



THE REGULATED WAREHOUSING & DISTRIBUTION GUIDE

The right lot leaves, and every hold stays held.

From the dock door to the customer's order, and back again in a recall

A practical evaluation guide for warehouses and distributors of medicines, food and other regulated goods, for their own stock or for clients: which rules apply to what you store, who is responsible for which decision, how licence plates, expiry and status keep the wrong stock off a truck, and what to do when a cold room goes out of range.



EU GDP 2013/C 343/01

21 CFR 205 · DSCSA

21 CFR 117 · FOOD

PEOPLE DECIDE

U.S. and EU edition / October 2026

v5ultimate.com

Scope: practical orientation, not legal advice. Photos are staged; clients, lots, readings and orders are worked examples.

INSIDE THE GUIDE

One order, one excursion, one expired lot.

Warehouses receive, store, pick and ship stock that someone else usually made and often still owns. This guide follows order SO-3104 for a 2–8 °C item through a cold-room excursion and an expired lot, and shows what the record needs at each step.

01 / FRAME

pp. 03–06

Rules and roles

What you store decides the rules: EU GDP for medicines, U.S. drug distribution, food storage, and who decides what.

02 / RECEIVE AND STORE

pp. 07–10

Status, place, conditions

Receiving and quarantine, licence plates and locations, temperature records and excursions, cycle counts.

03 / PICK

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FEFO and genealogy

First-expiry-first-out, exceptions with reasons, and licence plates that split, merge and move.

04 / HOLD

pp. 13–15

One order, worked end to end

Holds, returns and disposal, the SO-3104 excursion and expired lot, and the disposition record.

05 / SHIP

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Dispatch, recall, software

Dispatch checks and transport, trace and recall, and the system you rely on.

06 / APPLY

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V5 fit, worksheets, sources

Where V5 fits and does not, two worksheets, a four-week evaluation and eight sources.

Who it is for. Warehouse, quality and operations managers at distributors, wholesalers and third-party logistics providers; responsible persons and quality leads at licensed sites; brand owners who choose and audit a warehouse; and anyone choosing a warehouse and quality system for regulated stock.

How to read it. Operational pages end with a teal Where V5 fits panel. Everything above it is regulation and practice; practice is labelled as such. Statements cite numbered sources; always check the current text.

WHERE V5 FITS

V5 records the receiving, storage, movement, monitoring, picking, shipping and quality work your procedures define. It does not hold a licence for you, connect to DSCSA or EU medicines-verification systems, control refrigeration, or release, return or destroy stock. Those stay with your licensed and qualified people.

FRAME / 01

What you store decides the rules.

A warehouse is not regulated in one way. The same racking can hold prescription medicines, chilled food and household chemicals, each under different rules and owners. Record, per client and product, which rules your team concluded apply and who concluded it.

WHAT YOU HOLD	STARTING POINT
Human medicines, wholesale in the EU	Wholesale authorisation; GDP guidelines [1]
Prescription drugs, wholesale in the U.S.	State licence (21 CFR 205 minimums); DSCSA [5][6]
Food in the EU	General food law incl. Article 18 traceability [2]
Packaged food in the U.S., storage only	21 CFR 117.7 and, if chilled, 117.206 [3][4]
Foods on FDA's Food Traceability List	Additional traceability records rule [7][8]
Devices, chemicals, other goods	Their own rules and your client's agreement

GDP is for medicines

The EU GDP guidelines are written for wholesale distribution of human medicinal products. Food and other goods have their own rules; GDP is not a general warehouse standard.

Licences are personal

Licences and authorisations are held by a legal entity for a site and activity. Software, a client or a 3PL contract cannot transfer them.

Clients add terms

Quality and technical agreements often add storage, notification and approval terms beyond the law. Record them per client.

PRACTICE: ONE PROFILE PER CLIENT AND PRODUCT CLASS

Record the client, the product class, the storage conditions on the label or agreement, the markets, the rules and licences your team concluded apply, who may release, return or destroy stock, and who concluded it.

WHERE V5 FITS

V5 item, client and storage-zone records can carry storage class, owner and your regulatory notes. V5 does not decide which rules apply to your operation or whether you need a licence.

FRAME / 02

EU medicines: what GDP asks a distributor for.

The EU GDP guidelines set out what a wholesale distributor of human medicines should have in place. They name a responsible person and cover storage, segregation, rotation, returns, falsified products and transport [1].

Responsible person	Designated by the distributor; may delegate duties but not responsibilities; decides final disposition of returned, rejected, recalled or falsified products and approves returns to saleable stock [1]	2.2
Segregation	Products pending disposition or removed from saleable stock segregated physically or by an equivalent electronic system, which should be validated [1]	3.2
Mapping and alarms	Initial temperature mapping before use; monitoring devices placed per mapping; alarms for excursions from storage conditions [1]	3.2.1
Stock rotation	First expiry, first out; exceptions documented; nearing-expiry stock withdrawn from saleable stock [1]	5.5
Customers	Supply only to persons authorised or entitled; checks and periodic rechecks [1]	5.3
Transport	Excursions or damage in transit reported to the distributor and recipient; a procedure for investigating excursions [1]	9.2

Status of the text. GDP guidelines are Commission guidelines that distributors apply under their wholesale authorisation and national law. Section numbers above refer to 2013/C 343/01; read the current text and your competent authority's expectations.

WHERE V5 FITS

V5 can hold stock on hold or quarantine in the system, record FEFO exceptions with reasons, log readings from supported sensors and keep calibration records. If you rely on V5 for electronic segregation, you validate that use; V5 does not replace the responsible person.

Sources: [1] (linked on page 23)

FRAME / 03

U.S.: drugs and food are different regimes.

In the U.S., wholesale distribution of prescription drugs is licensed by states against federal minimum requirements and is subject to the DSCSA. Food warehouses fall under FDA's food rules, with lighter requirements for storing unexposed packaged food [3][5][6].

PRESCRIPTION DRUGS

State licensing minimums

21 CFR 205 lists minimums for state law: a quarantine area for outdated, damaged or adulterated drugs, storage per labeling, temperature and humidity records, and outgoing shipment inspection [5].

DSCSA

Sets steps toward interoperable, electronic tracing of certain prescription drugs at the package level. Trading-partner duties and FDA policies apply; check them for your role [6].

FOOD

Storage of unexposed packaged food

A facility solely doing this is outside the hazard analysis subparts but subject to modified requirements when food needs time/temperature control [3].

117.206 for chilled packaged food

Establish and monitor temperature controls, take corrective action on loss of control, verify by calibration and record review, and keep records [4].

FOOD TRACEABILITY RULE: CHECK THE CURRENT DATE

FDA's additional traceability records rule covers foods on its Food Traceability List and the persons who manufacture, process, pack or hold them, with exemptions. FDA's page shows the original compliance date and a proposed extension; confirm the current status before planning to it [7][8]. In the EU, food business operators must be able to identify their suppliers and business customers [2].

WHERE V5 FITS

V5 records receipts, holds, temperature readings, corrective actions and shipments, and can publish validated tracking events to EPCIS repositories where configured. V5 does not perform DSCSA verification, hold transaction data for you or decide whether a rule applies.

Sources: [2], [3], [4], [5], [6], [7], [8] (linked on page 23)

FRAME / 04

Who is responsible for what.

In a third-party warehouse, at least three parties touch every decision: the stock owner, the licensed operator and the people on the floor. Write down who decides, who acts and who must be told, before the first excursion.

DECISION (PRACTICE)	DECIDES	ACTS OR IS TOLD
Accept stock into saleable status	Licensed operator / owner per agreement	Warehouse quality
Place stock on hold	Anyone per procedure	Supervisor, quality
Assess a temperature excursion	Owner, with product data	Warehouse quality
Release from hold or return to stock	Responsible / qualified person	Owner per agreement
Approve a FEFO exception	Named role in procedure	Warehouse quality lead
Destroy or return to supplier	Owner instruction; licensed operator	Warehouse
Recall and notify customers	Owner / authorisation holder	Distributor executes
Report suspected falsified medicine	Distributor (EU), per law [1]	Authority, owner

Write it per client

Quality or technical agreements should name these roles. Where they are silent, ask before you need the answer.

One name per decision

A decision with two owners has none. Name a role, a deputy and how to reach them out of hours.

Evidence goes both ways

Owners need your readings and records to assess; you need their stability data and instructions to act.

WHERE V5 FITS

V5 roles and permissions can limit who places, releases or overrides a hold, and every action records who did it and when. The agreement that assigns those roles is yours and your client's.

Sources: [1] (linked on page 23)

RECEIVE / 01

Receive it, identify it, quarantine it until checked.

Receiving is where identity is set. Check the delivery against the order or advance notice, record lot and expiry, check condition and, for temperature-controlled goods, transport conditions, then keep stock out of saleable status until checked [1][5].

RECEIVING RECORD FIELD	WORKED EXAMPLE
Client and item	Northwind · CX-20 · stored 2–8 °C
Inbound notice	ASN 77120 · PO 4418
Licence plate	LPN-00431 (one pallet)
Lot and expiry	L-2307 · April
Quantity	60 cases, counted and matched
Condition	No damage; seals intact
Transport record	Logger download attached; within range
Status	Quarantine, then released by quality at 14:10

Identity from the label

Scan or record item, lot and expiry from the pack. Do not type a lot from the paperwork alone.

Quarantine by default

Stock is not pickable until the checks your procedure requires are recorded.

Supplier and customer checks

Medicines distributors qualify suppliers and customers and recheck them periodically [1].

WHERE V5 FITS

V5 receiving records licence plates with item, lot, expiry, owner and quantity against purchase orders or inbound notices, attaches documents and keeps stock in quarantine until released. Your procedure decides what must be checked.

RECEIVE / 02

The right place for each storage class.

Every location should have a storage class the product's label or agreement allows, and stock should only go where it fits. For medicines, storage areas are mapped before use and monitoring devices placed where the mapping shows [1].



Storage class per zone

Ambient, controlled room temperature, 2–8 °C, frozen, hazardous or secure: set per zone and bin by your team.

Mapping is your evidence

Mapping reports, their dates and the probe positions they led to belong with the zone record.

Every move scanned

Putaway and transfers scan bin and licence plate, so the system knows where stock is.

ZONE (WORKED EXAMPLE)	CLASS AND EVIDENCE	ITEMS
CR-1 · cold room	2–8 °C · mapped March	CX-20, CX-31
CR-2 · cold room	2–8 °C · mapped March	CX-20
A · ambient racking	15–25 °C	General
Q · quarantine cage	Restricted access	Held stock

WHERE V5 FITS

V5 storage zones carry a temperature class, default material status and notes, editable without rebuilding the zone, and putaway and transfers scan the bin. Mapping studies are done by your team or a contractor.

Sources: [1] (linked on page 23)

STORE / 01

When a cold room goes out of range.

An excursion is a record and a question, not a verdict. The reading says a room left its band; whether the stock in it is still fit depends on the product, the owner's data and your procedure [1][4].

TIME	STEP (WORKED EXAMPLE)	STATUS
02:10	CR-2 reading above the 2–8 °C band; alarm raised	FLAG
02:25	On-call technician acknowledges; door found ajar and closed	Done
03:00	Reading back inside the band	Done
07:05	Supervisor places lots in CR-2 on hold	HOLD
07:30	Excursion report with readings sent to owner	Done
—	Owner's assessment with product data	PENDING

Record, then decide

Capture start, end, peak and the stock affected. Do not edit readings to fit a conclusion.

Hold what was there

Place the stock stored in the area on hold until a person assesses it; your procedure decides scope.

Review the records

U.S. chilled packaged food storage requires monitoring, corrective action and record review, normally within 7 working days [4].

WHAT THIS GUIDE DOES NOT SAY

It quotes no allowable excursion times or temperatures for any product. Those come from the product's labelling and the owner's stability data, and the decision belongs to the owner and your qualified people.

WHERE V5 FITS

V5 Sensors & IoT logs readings from supported devices against bands and flags excursions with alerting, depending on plan. A person places the hold and records the assessment. V5 does not quarantine stock automatically or judge fitness.

STORE / 02

Counts you can trust, adjustments you can explain.

Inventory accuracy is a quality matter when lots and expiry are involved: a miscount can put the wrong lot on an order or hide a short. Count by location and lot, review differences before adjusting, and investigate patterns.

LOCATION, ITEM, LOT (WORKED EXAMPLE)	SYSTEM	COUNTED	RESULT
CRI-04 · CX-20 · L-2307	60	60	OK
CR2-02 · CX-20 · L-2291	48	48	OK
A-11 · CX-44 · L-1903	120	118	REVIEW
Q-01 · CX-20 · L-2240	12	12	OK

Count by lot

A total that matches can hide two lots swapped. Count and record lot as well as quantity.

Review before adjusting

A second count or a person's review comes before the stock record changes, with a reason.

Look for patterns

Repeated differences in one zone, client or picker point to a process to fix, not a number to adjust.

PRACTICE: RECONCILE OWNER STOCK

For client-owned stock, reconcile your records with the owner's at an agreed interval and record who agreed each difference. An unexplained short of a controlled or high-value item may need to be reported under your procedures.

WHERE V5 FITS

V5 cycle counts run by location or item, and differences are reviewed before stock is adjusted, with the reason and who approved it in the audit trail. Count frequency and reporting stay with your procedures.

PICK / 01

First expiry first out, and exceptions with reasons.

Picking is where a held or expired lot most easily slips out. The pick should offer only released, in-date stock, earliest expiry first, and any deviation from that order should carry a reason and an authorisation [1].



- Only pickable stock offered**

Held, quarantined and expired lots are not offered, whatever their expiry date.
- Scan bin and plate**

The picker scans the location and the licence plate; a wrong lot is caught at the shelf.
- Exceptions recorded**

GDP says exceptions to FEFO should be documented; record the reason and who approved it [1].

PICK FOR SO-3104 (WORKED EXAMPLE)	PICK STATUS	PICK?
LPN-00377 · L-2240 · expired 30 Sep	Not offered	EXPIRED
LPN-00418 · L-2291 · expires Jan	On hold (CR-2)	HOLD
LPN-00431 · L-2307 · expires Apr	Suggested · picked 40	YES
Exception reason	L-2291 held; awaiting authorisation	EXCEPTION

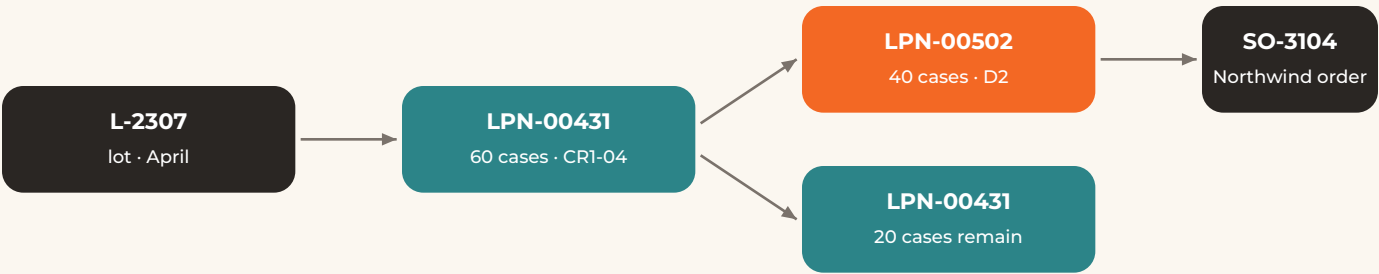
WHERE V5 FITS

V5 warehouse operations suggest lots by FEFO or FIFO, show status and expiry at the bin, and scan picks against the order. Whether a skipped lot is an exception that needs approval is set by your procedure.

PICK / 02

Licence plates split, merge and move.

A licence plate identifies a handling unit. Picking splits plates; building a mixed pallet merges them; transfers move them. Each change should keep the link from the new plate back to its source plates and lots.



FROM	TO	QUANTITY	NOTE (WORKED EXAMPLE)
LPN-00431 (L-2307)	LPN-00502	40 cases	Pick split for SO-3104
LPN-00431 (L-2307)	LPN-00431	20 cases	Remains in CR1-04
LPN-00502	Dispatch lane D2	1 pallet	Transfer, scanned
LPN-00502	SO-3104 shipment	40 cases	Shipped after authorisation

Mixed pallets keep every lot. When a pallet carries cases from several lots, its record should list each lot and quantity, so a recall of one lot finds the pallet, the order and the customer without opening it.

WHERE V5 FITS

V5 licence plates follow stock from receipt through putaway, picking and shipping with lot and expiry, and traceability shows the tree forward and back. Accuracy depends on scanning every split, merge and transfer.

HOLD / 01

Holds, returns, damage and disposal.

Stock that cannot be sold yet, or ever, needs a status, a place and an owner for the decision. In the EU, returns to saleable stock and final disposition of returned, rejected, recalled or falsified medicines are the responsible person's decisions [1].



Returns are assessed

GDP returns need a risk-based assessment; for temperature-sensitive products, documented evidence of storage conditions throughout [1].

Suspected falsified

Physically segregate in a dedicated area and inform the competent authority and authorisation holder, per GDP [1].

Destruction by procedure

Stock for destruction is identified, held separately and handled under a written procedure and national requirements [1], on the owner's instruction.

STATUS (WORKED EXAMPLE)	WHERE AND NEXT STEP	PICKABLE?
Held: excursion review	LPN-00418 · CR-2	HOLD
Expired	LPN-00377 · in Q-01	BLOCKED
Returned by customer	Assess before any decision	REVIEW
Damaged in storage	Hold; owner informed	HOLD
Awaiting destruction	Owner instruction on file	HOLD

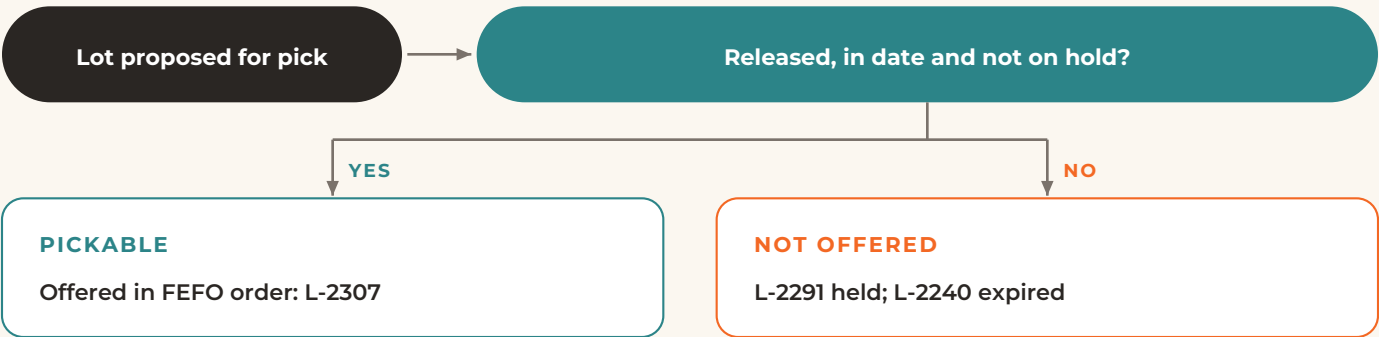
WHERE V5 FITS

V5 holds keep lots out of picking until a person with permission releases them, and dispositions are recorded with an electronic signature. Returns, destruction and falsification reporting follow your procedures; V5 does not dispose of stock or report to authorities.

HOLD / 02

One cold-store order, worked end to end.

07:40: order SO-3104 needs 40 cases of CX-20. FEFO points at lot L-2291, held since 07:05 after the CR-2 excursion. Lot L-2240 expired on 30 September. Lot L-2307 is released and in date.



TIME	STEP (WORKED EXAMPLE)	STATUS
07:05	LPN-00418 (L-2291) placed on hold after CR-2 excursion	HOLD
07:40	Pick offers LPN-00431 (L-2307); L-2240 not offered	Done
07:55	40 cases picked to LPN-00502, scanned to lane D2	Done
08:05	Pack check: item, lot, quantity and label matched	Done
08:10	FEFO exception raised: earlier-expiry lot skipped	PENDING
08:30	Quality lead authorises exception; order ships	Done

Authorising the exception is not releasing the hold. The quality lead approves shipping a later-expiry lot for this order. L-2291 stays on hold until the owner's assessment; L-2240 stays blocked until the owner gives a disposal instruction.

WHERE V5 FITS

V5 offers only pickable lots, records the exception with its reason and who authorised it, and keeps the hold on the other lot. V5 does not decide whether the excursion affected the product.

HOLD / 03

A person decides, and the record says who.

Each outcome needs a decision by the right role under your procedures and the client's agreement: release from hold, return to the owner or supplier, destroy on instruction, or keep held while evidence is gathered.

Release
Owner's assessment and your review complete. Record the basis and who decided.

Return or destroy
On the owner's written instruction, by an approved route, with quantities.

Keep held
Evidence incomplete. The lot stays held and visible, with an owner and a next step.

DISPOSITION RECORD FIELD	WORKED EXAMPLE
Order	SO-3104, 40 cases CX-20, lot L-2307
Exception	FEFO: L-2291 skipped because on hold
Decision	Exception authorised (worked example)
Held lot	LPN-00418 · L-2291 · stays on hold
Expired lot	LPN-00377 · L-2240 · blocked
Decided by	Warehouse quality lead, e-signature, 08:30
Follow-up	Owner assessment requested; CAPA CA-0412 for door alarm

The example is not a rule. Another client agreement may require the owner to approve every FEFO exception, or forbid shipping until the excursion is assessed. What matters is that each decision, its basis and its owner are recorded.

WHERE V5 FITS
V5's release queue shows each lot's status, holds, readings and open deviations in one view. A named person records the decision with an electronic signature. V5 never releases, returns or destroys stock automatically.

SHIP / 01

Check it before it leaves the dock.

Outgoing shipments should be checked for identity and condition, and storage conditions kept during transport within the limits on the outer packaging or set by the manufacturer [1][5].

DISPATCH CHECK (WORKED EXAMPLE)	RECORD	OK?
Item, lot and quantity vs order	CX-20 · L-2307 · 40 cases	YES
Shipping label and lot on label	Printed, scanned, matched	YES
Status of every lot on pallet	Released; exception authorised	YES
Vehicle and conditions	Per route risk assessment	YES
Consignee	Address on delivery note	YES



WHERE V5 FITS

V5 shipping scans picks against the order, prints GS1-128 labels, links each shipment to its licence plates and lots, and can send advance ship notices where EDI is set up. Vehicle qualification and transport monitoring stay with you and your carrier.

Sources: [1], [5] (linked on page 23)

SHIP / 02

From one lot to every customer.

A recall starts with a lot and a question: where did it go? The answer should come from records, in minutes, and include stock on hand, on hold, in transit and shipped, by customer [1][2].

TRACE STEP	RECORD (WORKED EXAMPLE)	STATUS
Recall notice	Owner recalls CX-20 lot L-2307	Done
Stock on hand	LPN-00431, 20 cases, CRI-04	HOLD
Shipped	SO-3104, 40 cases, Northwind's customer	Done
In transit	None	Done
Customers notified	By owner; distributor supports	REVIEW
Mock recall time	Recorded for review	Done

Trace both ways

Back to receipt, supplier and inbound notice; forward to every order, pallet and customer.

Mock recalls

Time a trace from one lot. Record what was found, what was missing and who did what.

Who notifies

The owner or authorisation holder usually leads; your agreement sets what the warehouse does.

PRACTICE: KEEP RECALLED STOCK SEPARATE

Move recalled stock to a held status and location at once, and keep it there until the owner's instruction is recorded.

WHERE V5 FITS

V5 traces any lot to licence plates, orders and customers, places stock on hold and records mock recalls with timings. Recall decisions and customer notifications stay with the owner and your people.

SHIP / 03

The software you rely on.

GDP expects distributors to decide which equipment and processes need qualification or validation, and an electronic system that replaces physical segregation should be validated [1]. Know what the system does and test it.

- 01 Define its job**
Which records it holds, which checks it enforces, and which decisions it supports.
- 02 Test with your data**
Run your clients, zones, holds, expiry and exceptions before relying on it.
- 03 Control change**
Assess supplier releases and configuration changes before they reach production.
- 04 Keep a fallback**
Decide how holds, picks and records work if the system or network is unavailable.

WHO DOES WHAT

You decide the intended use, test it and approve go-live, including any performance qualification your clients expect. **A supplier** can provide documentation and, where agreed, installation and operational qualification support. In V5's case, IQ/OQ and validation support are part of the Enterprise plan, scoped in the accepted quote or statement of work.

WHERE V5 FITS

V5 records configuration changes in an audit trail and releases software in versions, so you can see what changed. It does not make a warehouse or a quality system compliant on its own.

Sources: [1] (linked on page 23)

APPLY / 01

Where V5 fits, and where it does not.

A plain map from the area to the V5 capability that keeps its record, and the decision that stays with you. Capabilities are from the V5 product reference reviewed 1 October 2026 and depend on plan and configuration.

AREA	V5 KEEPS THE RECORD	YOUR PEOPLE DECIDE
Receiving	Licence plates, lots, expiry, quarantine	Acceptance criteria
Locations	Zones, bins, storage class, putaway	Mapping, zone limits
Conditions	Sensor readings, bands, excursions	Product impact
Counts	Cycle counts, reviewed adjustments	Count policy
Picking	FEFO/FIFO, status at bin, scanning	Exception approval
Holds	Hold, release queue, e-signature	The decision itself
Shipping	Labels, ASN, shipment to lot	Transport, vehicles
Owners	Customer portal (plan-dependent)	What is shared
Recall	Trace, holds, mock recall timing	Recall, notices
Equipment	Calibration and maintenance	Mapping, qualification

Plan-dependent: sensors and device integration, customer and supplier portals, EDI and multi-warehouse, and IQ/OQ and validation support (Enterprise only, scoped in the accepted quote or statement of work).
Coming soon, not available today: AI demand forecasting and anomaly detection. **Not offered:** DSCSA or EU medicines-verification connections, refrigeration control, licensing, automatic disposition, quarantine or disposal.

WHERE V5 FITS

Nothing in V5 holds a licence, assesses an excursion, releases a hold, destroys stock or starts a recall. It keeps the evidence connected so the licensed and qualified people who make those decisions can see it.

WORKSHEET 01

Responsibility and evidence for one client.

Use with one real (or test) client and product. Tick what your agreement and records show today without asking anyone.

	SHOWN	PARTLY	NOT SHOWN
Rules and licences Which rules apply to this product, and the licence they rest on	☐	☐	☐
Roles Who decides acceptance, holds, release, returns, disposal, recall	☐	☐	☐
Storage class Label or agreement conditions matched to zones	☐	☐	☐
Mapping Current mapping report and probe positions for each zone used	☐	☐	☐
Receiving Lot, expiry, condition and transport record per licence plate	☐	☐	☐
Excursions Procedure, contacts, and the owner's data needed to assess	☐	☐	☐
FEFO exceptions Who may approve, and how it is recorded	☐	☐	☐
Returns and disposal Assessment steps and the owner's instruction route	☐	☐	☐
Recall Last mock recall time and gaps found	☐	☐	☐
Records to owner What is shared, how often, and how it is agreed	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Questions for any software demo.

Ask the vendor to show, not tell, using test data. Record what you saw.

	SHOWN	PARTLY	NOT SHOWN
Quarantine Receive a pallet; show it cannot be picked until released.	☐	☐	☐
Expired lot Let a lot pass its expiry; show it is not offered to a pick.	☐	☐	☐
Hold Hold one lot; try to pick it; show what happens.	☐	☐	☐
FEFO exception Pick a later lot; show the reason and approval recorded.	☐	☐	☐
Excursion Show a reading out of band and the stock in that zone.	☐	☐	☐
Split and merge Pick part of a plate; build a mixed pallet; show genealogy.	☐	☐	☐
Cycle count Record a difference; show review before adjustment.	☐	☐	☐
Owner view Show what a client sees about its own stock.	☐	☐	☐
Recall trace From one lot, list stock, orders and customers, timed.	☐	☐	☐
Audit trail Show who changed a status, when and why.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

A fair evaluation in four weeks.

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

WEEK 1

Agree one client or product family and the five questions that matter most. Load items, zones, bins, storage classes and roles.

WEEK 2

Run an order end to end with test data: receipt, quarantine, release, putaway, pick, pack, ship.

WEEK 3

Break it on purpose: expired lot, held lot, excursion, FEFO exception, count difference, return.

WEEK 4

Run a timed mock recall from one lot. Review with quality, operations, the client and IT.

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

ASK V5

“We store [medicines / food / chemicals / devices] for [ourselves / clients] at [number] sites. Our hardest moment is [e.g. a cold-room excursion]. 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 family in a trial workspace using test data. The assistant answers questions about features and plans; it does not give regulatory advice.

SOURCES

Keep the evidence close.

Sources behind this guide, read 3 October 2026. Click a title.

- | | | |
|-----|--|-------------------------|
| [1] | <u>EU Guidelines on Good Distribution Practice of medicinal products for human use (2013/C 343/01)</u>
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013XC1123(01) | EU COMMISSION GUIDELINE |
| [2] | <u>Regulation (EC) No 178/2002, general food law, Article 18 traceability</u>
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02002R0178-20240701 | BINDING EU REGULATION |
| [3] | <u>U.S. eCFR, 21 CFR 117.7: storage of unexposed packaged food</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117/subpart-A... | BINDING U.S. REGULATION |
| [4] | <u>U.S. eCFR, 21 CFR 117.206: modified requirements for that storage</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117/subpart-C... | BINDING U.S. REGULATION |
| [5] | <u>U.S. eCFR, 21 CFR Part 205: state licensing of wholesale prescription drug distributors</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-205 | U.S. FEDERAL GUIDELINES |
| [6] | <u>U.S. FDA, Drug Supply Chain Security Act (DSCSA)</u>
https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-securit... | FDA INFORMATION PAGE |
| [7] | <u>U.S. FDA, FSMA Final Rule on Requirements for Additional Traceability Records</u>
https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-req... | FDA INFORMATION PAGE |
| [8] | <u>U.S. FDA, Food Traceability List</u>
https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-l... | FDA LIST PAGE |

How to read the status labels. Binding regulations are law in their jurisdiction. The GDP guidelines are Commission guidelines applied under wholesale authorisations and national law. 21 CFR 205 sets minimums for state licensing laws. FDA pages explain and list; they are not themselves the rules.

SCOPE

What this guide does and does not do.

This guide is practical orientation for evaluating regulated warehousing and distribution operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you. It covers selected EU and U.S. federal texts; national, state, product-specific, controlled-substance, hazardous-goods, transport, customs, client and certification requirements add to them.

Regulatory text was read on 3 October 2026; confirm the current text and any dates before relying on it. The DSCSA and FDA food traceability descriptions summarise FDA's own pages; read the law, regulations and FDA policies for your role.

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 hold licences, perform DSCSA or EU medicines verification, control refrigeration, map storage areas, assess excursions, release, return or destroy stock, report to regulators or decide recalls, and does not by itself make you compliant.

Photography is staged and illustrative; every person on the floor is shown in protective clothing. Clients, lots, readings and orders are worked examples, not customer data.



The right lot leaves, and every hold stays held.

See warehouse and distribution workflows at v5ultimate.com · October 2026