with dates, equipment and the people involved [1].



TYPICAL IN-PROCESS CHECKS (EXAMPLES; YOUR MASTER RECORD SETS THEM)

Oral solution	Dissolution complete, pH, appearance, fill volume
Bolus / tablet	Weight, hardness, thickness, friability, appearance
Paste / gel	Homogeneity, fill weight, syringe graduation
Injectable	Bioburden before filtration, filter integrity, fill volume
Pour-on	Viscosity, fill volume, closure torque

Large doses, large tablets
Boluses for cattle can weigh grams each; weight checks matter as much as in small tablets.

Record actual values
Write the reading, not just pass.
Trends need numbers.

Out of limit is a deviation
The step stops and the event is recorded and assessed.

WHERE V5 FITS

Execution steps with limits run at the kiosk; a reading outside limits blocks or flags the step and can open a deviation. Equipment used is recorded against the batch, and the record shows who did and checked each step.

Sources: [1] (linked on pages 36–37)

MAKE / 05

Sterile products need more.

The EU veterinary GMP regulation has additional requirements for sterile and aseptic manufacture in Annex I. Its recitals note that an end-product sterility test is limited, so sole reliance on end testing to show sterility should not be possible [7].



Process evidence

Sterilisation parameters, filter integrity and in-process data support sterility assurance.

Environment and people

Environmental and personnel monitoring results belong with the batch they cover.

Interventions

Interventions in critical zones are recorded and assessed.

Not every site

Only sites making sterile products need these controls; check Annex I scope.

WHERE V5 FITS

Batch steps can capture sterilisation and filtration records, in-process results and interventions, and lab results sit against the batch. V5 does not control isolators, sterilisers or filling machines, or replace your contamination control strategy.

Sources: [7] (linked on pages 36–37)

MAKE / 06

Expected yield, explained.

U.S. CGMP requires investigation of any unexplained discrepancy, including yield outside the limits in the master record [1]. A worked example for VO-2217.

VO-2217 BULK AND FILL BALANCE

Theoretical bulk		40.00 L
Filled 157 x 250 mL		39.25 L
QC samples		0.30 L
Line losses		0.35 L
Unexplained		0.10 L

39.25 + 0.30 + 0.35 + 0.10 = 40.00 L. Yield of filled product: 39.25 / 40.00 = 98.1%. If the master's limits are 97.0–100.0%, this is inside; the 0.10 L unexplained is still noted.

Limits belong on the master

Yield ranges come from development and history, set by your people.

Investigate the unexplained

Even inside limits, a growing unexplained loss is a signal.

Extend to related batches

Investigations extend to other batches that may be affected [1].

WHERE V5 FITS

Batch quantities at each stage are recorded, and yield is calculated against the master's limits; a result outside the range can be flagged for review. Yield and variance views come from the quantities your team records.

RELEASE / 01

Test it, and keep the whole record.

Each batch needs lab testing against final specifications, including the identity and strength of each active ingredient, before release [1]. Laboratory records include the sample, the method, the data and who did and checked the work [1].



VO-2217 RESULTS

Identity	Conforms	OK
Assay	100.4% of label	OK
Related substances	Within limits	OK
pH	6.1	OK
Preservative content	Within limits	OK
Microbial limits	Awaiting lab	Pending

Methods are controlled

Use the approved method revision, and record which one.

Pending is visible

A result not yet entered must not look like a pass.

Retained samples

EU rules require samples of each batch to be kept [6].

WHERE V5 FITS

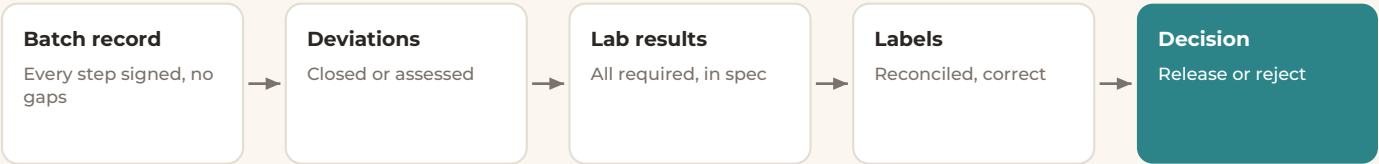
Lab & QC plans samples, holds methods and specifications, records results against the batch and keeps pending tests visible; certificate of analysis inputs come from approved results. A result outside specification is flagged for investigation.

Sources: [1], [6] (linked on pages 36–37)

RELEASE / 02

Review everything, then a person decides.

In the U.S., the quality control unit reviews and approves production and control records, including packaging and labelling, before a batch is released [1]. In the EU, the qualified person ensures each batch meets GMP and the marketing authorisation [6].



VO-2217 REVIEW SUMMARY	
Batch record	All steps complete; 1 comment resolved
Deviations	None open
Lab results	5 of 6 in; microbial limits pending
Labels	Reconciled 157 issued = 157 used
Decision	Cannot release yet

Review by exception, carefully

Highlighting exceptions helps a reviewer; it does not replace the review.

Who may release

Only people your procedures name, with the right permission.

Reasons recorded

A rejection or a conditional decision needs a written reason.

WHERE V5 FITS

QC release review gathers the batch record, deviations, results and label reconciliation, and the decision is recorded with name, time and reason under electronic signature. V5 does not release batches by itself; a release waits for the results your specification requires.

RELEASE / 03

When a result does not fit.

Any failure of a batch to meet its specifications must be thoroughly investigated, whether or not the batch has been distributed, and the investigation extended to other batches that may be affected [1].

A WORKED HOLD

Batch VO-2219, the sheep version of the same solution, shows an assay of 93.8% against a limit of 95.0–105.0%. The batch is placed on hold. The lab checks for laboratory error before any retest, per your procedure. The investigation finds that the co-solvent lot was dispensed by volume, not weight. VO-2217 used the same lot, so it is checked too: it was dispensed by weight and is not affected. A CAPA changes the dispensing step to scale-only.

HOLD SCOPE

VO-2219 bulk and filled	HOLD
Co-solvent lot RM-4377 stock	HOLD
Other batches using RM-4377	VO-2217 checked, not affected
Shipped units	None
Decision	Reject VO-2219; CAPA-31 opened

- Hold scope**
Hold the batch, the suspect material and anything made with it until assessed.
- No testing into compliance**
Retests follow a written procedure, not hope.
- Overrides are events**
Who removed a hold, when and why, is recorded.

WHERE V5 FITS

Lots and batches carry status; a held lot is blocked at picking and dispatch until an authorised person releases or rejects it. Holds link to the deviation or investigation that caused them.

RELEASE / 04

Species and strength on every label.

Veterinary labels carry information people act on in the field: species, strength, route, and for food-producing animals a withdrawal period. EU Article 10 lists what immediate packaging must show [6].



LABEL CHECK FOR VO-2217

Product and form	Oral solution A	OK
Strength	100 mg/mL	OK
Target species	Cattle	OK
Withdrawal period	As authorised	OK
Lot and expiry	VO-2217 · 09/2028	OK
Artwork version	ART-0541 v6	OK

Withdrawal periods matter

The wrong withdrawal period can put residues into milk or meat.

Look-alike labels

Same brand, different species: design and checks should make them hard to confuse.

Expiry from stability

U.S. expiry dates come from stability testing [1].

WHERE V5 FITS

Label templates are controlled with revisions and approval; printing pulls product, strength, species, lot and expiry from the batch and master record, and a label check can confirm species and strength match before release. V5 does not write label text or approve artwork for a market.

Sources: [1], [6] (linked on pages 36–37)

RELEASE / 05

Count every label.

U.S. CGMP calls for written procedures so the correct labels and packaging are used, with separation from other products [1]. Counting what was issued, used, damaged and returned shows nothing went astray.

VO-2217 LABEL RECONCILIATION	
Labels issued	170
Applied to bottles	157
Used for set-up and vision checks, destroyed	8
Damaged, destroyed	3
Returned to store	2
Balance	170 = 157 + 8 + 3 + 2

Zero difference expected

For printed labels, any unexplained difference is investigated.

Cartons and leaflets too

Reconcile each printed component your procedure lists.

Coding checks

Lot and expiry printed on line are checked at start, during and at end.

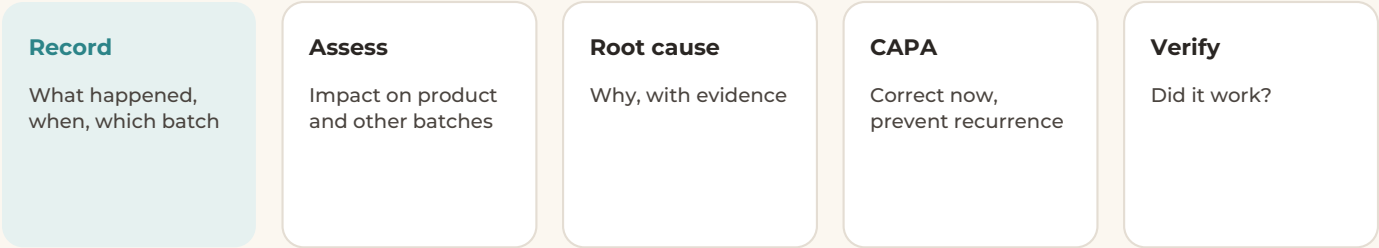
WHERE V5 FITS

Label issue, use and return are recorded against the batch, and the balance is calculated for the reviewer. Lot and expiry coding checks can be scheduled as kiosk steps during the run.

CONTROL / 01

Record, assess, correct, prevent.

Deviations from written procedures are recorded and justified; unexplained discrepancies are investigated [1]. EU GMP requires product quality reviews that assess whether CAPA or revalidation is needed [7].



CAPA-31

Source	Assay failure VO-2219
Root cause	Co-solvent dispensed by volume; density varies with temperature
Correction	VO-2219 rejected
Prevention	Master records changed to scale-only dispensing
Effectiveness	Next 10 batches assayed in range
Status	OPEN

WHERE V5 FITS

Deviations are recorded from the batch, classified and investigated, and CAPA actions are assigned with owners, due dates and effectiveness checks. AI can suggest a classification or draft a summary for a person to edit; people decide.

CONTROL / 02

Complaints, adverse events and defects.

Complaints are reviewed by the quality unit and assessed for investigation and for reportable adverse experiences [1]. U.S. application holders have 3-day and 15-day report clocks [3]; EU marketing authorisation holders run a pharmacovigilance system [6].

Receive

Learn

Complaint

Triage

Act

Start from the lot
The lot number links the complaint to the batch record, materials and other complaints.

Quality or safety?
A cracked bottle is a quality complaint; a sick animal after use is a possible adverse event. Route each to its owner.

Clocks start early
Report timings run from when you first receive or become aware of information [3].

WORKED EXAMPLE: COMPLAINT RECORD

Received	Vet reports cloudy solution, lot VO-2217
Triage	Quality complaint; no animal harm reported
Linked	Retained sample, batch record, other complaints: none
Finding	Retained sample clear; bottle stored frozen in transit
Status	Closed; customer advised

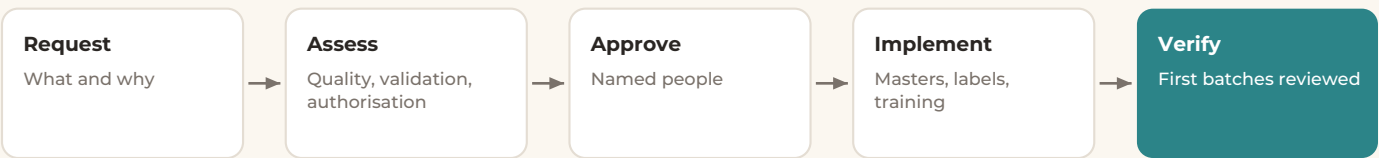
WHERE V5 FITS

Complaints are logged against lots with categories, owners and due dates, and can open deviations or CAPA. V5 does not decide whether an event is a reportable adverse event or submit reports to regulators; your pharmacovigilance team does.

CONTROL / 03

Change on purpose.

A new active supplier, a revised master record, a new filling line or a label change can affect quality, the marketing authorisation, or both. Changes need assessment before they reach production.



IMPACT QUESTIONS FOR CC-22: NEW ACTIVE SUBSTANCE SITE

Authorisation	Does each market need a variation first?	Regulatory
Supplier	Qualified, audited, GMP evidence?	OPEN
Specification	Same impurity profile?	QC
Validation	Process validation batches needed?	Validation
Stability	Stability data needed?	QC
Training	Who must be trained?	Done

Regulatory first

Some changes need approval in each market before use. Your regulatory team decides.

Masters follow

Approved changes create new master record revisions, not edits.

Train before use

People are trained on the new revision before the first batch.

WHERE V5 FITS

Change control links requests to masters, specifications, labels and suppliers with impact assessments and approvals; approved changes release new revisions and can assign read-and-understood training. V5 does not assess regulatory variations.

CONTROL / 04

Qualified, trained and permitted.

Staff must have the education, training and experience for their jobs [1][2]. In the EU, the qualified person has defined qualifications and experience [6]. Who may release a batch, remove a hold or change a master must be clear.

WORKED EXAMPLE: PERMISSION MATRIX

	DISPENSE	CLEAR LINE	ENTER RESULTS	RELEASE BATCH	CHANGE MASTER
Operator	Permitted	—	—	—	—
Supervisor	Permitted	Permitted	—	—	—
QC analyst	—	—	Permitted	—	—
Qualified person	—	—	—	Permitted	—
QA manager	—	—	—	Permitted	Permitted

Trained on the revision

Training links to the procedure revision, not just the title.

Expired training blocks

Where configured, an operator without current training cannot sign the step.

Gowning is training too

Sterile areas need gowning qualification records.

WHERE V5 FITS

The skills matrix tracks training by procedure revision and role; kiosk steps can check that the signer is trained, and role permissions decide who may release, override or approve.

SUSTAIN / 01

Clean, maintained, ready to use.

Equipment is cleaned, maintained and, where appropriate, sanitised or sterilised at intervals, under written procedures [1]. Records show what was done to each item and which batches ran on it.



EQUIPMENT RECORD, MIXING VESSEL MV-03

Last batch	VO-2217, cleaned per CL-12 rev 4	Done
Status	Clean, hold until 2 Oct 18:00	OK
PM due	Seal and agitator inspection	9 days
Last repair	Agitator seal replaced, parts counted	Done
Next action	Calibrate temperature probe	OPEN

Status at the door

Clean, dirty or under maintenance should be visible before use.

Maintenance is a risk

Repairs can leave parts or lubricants; inspect and clean before release.

Ran on it

Know which batches used a piece of equipment between checks.

WHERE V5 FITS

Equipment records hold PM schedules, cleaning, repairs, spare parts and the batches each item ran. Work orders are tracked in maintenance. Predictive failure analytics are not offered today.

Sources: [1] (linked on pages 36–37)

SUSTAIN / 02

Trust the instruments. Know where time goes.

Balances, pH meters, temperature probes, fillers and lab instruments need calibration you can show. And a shared line loses time to changeovers and cleaning; the arithmetic below shows how much.

CALIBRATION STATUS

Balance B-07 **OK**

Balance B-02 **OK**

pH meter PH-3 **OK**

Probe TP-11 **HOLD**

Filler FL-2 volumes **OK**

HPLC LC-04 **OK**

TP-11 failed its check, so it is blocked; the batches measured since the last good check are listed for assessment.

FILLING LINE 2, ONE 8-HOUR SHIFT

Availability **75%**
6.0 h run of 8 h

Performance **90%**
actual vs rated speed

Quality **98.1%**
good bottles

OEE **66.2%**
0.75 x 0.90 x 0.981

Calibrate by risk

Intervals and tolerances come from your procedures and history.

Out of tolerance looks back

Assess what was measured since the last good check.

Changeover is the big loss

On shared lines, cleaning and clearance often cost more than breakdowns.

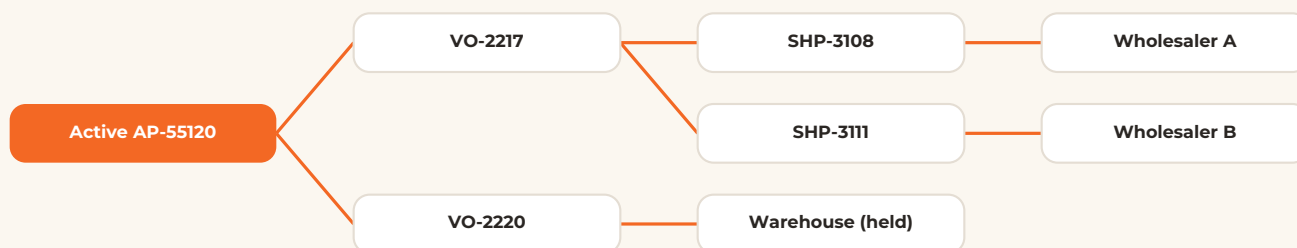
WHERE V5 FITS

Each instrument has a calibration schedule, results, certificates and history; out-of-calibration equipment can be blocked at the kiosk. Downtime reasons and OEE come from events your team records and supported connected equipment. AI forecasting and anomaly detection are coming soon, not available today.

SUSTAIN / 03

Trace one lot and practise recall.

A supplier notifies that active lot AP-55120 may contain an impurity above its limit. Which batches used it, where did they go, and how fast can you find out? Recall decisions and notifications belong to your qualified people and regulators.



MOCK RECALL, TIMED

- 0:00 ● Start: active lot AP-55120 named
- 0:03 ● Batches found: VO-2217, VO-2220
- 0:08 ● Shipments and wholesalers listed with quantities
- 0:12 ● Remaining active and VO-2220 stock held
- 0:30 ● Balance: 40.0 kg received = used + samples + stock

WHERE V5 FITS

Genealogy links material lots to batches, packed lots, shipments and customers, so a trace runs forward from a material lot or back from a finished lot, with quantities, and can be exported. Mock recalls can be timed and their findings fed into CAPA. V5 does not decide or notify recalls.

SUSTAIN / 04

Shared well, recorded honestly.

Contract givers, wholesalers and suppliers ask for certificates, records and changes. Records help only if made at the time, by a known person, with actual values, and AI stays a helper under human control. EU veterinary GMP has an annex on computerised systems [7].

PORTALS

Customer portal

Orders, lot lookups and approved certificates, as you allow.

Supplier portal

Certificates and documents uploaded for a person to review.

RECORDS

Audit trail

Who did what, when, with old and new values.

Electronic signatures

Signature meaning, name and time on each decision.

AI CAN HELP

- Read certificate values for a person to confirm
- Draft a deviation summary for editing
- Suggest a classification for review
- Explain a lot's history in plain words
- Find records faster

AI NEVER

- Releases or certifies a batch
- Decides if an event is reportable
- Approves labels or master records
- Sets specifications or doses
- Predicts failures (coming soon only)

WHERE V5 FITS

Customer and supplier portals share only what you approve, and every record keeps an audit trail; electronic signatures and validation packs are available where your plan includes them. Your validation decides fitness for your intended use.

Sources: [7] (linked on pages 36–37)

APPLY / 01

Evidence map.

One page to check that every theme an inspector, qualified person or contract giver may ask about has an owner and a record. Map it to the rules that apply to you [1][3][6][7].

THEME	TYPICAL EVIDENCE	WHERE IT LIVES IN V5	OWNER
Suppliers	Approvals, audits, agreements	Approved suppliers	QA
Receipts	Inspection, samples, status	Receiving	Warehouse
Storage	Status, dates, conditions	Warehouse	Warehouse
Masters	Approved revisions	Master records	QA
Dispensing	Lots, weights, checks	Weigh and dispense	Production
Changeover	Clearance, cleaning	Kiosk steps, equipment	Production
In-process	Readings, deviations	Batch record	Production
Lab	Methods, data, results	Lab & QC	QC
Release	Review, decision	Release review	QP / QA
Labels	Versions, checks, counts	Label control	Packaging
Complaints	Records, links	Complaints	QA / PV
CAPA	Actions, effectiveness	CAPA	QA
Equipment	Cleaning, PM, calibration	Maintenance	Engineering
Trace	Genealogy, drills	Traceability	QA
Training	Records by revision	Skills matrix	HR + QA

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

WORKSHEET 01

Could you defend this batch?

Pick one batch released last quarter. Find each record and time it. Mark Yes, Partly or No, then note the gap and its owner.

	YES	PARTLY	NO
Master The approved revision used, and why it was the right species and strength.	☐	☐	☐
Materials Every lot used, its release and its supplier approval.	☐	☐	☐
Dispensing Weights, scans and who checked.	☐	☐	☐
Changeover Line clearance and cleaning before this batch.	☐	☐	☐
In-process Readings and any deviations with assessments.	☐	☐	☐
Lab All results, methods and raw data location.	☐	☐	☐
Labels Artwork version, checks and reconciliation.	☐	☐	☐
Release Who released, when and on what evidence.	☐	☐	☐
Equipment Calibration and cleaning status of each item used.	☐	☐	☐
Shipments Customers, dates and quantities.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Wrong-species label drill.

Walk through a real or invented case: bottles of the cattle product were labelled with the sheep label. Mark Yes, Partly or No.

	YES	PARTLY	NO
Detection Which check should have caught it, and did it?	☐	☐	☐
Scope Can you find every unit labelled in that run?	☐	☐	☐
Other batches Did the same labels go to other runs?	☐	☐	☐
Hold Can affected stock be held within an hour?	☐	☐	☐
Shipped Do you know what shipped, and to whom?	☐	☐	☐
Decision Is it clear who decides on recall and notification?	☐	☐	☐
Reporting Does your team know which report clocks may apply?	☐	☐	☐
Root cause Look-alike artwork, line clearance or reconciliation?	☐	☐	☐
CAPA Will the fix stop it, not just this batch?	☐	☐	☐
Records Is the whole story in one place?	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 03

Ask to see it work.

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

	SHOWN	PARTLY	NOT SHOWN
Master per species Issue a batch only from the approved revision for that species and strength.	☐	☐	☐
Wrong lot Scan a lot released for another product and show the block.	☐	☐	☐
Line clearance Require a signed clearance before the next batch.	☐	☐	☐
Out of limit Enter an out-of-range reading and show the deviation.	☐	☐	☐
Pending result Show release waiting for a missing result.	☐	☐	☐
Label check Check species and strength on a label against the master.	☐	☐	☐
Reconciliation Show label issue, use and return balance.	☐	☐	☐
Trace Run a timed trace forward from a material lot.	☐	☐	☐
Audit trail Show who changed a value and why.	☐	☐	☐
Training block Show an untrained person blocked from a step.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

Roll out in phases.

Start where value is visible and risk is contained, often receiving, dispensing and release for one product family. Run old and new side by side until each phase is verified by your validation approach.

PHASE 1 Foundations	Documents, training, equipment register, supplier list, master records for one product family.
PHASE 2 Material	Receiving, quarantine and release, warehouse status, retest and expiry, FEFO.
PHASE 3 Make	Dispensing, line clearance, kiosk steps and in-process checks; paper record kept in parallel.
PHASE 4 Release and pack	Lab results, release review, label control and reconciliation, holds, deviations and CAPA.
PHASE 5 Connect	Complaints, trace and mock recall, portals, OEE; extend to other product families.

Validate for intended use

Your validation approach decides what evidence each phase needs.

One family first

A product family with several species shows the master logic early.

Measure the before

Time a trace and a release review before you start.

WORKSHEET 04

Find your first improvement.

Score each area today: E evidenced, P partial, G gap. Start with the gap that carries the most risk to animals, consumers of animal products or customers.

	E	P	G
Suppliers Approvals and active substance evidence current	☐	☐	☐
Receiving Quarantine and release enforced	☐	☐	☐
Masters Species and strength selection deliberate	☐	☐	☐
Dispensing Lots and weights checked at the scale	☐	☐	☐
Changeover Clearance signed before start	☐	☐	☐
Lab Results and pending tests visible	☐	☐	☐
Release Review complete before decision	☐	☐	☐
Labels Checks and reconciliation	☐	☐	☐
Complaints Linked to lots, triaged for safety	☐	☐	☐
Equipment Cleaning, PM and calibration current	☐	☐	☐
Trace Timed drill in the last year	☐	☐	☐

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 live records.

WEEK 1

Agree the product family, species and strengths, the steps that matter and the evidence you need. Load suppliers, materials, masters and equipment.

WEEK 2

Run test batches end to end with test data: receive, dispense, clear, make, test, label.

WEEK 3

Break it on purpose: wrong lot, out-of-limit reading, pending result, wrong label, untrained person.

WEEK 4

Run a timed trace and mock recall, a release review, and an export. Review with QA, the QP and IT.

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

ASK V5

"We make [oral solutions / boluses / injectables] for [species] at [number] sites. Our hardest moment is [e.g. changeover between species versions]. 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 one product family in a trial workspace using test data. The assistant answers questions about features and plans; it does not give legal, regulatory or veterinary advice.

SOURCES

Keep the evidence close.

Primary sources behind this guide, October 2026. The source ledger records which were re-read for this edition. Click a title to open the publisher's page.

[1]

U.S. eCFR, 21 CFR Part 211: CGMP for finished pharmaceuticals

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211>

[2]

U.S. eCFR, 21 CFR Part 210: CGMP general

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210>

[3]

U.S. eCFR, 21 CFR 514.80: Records and reports, approved new animal drugs

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-514/subpart-B...>

[4]

U.S. eCFR, 21 CFR Part 225: CGMP for medicated feeds

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-225>

[5]

FDA Center for Veterinary Medicine, Animal and veterinary

FDA GUIDANCE

<https://www.fda.gov/animal-veterinary>

[6]

EU, Regulation (EU) 2019/6 on veterinary medicinal products

BINDING EU LAW

<https://eur-lex.europa.eu/eli/reg/2019/6/oj>

[7]

EU, Implementing Regulation (EU) 2025/2091: GMP for VMPs

BINDING EU LAW

https://eur-lex.europa.eu/eli/reg_impl/2025/2091/oj

[8]

EU, Implementing Regulation (EU) 2025/2154: GMP for active substances

BINDING EU LAW

https://eur-lex.europa.eu/eli/reg_impl/2025/2154/oj

SOURCES

Sources, continued.

[9]	<u>European Commission, Implementing the EU veterinary medicines rules</u>	COMMISSION GUIDANCE
	https://food.ec.europa.eu/animals/animal-health/veterinary-medicines/implementi...	
[10]	<u>UK SI 2013/2033, The Veterinary Medicines Regulations 2013</u>	BINDING LAW (AS AMENDED)
	https://www.legislation.gov.uk/uksi/2013/2033/contents	
[11]	<u>VICH, International cooperation on veterinary medicines</u>	INTERNATIONAL GUIDELINES
	https://vich.org/	
[12]	<u>PIC/S, GMP guide</u>	INSPECTORATE GUIDE
	https://picscheme.org/en/publications	
[13]	<u>EMA, Veterinary regulatory overview</u>	AGENCY GUIDANCE
	https://www.ema.europa.eu/en/veterinary-regulatory-overview	
[14]	<u>UK SI 2024/567, Veterinary Medicines (Amendment etc.) 2024</u>	BINDING GB LAW
	https://www.legislation.gov.uk/uksi/2024/567/made	
[15]	<u>VMD, Active substance registration (Great Britain)</u>	VMD GUIDANCE (GB)
	https://www.gov.uk/guidance/apply-to-register-as-a-manufacturer-importer-or-dis...	

How to read the status labels. Regulations are law in their jurisdiction. Agency and Commission pages explain and apply them and may change. VICH guidelines apply through each region's adoption. The PIC/S guide is used by participating inspectorates.

SCOPE AND LIMITS

Practical orientation for evaluating veterinary medicine manufacturing and software; not legal, regulatory or veterinary advice, and not a list of every requirement. Rules depend on market, product type and authorisation. Specifications, doses, withdrawal periods, label text and reporting decisions are deliberately not given; take them from your authorisations, current rules and qualified people. Values shown are examples. V5 capability statements reflect the V5 product reference reviewed on 1 October 2026 and depend on plan, configuration, devices and permissions. AI forecasting and anomaly detection are coming soon. V5 does not certify or release batches, approve labels, decide or file regulatory reports or decide recalls, and does not by itself make you compliant.



The right product, strength and species. Every batch.

See veterinary medicine workflows at v5ultimate.com · Global edition · October 2026