



THE CANNABIS AND HEMP GUIDE

Authorised inputs. Tested batches. Packs that meet your market's rules.

From authorised supplier to labelled pack, recall and report

A capability and evaluation guide for licensed cannabis processors, hemp extractors and formulators who want inputs, extraction, testing, gram reconciliation, labels and distribution in one connected record. Rules differ sharply by country and state; this guide is jurisdiction-aware, not jurisdiction-specific.



INPUT TO PACK

TEST, APPROVE, RECONCILE

RECALL AND REPORT

Global edition / October 2026

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 advice.

INSIDE THE GUIDE

Input to pack, gram by gram.

Cannabis and hemp processors turn dried plant material into extracts, oils, edibles and topicals under some of the tightest controls in manufacturing. This guide follows one batch, CB-0619, a 30 mL extract tincture, and shows what each step must leave behind.

01 / FRAME

pp. 03–05

Rules, QA, one day

Canada's Cannabis Regulations in detail, U.S. hemp and FDA context, EU, UK and Australian medicinal cannabis, the 1961 Convention; one production day.

02 / MATERIAL

pp. 06–08

Supplier to vault

Authorised suppliers and specifications, receipts with weights and seals, secure storage, status and expiry.

03 / MAKE

pp. 09–16

Extract, formulate, test, pack

Approved methods, extraction and yield, formulation by potency, gram reconciliation, lab testing, QA approval, holds, filling and labels.

04 / CONTROL

pp. 17–20

Fix, respond, change, train

Investigations and CAPA, complaints and adverse reactions, changes, people and permissions.

05 / SUSTAIN

pp. 21–27

Equipment, trace, share

Extraction equipment, scales and instruments, yield and OEE, distribution and trace, recall simulation, portals, records and AI.

06 / APPLY

pp. 28–36

Evidence map, tools, sources

Evidence map, four worksheets, roadmap, four-week evaluation and 16 linked sources.

Who it is for. Quality assurance people, plant and production managers, extraction and formulation leads, lab, packaging and shipping teams at licensed processors and hemp manufacturers, and anyone choosing a system for them.

How to read it. Canada's federal rules are covered in most detail because they are national and published in one place. Elsewhere, rules depend on the country, state or province and whether the product is medical, adult-use or hemp. Every operational page ends with a teal Where V5 fits panel.

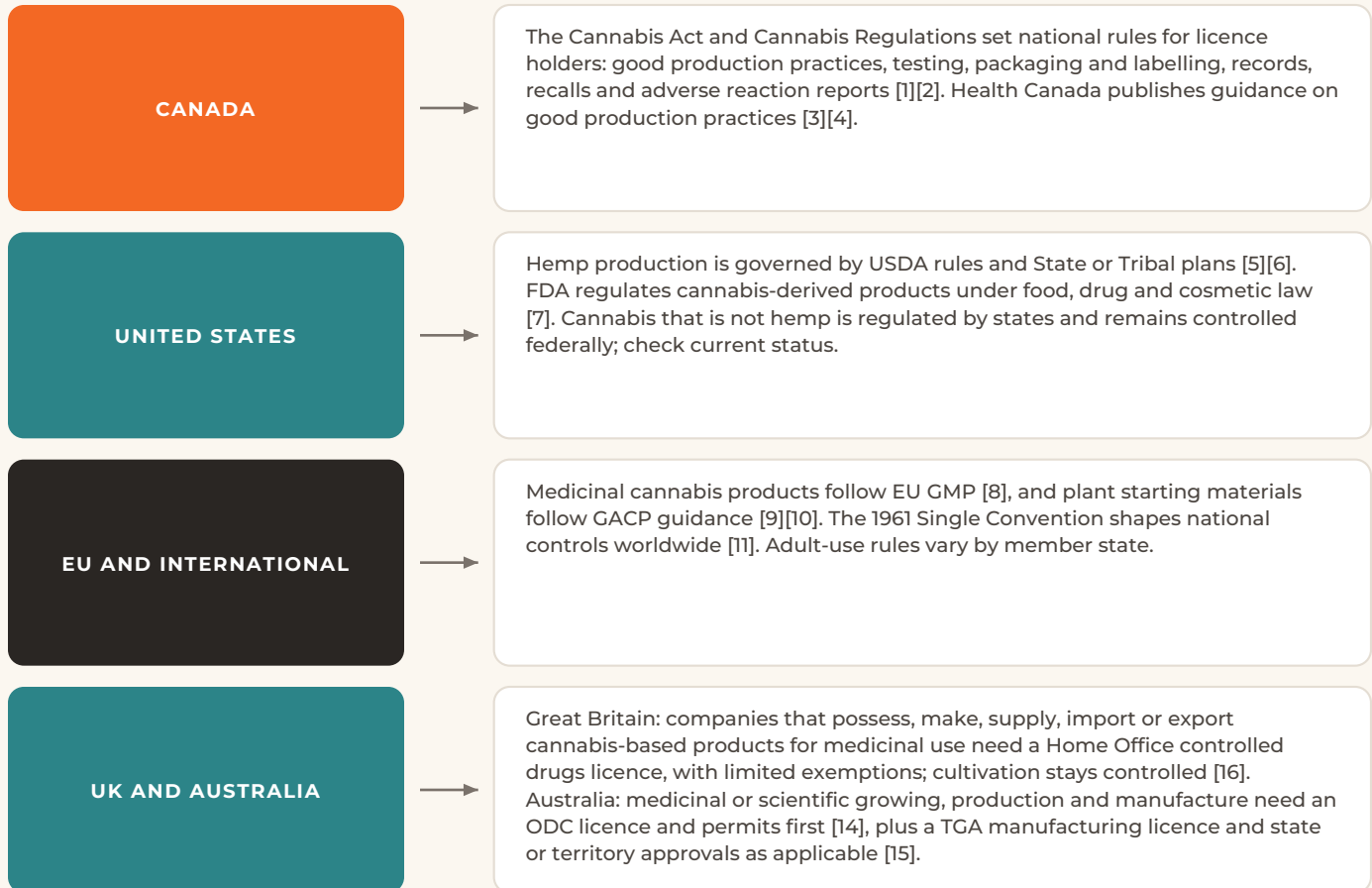
WHERE V5 FITS

V5 records the receiving, storage, extraction, formulation, testing, packaging and shipping work your procedures define, and links it to lots, batches and customers. It does not connect to government track-and-trace systems, decide which rules apply, approve lots, write label claims, file reports or decide recalls. Your QA person and regulatory team do.

FRAME / 01

Which rules reach your product?

No other product in this series changes legal status so much across borders. The same tincture can be a licensed cannabis product in Canada, a hemp product in the U.S., a medicine in Germany and illegal elsewhere.



Product form first

Medicinal, adult-use, hemp, food, supplement and cosmetic products sit in different regimes. Classify each product per market.

State systems differ

U.S. states run their own licensing, testing and track-and-trace programs with different rules.

Change is constant

Cannabis law changes often. Assign someone to watch for changes in each market you serve.

WHERE V5 FITS

Keep licences, scope, specifications and SOPs as controlled documents with revisions, owners and review dates. V5 does not decide which rules apply and does not integrate with government track-and-trace systems.

Sources: [1], [2], [3], [4], [5], [6], [7], [8], [9], [10], [11], [14], [15], [16] (linked on pages 35–36)

FRAME / 02

Canada: the QA person, testing and recall.

Canada's Cannabis Regulations put a named quality assurance person at the centre of processing. The details below are from the current regulation text [2]; read the full sections for your licence class.

SELECTED REQUIREMENTS, CANNABIS REGULATIONS SOR/2018-144 [2]

s. 19	Processing licence holders retain one quality assurance person with relevant training, experience and knowledge
s. 80	Production, packaging, labelling, distribution, storage, sampling and testing follow SOPs
s. 87	A sanitation program covers buildings, equipment, substances and personnel hygiene
s. 88	QA person approves methods and procedures before use, and approves every lot or batch before sale
s. 90–91	Each lot or batch tested for THC, THCA, CBD and CBDA, and for microbial and chemical contaminants
s. 46	A system for rapid and complete recall; a recall simulation at least every 12 months, documented and kept 2 years
s. 248.1	Serious adverse reactions reported within 15 days; annual summary; reports kept 25 years

This is a summary, not the full text. Testing has exceptions by product class; packaging, labelling and THC limits are in Part 6 and other parts not summarised here.

WHERE V5 FITS

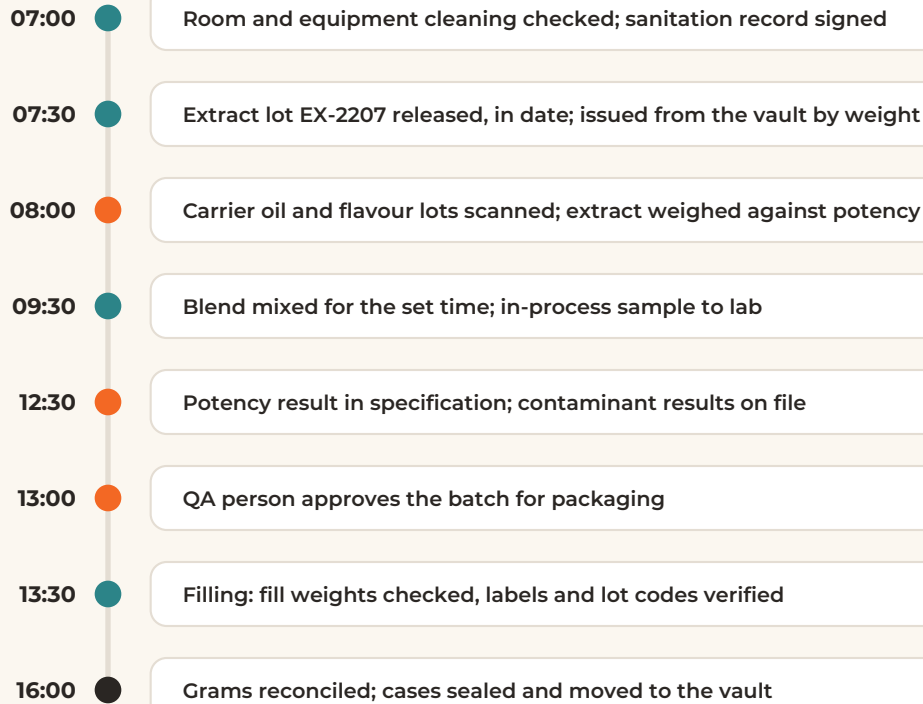
V5 can hold SOPs with QA approval before release, run sanitation checklists, keep test results per lot, record QA lot approval before stock can ship, log recall simulations with times and results, and keep adverse reaction records. Retention and reporting stay with your team.

Sources: [2] (linked on pages 35–36)

FRAME / 03

One production day.

A worked example: batch CB-0619, a hemp extract tincture in 30 mL bottles, made from a released extract lot. Times and values are an example only.



Potency drives the recipe

Extract strength varies lot to lot. The amount charged is calculated from the lot's potency.

Orange is where risk lives

Potency, testing and QA approval decide whether the label is true.

Every gram matters

Weights at each step let you reconcile and explain any difference.

WHERE V5 FITS

Batches sit on the schedule with product, room, equipment and materials. Kiosk steps capture issues from the vault, charges, readings, samples and fill counts, and the batch record grows with them.

MATERIAL / 01

Authorised suppliers, specified inputs.

Every input must come from a source permitted to supply it: a licensed producer, a licensed hemp grower or an approved ingredient supplier. Each input needs a specification and supporting test evidence.

Source

Licence or authorisation

Identity

Cultivar, part, form

Potency

Cannabinoid profile

Contaminants

Micro, metals, pesticides, solvents

Packaging

Seals, lot label, weight

Check the licence

Confirm the supplier's licence or authorisation is current before each order, and keep the evidence.

Pesticides

In Canada, cannabis must not be treated with a pest control product unless registered or authorised for use on cannabis [2]. Ask suppliers for evidence.

Hemp origin

U.S. hemp must come from producers licensed under a USDA, State or Tribal plan [5]; ask for the licence and test report.

WHERE V5 FITS

Approved supplier lists hold licence numbers, expiry dates, qualification documents and scorecards, so receiving can see which supplier is approved. Suppliers can upload licences and certificates through the supplier portal where configured; a person reviews each before it counts.

Sources: [2], [5] (linked on pages 35–36)

MATERIAL / 02

Receive by weight, check every seal.

Cannabis receipts are counted and weighed, not just booked. Seals, weights and documents must match before material enters inventory.



Match the paperwork

Shipper, licence, product, lot, containers and declared weight match the order and transfer documents.

Weigh and inspect

Weigh each container on a checked scale; record seal numbers and any damage.

Explain differences

A weight difference beyond your tolerance is investigated and recorded before acceptance.

WORKED EXAMPLE: RECEIPT

Material	Hemp extract, full spectrum, 2 sealed containers
Supplier / lot	Approved supplier S-008, lot EX-2207
Declared / weighed	4,000.0 g / 3,998.6 g, within tolerance
Seals	Both intact, numbers recorded
Status	Quarantine until QA reviews test report

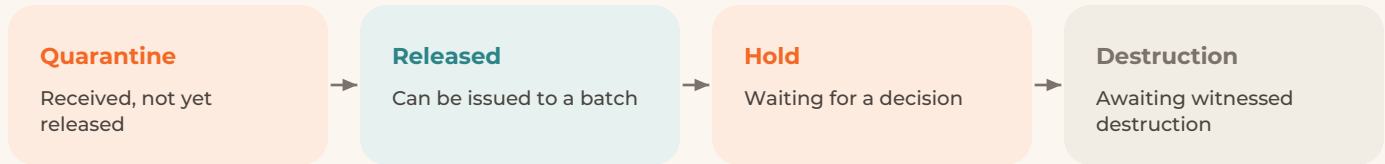
WHERE V5 FITS

Receiving records supplier, licence, lot, containers, seal numbers, declared and weighed quantities, and places material in quarantine until release. Supported connected scales send weights. Certificate values can be read from an upload for a person to confirm; AI never releases a lot.

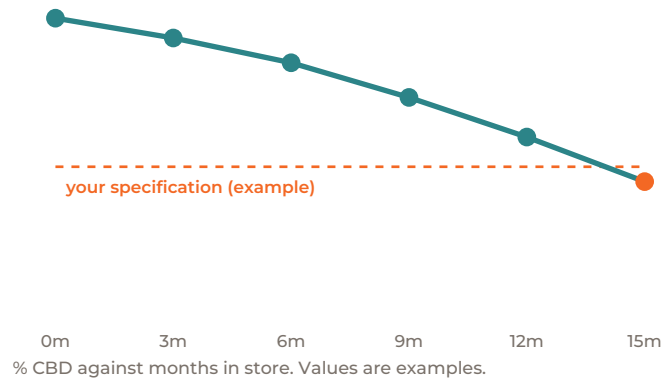
MATERIAL / 03

Secure, segregated, in date.

Cannabis must be stored securely, with access limited to authorised people. Inventory must be accurate at all times, and potency and quality change with time, so expiry or retest dates matter.



EXTRACT LOT EX-1904 • CBD AT RETEST



Access is a control

Record who entered secure areas and moved stock; your licence will set specific security requirements.

Count often

Regular counts against the system catch loss and data errors early.

Waste is inventory too

Material for destruction stays secure and counted until destroyed and recorded.

WHERE V5 FITS

Warehouse locations, lot status and expiry or retest dates support FEFO picking and holds; a lot past its date can be blocked at picking. Cycle counts, adjustments with reasons and material awaiting destruction are recorded by user and time.

MAKE / 01

Extract under approved methods.

Extraction turns plant material into concentrate. In Canada, methods and procedures must be approved by the QA person before they are used [2]. Inputs, settings, outputs and yield are all part of the record.



EXTRACTION RUN XR-0412			
STEP	RECORD	VALUE	CHECK
1	Biomass lots in	12,000 g	Weighed
2	Method and revision	SOP-EX-03 rev 5	QA approved
3	Settings	Per method	Recorded
4	Crude extract out	1,620 g	Weighed
5	Spent biomass	10,310 g	To destruction

Yield is a quality signal
1,620 g from 12,000 g is 13.5%. A sudden change points to input or process problems.

Solvents
Residual solvent testing applies where solvents are used; your limits come from the rules.

Spent material
Spent biomass still counts until it is destroyed and recorded.

WHERE V5 FITS
Extraction runs can be recorded as batch steps with input lots and weights, method revision, settings, outputs and waste, giving a yield per run. V5 does not control extraction equipment.

Sources: [2] (linked on pages 35–36)

MAKE / 02

Formulate to the label, not the guess.

A tincture labelled 1,000 mg CBD per bottle needs the right amount of extract for that lot's potency. Scanning and weighing at the charge point stops wrong lots and wrong amounts.

CHARGE CHECKS, CB-0619

Room released	Sanitation signed	OK
Extract lot	EX-2207 released	OK
Extract amount	From potency, 1,703 g	OK
Carrier oil	MCT lot scanned	OK
Flavour	Unreleased lot	Block

Worked example: 1,000 bottles x 1,000 mg CBD = 1,000 g CBD. At 58.7% CBD, $1,000 \div 0.587 = 1,703$ g extract.



Second check

A second person or scale-linked check confirms the extract charge.

Overage is a decision

Any overage for losses is set in the approved formula, not added on the floor.

Edibles add food rules

Edible products bring extra controls, such as a preventive control plan in Canada [2].

WHERE V5 FITS

Weigh and dispense steps run at the kiosk with lot scanning, target and tolerance checks, and blocks on wrong or unreleased lots. Your team sets the potency-based target in the approved formula; the kiosk checks the weighed amount against it. Supported connected scales send weights.

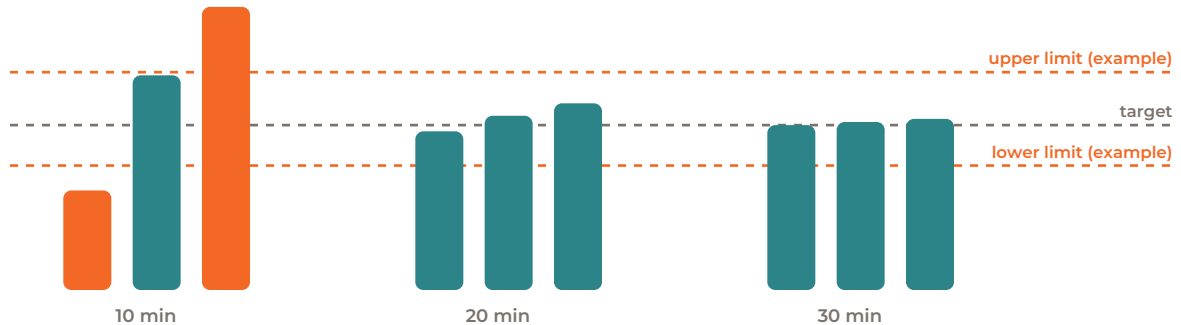
Sources: [2] (linked on pages 35–36)

MAKE / 03

Check the blend before you fill.

Mixing time, appearance and an in-process potency check catch a poorly mixed or mis-charged batch before thousands of bottles are filled.

CB-0619 · BLEND UNIFORMITY, TOP / MIDDLE / BOTTOM SAMPLES



mg CBD per mL. At 10 min the bottom is too strong; by 30 min all three agree.

Uniformity matters

Every bottle should carry what the label says. Sampling top, middle and bottom shows whether it will.

Validate mixing

Set mixing times from data like this, then record that they were followed.

In-process is not release

Final testing and QA approval still decide whether the batch can be sold.

WHERE V5 FITS

In-process checks run as kiosk steps with limits; results feed control charts in quality, and an out-of-limit result can hold the batch. Mixing times and sample IDs are recorded with the step.

MAKE / 04

Account for every gram.

Losses happen: residue in vessels, samples, spills, rejects. In cannabis they must be measured, explained and recorded, because unexplained loss is both a quality and a regulatory problem.

EXTRACT RECONCILIATION, CB-0619

ISSUED FROM VAULT

1,703.0 g extract

IN FILLED BOTTLES

1,681.8 g (by potency)

LAB AND RETAINED SAMPLES

8.5 g

VESSEL AND LINE RESIDUE

11.9 g, to destruction

UNEXPLAINED

0.8 g, within tolerance

REVIEWED BY

QA person

Weigh at every hand-off

Vault to room, room to filler, filler to packaging, packaging to vault.

Set a tolerance

Decide what unexplained difference triggers an investigation.

Destruction is recorded

Waste is weighed, stored securely and destroyed with the record your rules require.

Reports draw on it

Inventory and destruction records feed regulatory reporting where required.

Trend losses

Rising residue or unexplained loss points to equipment, method or security issues.

Yield by product

Track output against input to spot drift early.

Investigate first

A difference outside tolerance is investigated before the batch is approved.

WHERE V5 FITS

Batch close calculates material balance from issues, outputs, samples and waste, and a difference outside your tolerance can hold the batch. Destruction can be recorded with weights, witnesses and dates. Regulatory reports themselves stay with your team.

MAKE / 05

Test, then the QA person approves.

In Canada every lot or batch is tested for cannabinoids and for microbial and chemical contaminants, and approved by the QA person before it is made available for sale [2]. Many other markets require similar testing by an accredited lab.



QA APPROVAL REVIEW, CB-0619

Inputs	Released, in date
Cannabinoids	CBD in spec; THC per rules
Microbial	Within limits
Chemical	Metals, solvents in limits
Reconciliation	Within tolerance
Decision	Approved by QA person

Limits and methods come from your market's rules.

Accredited labs

Many markets require testing by labs accredited to ISO/IEC 17025 or licensed for cannabis testing [12].

Certificates of analysis

Link the lab's certificate to the lot it covers, and check it matches.

Out of specification

Investigate a failing result under the QA person's responsibility before any retest [2].

WHERE V5 FITS

Lab & QC holds methods, specifications and results, including uploaded external certificates; the QA approval is recorded by the named QA person before stock can ship. V5 does not approve results or lots.

Sources: [2], [12] (linked on pages 35–36)

MAKE / 06

A hold that actually holds.

A failed test, an unexplained loss or a label mix-up means product must stop.
A hold that only lives in an email does not stop a shipment.

A WORKED HOLD

The lab reports a microbial result above the limit for gummies batch CB-0602. The batch and its **4,800 packs** are held, along with the gelatin lot used. Investigation under the QA person finds a cooling step ran long after a chiller fault. The batch is rejected and sent for witnessed destruction; CAPA opens.

HOLD SCOPE, CB-0602

Packs in vault	4,800 held
Packs shipped	0
Gelatin lot	GL-3310, held pending review
Disposition	Destruction, witnessed and recorded
Decision by	QA person

Hold by scope

Hold the batch, its stock and anything made with the same suspect input or equipment.

One named decision

Only the roles you authorise can release, rework or destroy, with a reason kept.

Destruction is a record

Weights, method, witnesses and date belong with the batch.

WHERE V5 FITS

Lots and batches carry status; a held lot is blocked at picking and at the dispatch scan according to your rules. Holds link to the nonconformance that caused them, and release or destruction is recorded by an authorised person.

MAKE / 07

Fill and count every unit.

Filling turns approved bulk into units. Fill weights prove each bottle holds what its label says, and counts prove no unit or label went missing.



UNIT RECONCILIATION, CB-0619

Theoretical units	1,000 x 30 mL
Units filled	992
Rejected at check weigh	6, to destruction
Samples	10 (lab and retained)
Labels issued / used / spoiled / returned	1,050 / 992 / 9 / 49
Unexplained	0 labels

Fill weight

Check weights at a set frequency and record each result.

Labels must balance

Issued equals used plus spoiled plus returned. A gap is a possible mislabelled unit.

Rejects count

Rejected units are weighed, stored securely and destroyed with a record.

WHERE V5 FITS

Filling runs as kiosk steps with fill weights and label verification; supported connected scales send weights. Unit and label reconciliation is calculated at batch close, and a gap holds the batch until explained.

MAKE / 08

Labels and packs set by each market.

Cannabis packaging and labelling rules are among the most detailed anywhere: plain packaging, child resistance, warnings, THC and CBD amounts, symbols and lot numbers. They differ by market.



WHAT TO CONTROL ON EVERY PACK

- Approved label version for this market
- Cannabinoid amounts from the approved batch
- Lot or batch number linking to the record
- Required warnings and symbols
- Packaging type, e.g. child-resistant, where required
- Packaging date or expiry where required
- Supplier or licence holder details

Canada

Packaging and labelling requirements are set out in the Cannabis Regulations [2]; Health Canada publishes guidance [4].

U.S. hemp products

FDA rules for foods, supplements and cosmetics apply to labelling claims [7]; states add their own.

Claims are regulated

Health claims are tightly limited in most markets. Your regulatory team approves claims.

WHERE V5 FITS

Label templates are controlled per market with revisions and approval; printing pulls lot numbers and approved cannabinoid results from the batch, and the kiosk verifies the label version at the line. V5 does not write label claims or decide which elements a market requires.

Sources: [2], [4], [7] (linked on pages 35–36)

CONTROL / 01

Investigate, correct, prevent.

In Canada, investigations of complaints and of matters that could affect quality are conducted under the QA person's responsibility, who causes risks to be mitigated [2]. The same discipline helps in any market.

CORRECTION

Act on the spot: fetch the right lot, re-weigh, hold the batch. Record what happened, what was done and by whom.

CORRECTIVE ACTION

When it repeats, reaches a customer or shows a weak process: find the root cause, fix it, check the fix worked, and update the SOP, specification or training.

WORKED EXAMPLE: ESCALATION

Month 1	Three batches with unexplained loss near tolerance	Corrections
Review	Trend reviewed; investigation opened	NC-071
Cause	Scale at filler not checked daily	Found
Action	Daily check weight added; scale blocked if missed	Done
Verify	Losses centred over the next 12 batches	Closed

WHERE V5 FITS

Nonconformances link to batches, lots, equipment and people, and can be escalated to CAPA with root cause, owners, due dates and effectiveness checks, with the QA person as owner where required. AI can suggest a classification or draft a summary for a person to edit.

CONTROL / 02

Complaints and adverse reactions.

A complaint about taste or a leaking dropper is a quality matter. A report that someone was hospitalised may be a serious adverse reaction with a reporting clock. Your team needs to tell them apart quickly.

```
graph TD; Receive[Receive] --- Triage((Triage)); Triage --- Assess[Assess]; Assess --- Act[Act]; Act --- Report[Report]; Report --- Receive;
```

Start from the lot number
It gives the batch record, inputs, tests, approval and retained sample.

Assess seriousness at once
In Canada, serious adverse reactions are reported to the Minister within 15 days of becoming aware [2].

Keep the evidence
Canadian adverse reaction reports are kept for at least 25 years [2].

WORKED EXAMPLE: COMPLAINT RECORD

Received	Retailer reports droppers leaking on lot CB-0588
Seriousness	No adverse reaction reported; quality complaint
Linked lots	Dropper lot DR-7720
Cause found	Dropper thread out of specification from supplier
Action	Supplier CAPA; incoming torque check added
Status	Closed after effectiveness review

WHERE V5 FITS

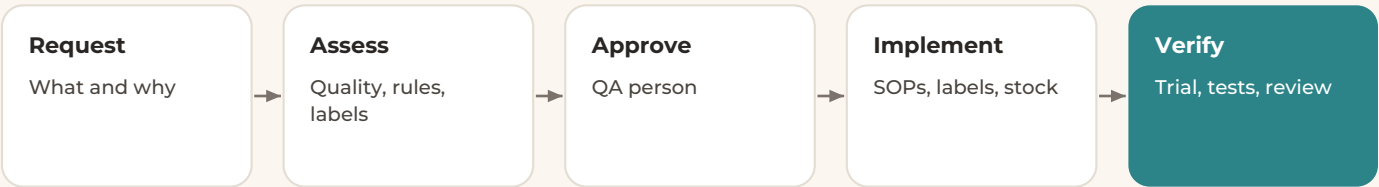
Complaints and adverse reaction records link to lots and retained samples, with a seriousness field and due dates your team sets. CAPA links to its sources. V5 does not decide whether a reaction is serious or submit reports.

Sources: [2] (linked on pages 35–36)

CONTROL / 03

Change on purpose.

A new extract supplier, a different carrier oil, a new extraction method or a revised label can change the product, its test profile or its legal status. Changes need assessment before they reach production.



IMPACT QUESTIONS FOR CHANGE CC-024: NEW EXTRACTION METHOD

Approval	Has the QA person approved the method before use?	OPEN
Testing	Does it change solvent or contaminant testing?	Yes
Licence	Does the change need notice to the regulator?	Check
Labels	Does the cannabinoid profile change?	Trial
Effective	From which run?	XR-0450

Licence changes

Some changes to premises, equipment or activities need regulator notice or approval; check your licence.

Labels follow change

A changed profile needs updated labels and withdrawal of old stock on a set date.

Train before you run

Changed SOPs are read and understood before the first changed batch.

WHERE V5 FITS

Change control links requests to SOPs, specifications, labels and suppliers with impact assessment, approvals and effectivity; approved changes release new revisions and can assign read-and-understood training.

CONTROL / 04

Qualified, trained and permitted.

The QA person, operators, lab staff and shippers each change the outcome. Who may enter secure areas, approve a lot or ship product must be clear and enforced.

The QA person

Processing licence holders retain a QA person with the training, experience and technical knowledge the rules require [2].

Hygiene

The sanitation program covers personnel health and hygienic behaviour [2].

Training to the task

Train on each SOP and instrument, with records of who was trained on which revision.

WORKED EXAMPLE: COMPETENCE AND PERMISSION MATRIX

	Charge materials	Enter results	Approve lot	Ship orders
Operator	Trained	Not permitted	Not permitted	Not permitted
Lab analyst	Not permitted	Trained	Not permitted	Not permitted
QA person	Not permitted	Not permitted	Trained	Not permitted
Shipper	Not permitted	Not permitted	Not permitted	Trained

Security clearance. Many jurisdictions require background checks or security clearances for some roles. Record status and expiry with the person, not in a separate spreadsheet.

WHERE V5 FITS

Document control keeps SOPs under revision with read-and-understood training. The skills matrix can block untrained people at the kiosk where configured, and role permissions decide who can record, approve or ship. Clearance dates can be tracked as qualifications.

SUSTAIN / 01

Look after extractors and fillers.

Extraction vessels, seals, pumps, evaporators and fillers wear and drift. Planned maintenance, cleaning and a record of what ran in each item protect product and people.



EQUIPMENT RECORD, EXTRACTOR EX-1

Last run	XR-0412, cleaned and released	OK
PM due	Vessel seals and pressure relief check	6 days
Last repair	Pump seal replaced	Done
Inspection	Pressure vessel inspection per your jurisdiction	Due
Next action	Seal wear noted at last clean	OPEN

Pressure and solvents

Extraction equipment may be subject to pressure, fire and solvent rules where you operate.

Clean between products

Clean and record between batches and products as the sanitation program sets [2].

Spare parts

Seals and gaskets must suit the solvent. Record what was fitted.

WHERE V5 FITS

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

SUSTAIN / 02

Trust the scales.

In a product counted in grams and milligrams, every scale and instrument matters. Receiving scales, formulation balances, check weighers and lab instruments need checks you can show.

DAILY AND PERIODIC CHECKS

Receiving scale RS-1 (check weight)	Within your tolerance	OK
Formulation balance FB-2	Calibration certificate current	OK
Check weigher CW-1	Daily check missed	HOLD
Vault scale VS-1	Within your tolerance	OK
HPLC-1	System suitability passed today	OK

WHEN A SCALE IS IN DOUBT

Check weigher CW-1 missed its daily check and is found reading low. Which batches did it check since its last good check? Fill weights are reviewed, retained units re-weighed on a good scale, and reconciliations for those batches rechecked. CW-1 is blocked until repaired and checked.

Identify every scale

A unique ID on each, recorded with each weight, makes the look-back possible.

Right scale for the job

Use a balance with the resolution the weight needs.

Lab instruments too

Chromatographs and balances in the lab need calibration and system checks.

WHERE V5 FITS

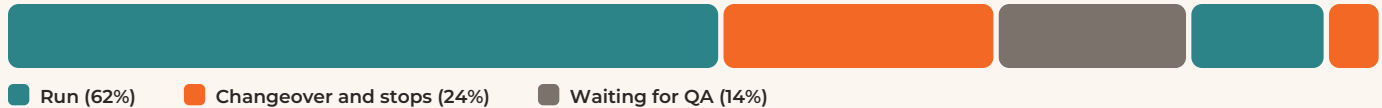
Each scale and instrument can have an equipment record with calibration schedule, results, certificates and use history. Out-of-calibration equipment can be blocked at the kiosk, and checks link to the weights they produced.

SUSTAIN / 03

Yield, losses and where the day goes.

Extraction yield, formulation losses and line time tell you where cannabinoids and hours go. A worked example shows the arithmetic.

FILL LINE 1 • ONE 8-HOUR SHIFT



WORKED OEE ARITHMETIC (WORKED EXAMPLE)

Availability

62%

4.96 h run of 8 h planned

Performance

90%

units ÷ rated speed

Quality

99.4%

good units of units filled

OEE

55.5% $0.62 \times 0.90 \times 0.994$

WORKED CANNABINOID BALANCE, BIOMASS TO BOTTLE (EXAMPLE)

12,000 g biomass at 8.0% CBD = 960 g CBD in. Crude extract 1,620 g at 52% = 842 g CBD. Extraction recovery = $842 \div 960 = 87.7\%$. Tracking recovery per run shows which inputs and settings lose the most.

Waiting for QA

Time waiting for test results and approval is a planning problem worth measuring.

Changeovers

Cleaning between products is necessary; sequencing products well reduces how often.

Recovery by run

A drop in recovery is worth investigating before it becomes normal.

WHERE V5 FITS

Downtime reasons, step times, yields and OEE come from events your team and supported connected equipment record, with reports and dashboards where your plan includes them. AI demand and yield forecasting and process anomaly detection are coming soon, not available today.

SUSTAIN / 04

Distribute securely, trace both ways.

A supplier warns that extract lot EX-2207 may contain a pesticide residue above the limit. Which batches, which retailers, and what is still in your vault?



Safekeeping in transit

In Canada, licence holders take the steps needed to keep cannabis safe during distribution [2].

Government tracking

Many markets require reporting to a government tracking system. That is separate from your own trace.

Recall decisions

Your QA person and regulatory team decide on recall and notifications.

WHERE V5 FITS

Genealogy links biomass, extract and ingredient lots to batches, cases and shipments, so a trace runs forward from an input lot or back from a lot number, with customers and quantities listed and exportable. V5 does not report to government tracking systems.

Sources: [2] (linked on pages 35–36)

SUSTAIN / 05

Run the yearly recall simulation.

Canadian licence holders must run a recall simulation at least every 12 months and document how it was done and the results [2]. It is good practice everywhere.

- 0:00 ● Start: extract lot EX-2207 named; QA person opens the trace
- 0:03 ● Batches found: CB-0619 and CB-0624
- 0:08 ● Cases, customers and shipped units listed
- 0:12 ● Remaining extract and finished units in the vault held
- 0:20 ● Customer contacts confirmed
- 0:30 ● Balance: received vs issued vs in product vs stock

BALANCE FOR EXTRACT LOT EX-2207

Received (weighed)	3,998.6 g
Issued to CB-0619	1,703.0 g
Issued to CB-0624	1,520.0 g
Still in vault	772.4 g, held
Retained sample	3.2 g
Unaccounted	0 g

Times are an example of what to measure, not a benchmark. Keep the simulation record with its findings for at least two years in Canada [2], and feed what you learn into CAPA.

WHERE V5 FITS

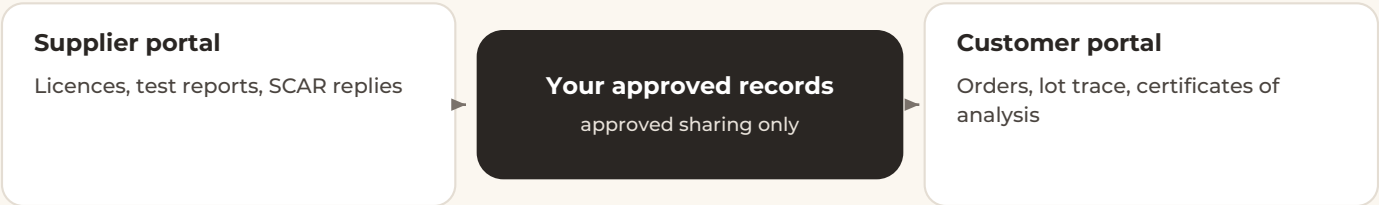
Trace reports list batches, cases, customers and quantities from an input lot or a lot number, and stock can be held from the trace. Recall simulations can be logged as exercises with times, results and findings that feed CAPA.

Sources: [2] (linked on pages 35–36)

SUSTAIN / 06

Suppliers, customers, shared well.

Retailers and distributors ask for certificates of analysis and lot data; brand owners want batch records from contract processors; suppliers send licences and test reports. Each sees only what you approve.



Contract processing

When you process for a brand owner, agree who holds which records and who approves lots.

Certificates per lot

Send certificates with each delivery from the approved results.

Review before it counts

A supplier upload is a claim until a person reviews it.

A SHARING POLICY TO AGREE BEFORE ANYONE LOGS IN

Certificates of analysis	With each delivery	Customer QA
Lot trace for their orders	Agreed scope	Customer QA
Batch records (contract)	Agreed scope only	Brand owner
Other customers' data	Never	—
Supplier licences and SCARs	Reviewed before they count	Your QA

WHERE V5 FITS

Customer and supplier portals give branded access to what you approve. EDI and ASN exchange (X12 850, 855, 856, 810) with GS1-128 SSCC labels is available where your plan includes it. Portal scope depends on configuration; check the current plan comparison.

SUSTAIN / 07

Trustworthy records. Honest AI.

Electronic records help only if they are made at the time, by a known person, with actual values, and if AI stays a helper under human control.

What a record holds

Who, what, which lot, the weight or result and limit, the instrument, and when. Corrections keep the original visible.

Long retention

Some records must be kept for years; Canadian adverse reaction reports for 25 [2]. Plan storage accordingly.

Make them findable

A batch record, a certificate or a trace is only useful if it can be produced quickly.

AI CAN HELP

- Read certificate values for a person to confirm
- Draft an SOP or instruction for QA approval
- Suggest a nonconformance classification or draft a summary
- Explain a lot's history in plain language
- Find records and screens faster

AI NEVER

- Approves a lot or replaces the QA person
- Decides seriousness or reporting duties
- Writes label or health claims
- Releases product or decides a recall
- Predicts defects or yield today (forecasting is coming soon)

WHERE V5 FITS

Every record keeps who, what and when in an audit trail every plan can view; tamper-evident trails, electronic signatures and a validation pack are available where your plan includes them. AI features need configured provider access and human review.

Sources: [2] (linked on pages 35–36)

APPLY / 01

Evidence map.

One page to check that every theme an inspector, customer or auditor may ask about has an owner and a record. Map it to the rules that apply to you [2][3][5][8][9].

THEME	TYPICAL EVIDENCE	WHERE IT LIVES IN V5	OWNER
SOPs	QA-approved before use	Document control	QA person
Suppliers	Licences, test reports	Suppliers, portal	Purchasing
Receipts	Weights, seals, documents	Receiving	Vault lead
Storage	Status, counts, access	Warehouse	Vault lead
Extraction	Inputs, method, yield	Batch steps	Production
Formulation	Potency-based charges	Weigh & dispense	Production
Sanitation	Cleaning, hygiene	Kiosk checklists	QA
Testing	Cannabinoids, contaminants	Lab & QC	QA
Lot approval	QA person sign-off	Release review	QA person
Reconciliation	Grams, units, labels	Batch close	QA
Destruction	Weights, witnesses	Inventory records	Vault lead
Recall simulation	Yearly record	Trace, exercises	QA person
Adverse reactions	Reports, summaries	Complaints	Regulatory
Training	SOPs, clearances	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 lot?

Pick one lot shipped last month. Find each record and time it. Mark Yes, Partly or No, then note the gap and its owner.

	YES	PARTLY	NO
Inputs Every input from an authorised supplier, with evidence.	☐	☐	☐
SOPs Methods used were approved before use.	☐	☐	☐
Charges Lots and actual weights, calculated from potency.	☐	☐	☐
Sanitation Room and equipment cleaning recorded.	☐	☐	☐
Tests Cannabinoid and contaminant results for this lot.	☐	☐	☐
QA approval Named QA approval before it was available for sale.	☐	☐	☐
Reconciliation Grams, units and labels balance, gaps explained.	☐	☐	☐
Label Label version and values matched the approved results.	☐	☐	☐
Shipments Customers, dates and quantities for every unit.	☐	☐	☐
Destruction Waste from this lot recorded and destroyed.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Ready for a serious report?

Walk through a real or invented case: a customer reports that someone was hospitalised after using your product. Mark Yes, Partly or No.

	YES	PARTLY	NO
Intake Staff know where to send the report at once.	☐	☐	☐
Details The information to collect is listed and recorded.	☐	☐	☐
Seriousness A named person assesses seriousness against the definition.	☐	☐	☐
Clock The reporting deadline for each market is known and tracked.	☐	☐	☐
Lot The lot can be identified and its records pulled.	☐	☐	☐
Retained sample A retained sample exists and can be tested.	☐	☐	☐
Hold Remaining stock can be held while you assess.	☐	☐	☐
Report The report is prepared, approved and submitted on time.	☐	☐	☐
Summary The case feeds the annual summary where required.	☐	☐	☐
Retention Records are kept for the required period.	☐	☐	☐

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 and rooms, not a slide.

	SHOWN	PARTLY	NOT SHOWN
Supplier licence Let a supplier licence expire; try to receive from them.	☐	☐	☐
Weight difference Receive with a weight difference; show the investigation.	☐	☐	☐
Potency charge Show an extract charge calculated from potency.	☐	☐	☐
Unreleased lot Scan an unreleased lot at the charge; show the block.	☐	☐	☐
QA approval Try to ship a lot before QA approval.	☐	☐	☐
Reconciliation Close a batch with an unexplained loss; show the result.	☐	☐	☐
Destruction Record destruction with weights and witnesses.	☐	☐	☐
Recall simulation Run a timed trace from an input lot with an export.	☐	☐	☐
Adverse reaction Log a report with seriousness and a due date.	☐	☐	☐
Audit trail Show who changed a recorded weight, when and why.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

Roll out in phases.

Start where value is visible and risk is contained, often receiving, vault and reconciliation for one product line. Run old and new side by side until each phase is verified.

PHASE 1
Foundations

Licences, scope, roles, SOPs with QA approval, training and clearance records, equipment register for extractors, scales and instruments.

PHASE 2
Material

Authorised suppliers, receipts with weights and seals, quarantine and release, vault locations, counts and destruction records.

PHASE 3
Make

Extraction and formulation records with potency-based charges, in-process checks, lab results and QA approval; paper kept in parallel.

PHASE 4
Pack and control

Filling and reconciliation, label control per market, holds, investigations and CAPA, complaints and adverse reactions, change control.

PHASE 5
Connect

Shipments, trace export, yearly recall simulation, customer and supplier portals, EDI and ASNs, yield and OEE review.

Keep government reporting separate. Where your market requires a government tracking system, keep using it as required; plan how data moves between it and your own records before go-live.

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 consumers or your licence.

	E	P	G
Supplier evidence Licences and test reports current	☐	☐	☐
Receipts Weights, seals, differences explained	☐	☐	☐
Vault Status, counts, access records	☐	☐	☐
SOP approval QA-approved before use	☐	☐	☐
Extraction Inputs, method, yield recorded	☐	☐	☐
Formulation Potency-based, scanned, weighed	☐	☐	☐
Testing Every lot, results linked	☐	☐	☐
QA approval Named, before sale	☐	☐	☐
Reconciliation Grams, units, labels	☐	☐	☐
Labels Per market, verified at line	☐	☐	☐
Recall simulation Yearly, documented	☐	☐	☐
Adverse reactions Triage, clocks, records	☐	☐	☐

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 live records.

WEEK 1

Agree the product, rooms, equipment and the five questions that matter most. Load suppliers, inputs, SOPs and specifications.

WEEK 2

Run a batch end to end with test data: receipt, vault, extraction or formulation, testing, QA approval, filling, shipping.

WEEK 3

Break it on purpose: expired supplier licence, weight difference, unreleased lot, unexplained loss, label gap.

WEEK 4

Run a timed recall simulation from an input lot with an export, and a mock serious report. Review with every team.

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

ASK V5

“We [extract / formulate / package] [oils / edibles / topicals / vapes] as a [licensed processor / hemp manufacturer] in [market]. Our hardest moment is [e.g. reconciling every gram]. 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 legal or regulatory 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]

Canada, Cannabis Act (S.C. 2018, c. 16)

BINDING CANADIAN LAW

<https://laws-lois.justice.gc.ca/eng/acts/C-24.5/>

[2]

Canada, Cannabis Regulations (SOR/2018-144)

BINDING CANADIAN LAW

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2018-144/>

[3]

Health Canada, Good production practices guide for cannabis

HEALTH CANADA GUIDANCE

<https://www.canada.ca/en/health-canada/services/cannabis-regulations-licensed-p...>

[4]

Health Canada, Cannabis laws and regulations

HEALTH CANADA GUIDANCE

<https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-...>

[5]

U.S. eCFR, 7 CFR Part 990: Domestic hemp production program

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-7/subtitle-B/chapter-IX/part-990>

[6]

USDA AMS, Hemp

USDA GUIDANCE

<https://www.ams.usda.gov/rules-regulations/hemp>

[7]

FDA, Regulation of cannabis and cannabis-derived products

FDA GUIDANCE

<https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and...>

[8]

European Commission, EudraLex Volume 4: EU GMP

EU GMP (BINDING FOR MEDICINES)

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

SOURCES

Sources, continued.

- | | | |
|------|---|-------------------------------|
| [9] | <u>EMA, Good agricultural and collection practice (GACP)</u> | EMA GUIDELINE |
| | https://www.ema.europa.eu/en/good-agricultural-collection-practice-starting-mat... | |
| [10] | <u>WHO, Guidelines on GACP for medicinal plants</u> | WHO GUIDELINE |
| | https://www.who.int/publications/i/item/9241546271 | |
| [11] | <u>INCB, Single Convention on Narcotic Drugs, 1961</u> | INTERNATIONAL TREATY |
| | https://www.incb.org/incb/en/narcotic-drugs/1961_Convention.html | |
| [12] | <u>ISO/IEC 17025:2017 Testing and calibration laboratories</u> | VOLUNTARY INTERNATIONAL |
| | https://www.iso.org/standard/66912.html | |
| [13] | <u>ISO 9001:2015 Quality management systems: requirements</u> | VOLUNTARY INTERNATIONAL |
| | https://www.iso.org/standard/62085.html | |
| [14] | <u>Australia ODC, Grow, produce or manufacture cannabis</u> | AUSTRALIAN REGULATOR GUIDANCE |
| | https://www.odc.gov.au/medicinal-cannabis/grow-produce-or-manufacture-cannabis-... | |
| [15] | <u>Australia TGA, Medicinal cannabis manufacturing</u> | AUSTRALIAN REGULATOR GUIDANCE |
| | https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis... | |
| [16] | <u>UK Home Office, Controlled drugs: domestic licences</u> | UK HOME OFFICE GUIDANCE |
| | https://www.gov.uk/guidance/controlled-drugs-domestic-licences | |

How to read the status labels. Acts and regulations are law in their jurisdiction. Regulator pages and guidelines explain and apply them and may change. EU GMP is binding for medicinal products. ISO standards are voluntary unless a rule or customer requires them.

SCOPE AND LIMITS

Practical orientation for evaluating cannabis and hemp manufacturing and software; not legal or regulatory advice, and not a list of every requirement. Legal status and rules depend on country, state, licence, product class and use. THC limits, testing limits and methods, packaging and labelling details, security requirements, tracking system obligations and U.S. federal scheduling status are deliberately not given; take them from current rules and your regulatory team. 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 integrate with government track-and-trace systems, approve lots, write label claims, file reports or decide recalls, and does not by itself make you compliant.



Authorised inputs. Tested batches. Packs that meet your market's rules.

See cannabis and hemp workflows at v5ultimate.com · Global edition · October 2026