



THE DIETARY SUPPLEMENT OPERATIONS GUIDE

What the label says. What the batch proves.

From specification and supplier to labelled, traceable lot

A capability and evaluation guide for supplement manufacturers, contract manufacturers, packagers and brand owners who want every ingredient, step, test and decision to reach quality control as one connected record.



CGMP

IDENTITY

LABEL TO LOT

INSIDE THE GUIDE

Capsule by capsule, claim by claim.

A supplement batch passes through purchasing, goods-in, the laboratory, the warehouse, dispensing, blending, encapsulation or tableting, packaging and quality control. This guide follows it, and shows what each handover must leave behind.

01 / FRAME

pp. 03–05

The rules and who decides

U.S. Part 111, EU, UK, Canada, Australia, Codex; quality control personnel; a batch week.

02 / FLOW

pp. 06–13

Specification to finished batch

Specifications, suppliers and certificates, goods-in, identity testing, status, the master record, dispensing, blending.

03 / DECIDE

pp. 14–18

Test, review, investigate

Finished batch testing, QC review and disposition, material review, complaints and adverse events, people.

04 / SUSTAIN

pp. 19–25

Equipment, labels, lots

Calibration, yield and overage, label reconciliation, reserve samples, trace and recall, portals, data integrity.

05 / APPLY

pp. 26–32

Evidence map and working tools

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

06 / SOURCES

pp. 33–35

What this guide rests on

Twenty-one linked primary sources with status and scope, plus the limits of this guide.

Who it is for. Quality control and QA leads, production and warehouse managers, laboratory leads, regulatory and label teams, brand owners who use contract manufacturers, and anyone choosing a production and quality system for vitamins, minerals, botanicals, probiotics, proteins or other supplements.

How to read it. Every operational page ends with a teal Where V5 fits panel. Everything above it is practice and regulation, useful whether or not you ever use V5. Regulatory statements cite numbered sources. Check the current text for your products and markets.

WHERE V5 FITS

V5 records the production, laboratory and quality work your procedures define. It does not write specifications, substantiate label claims, decide new dietary ingredient status, decide which adverse events are reportable, or approve batches. Those stay with your people and your regulatory process.

FRAME / 01

Start with where you sell.

The same capsule can be a food in one market and a health product or medicine in another, each with its own manufacturing, labelling and notification rules. Start by classifying it in every market you sell.



Part 111, not Part 117

In the U.S., the preventive controls subparts of Part 117 do not apply to supplement manufacturing that complies with Part 111 and sec. 761 [6]. Other parts of 117 and other rules can still apply.

Food, not medicine (U.S., EU, UK)

There, supplements are not approved before sale like medicines. That puts more weight on your own specifications, testing and records to show the product is what the label says.

Write it down once

Record which markets, regimes and product categories apply, and why, in a controlled document quality owns. Revisit it when products, sites or markets change.

WHERE V5 FITS

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

Sources: [1], [2], [4], [5], [6], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21] (linked on pages 33–35)

FRAME / 02

Quality control decides.

Part 111 gives named, qualified quality control personnel the job of approving records, reviewing monitoring and making disposition decisions. Systems should make that responsibility visible.

WHO	WHAT THE TEXT SAYS	PRACTICAL NOTE
QC personnel	111.12(b) requires you to identify who is responsible for quality control operations; each must be qualified and have distinct, separate QC responsibilities [1].	Configure roles so production cannot approve its own batch.
Records approval	111.123 has QC review and approve master manufacturing records and their changes, all batch production-related records, and required monitoring [1].	Approval is a signature with meaning, time and identity.
Material review	111.113 requires a material review and disposition decision when a specification is not met, a batch deviates from the master record, or an unanticipated occurrence may lead to adulteration [1].	Record the reasoning, not only the outcome.
Responsible person	For serious adverse events, sec. 761 places reporting duties on the manufacturer, packer or distributor named on the label [4].	Brand owners and contract makers must agree who holds which records.

Contract manufacturing. When a brand owner sells a product another company makes, both have work to do. Agree in writing who sets specifications, who tests, who approves release, who holds which records and who handles complaints, and check it against the rules in each market.

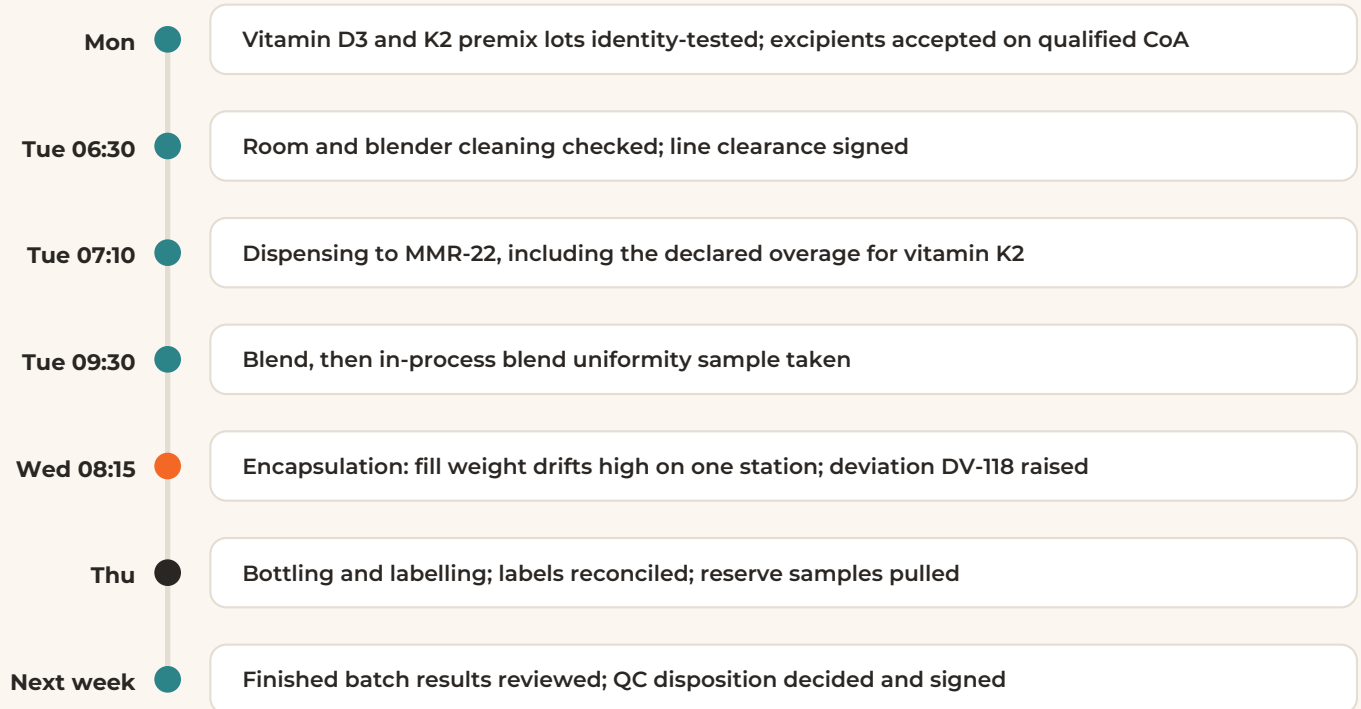
WHERE V5 FITS

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

FRAME / 03

One batch, start to release.

A worked example: vitamin D3 and K2 capsules, batch DK-0418, made to master record MMR-22 rev 4. Follow one batch through every handover.



One record grows

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

Deviations stay attached

DV-118 is not a footnote. The material review, the disposition of affected capsules and any CAPA link to the record.

The label is part of the batch

Labels issued, used and returned, and the lot number printed, belong to the same record as the blend.

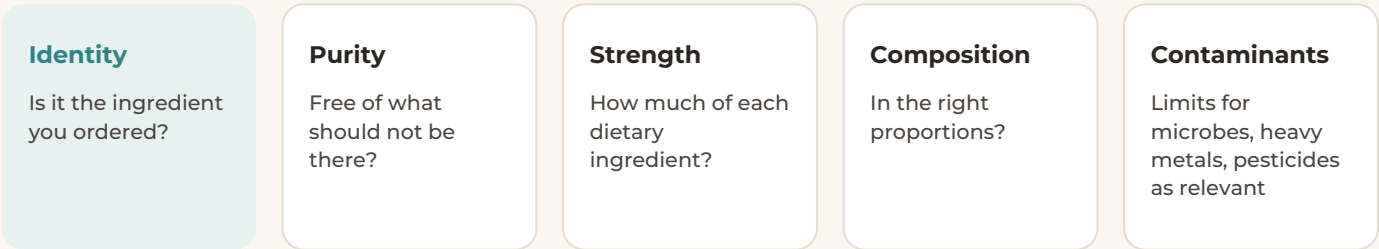
WHERE V5 FITS

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

Sources: [1] (linked on pages 33–35)

Specifications come first.

Part 111 starts from specifications. Without them, there is nothing to test against, nothing to review against and no way to show the label is true.



WHERE PART 111 ASKS FOR SPECIFICATIONS [1]

Any control point	111.70(a): a specification at each point, step or stage where control is necessary to ensure quality.
Each component	111.70(b): an identity specification, plus specifications for purity, strength, composition and contaminant limits as needed.
In-process	Specifications for in-process points where control is needed, monitored under 111.75(b).
Finished batch	Specifications for the finished supplement's identity, purity, strength, composition and contaminant limits.
Packaging and label	Specifications so packaging protects the product and the label matches the master record.

Botanicals and probiotics need thought. Plant part, species, extract ratio, marker compounds, strain identity and viable count all shape what an appropriate specification and test look like. Write the reasoning down with the specification.

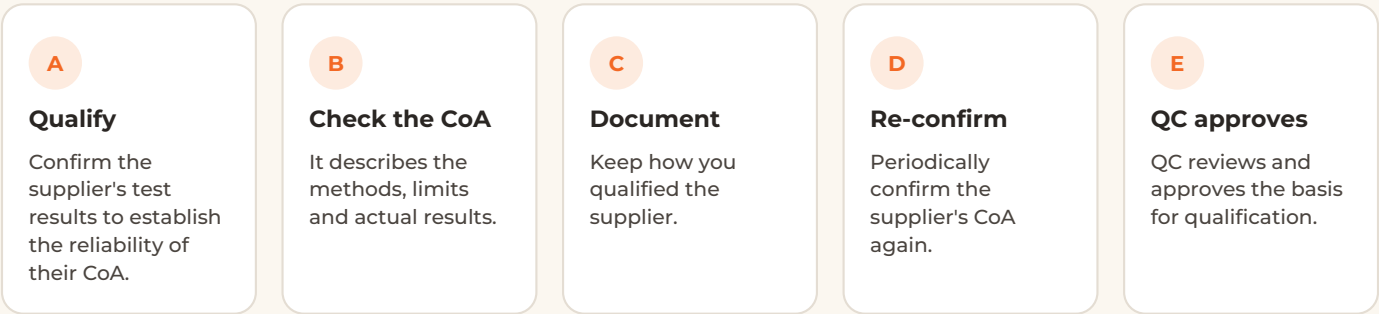
WHERE V5 FITS

Specifications sit with each material, intermediate and finished product with revisions and approval. Lab & QC test plans and results are compared against them, so an out-of-limit value is shown at once. V5 does not choose your limits or test methods.

Sources: [1] (linked on pages 33–35)

A certificate is only as good as its supplier.

For components other than dietary ingredients, Part 111 lets you rely on a supplier's certificate of analysis, but only once you have earned that reliance and keep checking it.



111.75(a)(2)(ii)(A)–(E) [1]

Dietary ingredients differ

For a component that is a dietary ingredient, you must conduct at least one appropriate identity test or examination yourself, unless FDA grants a petition for an exemption [1]. A certificate does not replace it.

Other components

For other components you either test, or rely on a qualified supplier's CoA under the five conditions above [1]. Decide which, per material, and record why.

New ingredients

A dietary ingredient not marketed in the U.S. before 15 Oct 1994 may need a new dietary ingredient notification before use [5]. Regulatory status is part of supplier approval.

WHERE V5 FITS

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

FLOW / 03

Quarantine first. Look properly.

Goods-in turns a supplier's drum into your lot. What is checked and recorded here makes every later test, trace and decision possible.



Examine each container

111.155(a): visually examine containers for the right content label, damage or broken seals that could mean contamination or deterioration [1].

Check the paperwork

111.155(b): examine the supplier's invoice, guarantee or certification to confirm it matches your purchase order [1].

Quarantine before use

111.155(c): quarantine components before use until they are released [1].

Your lot number

Give each receipt a unique identifier that links supplier, supplier lot, quantity and date, so later records can point to it.

Containers, not just lots

A lot can arrive in many drums or bags. Know which were sampled and keep each container's status visible.

Reject cleanly

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

WHERE V5 FITS

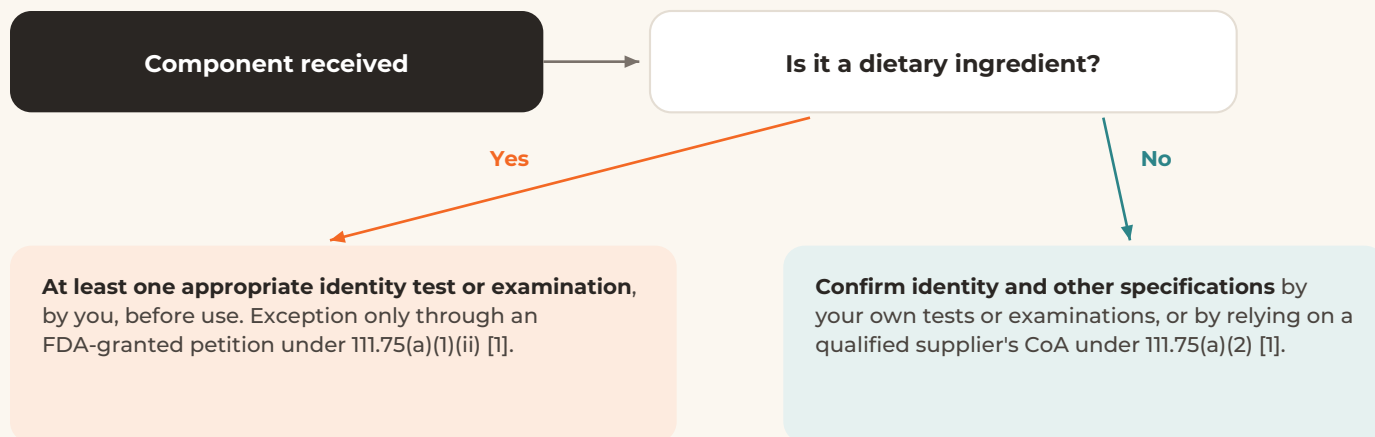
Receiving records lot, expiry and status against the purchase order, and lots start in quarantine where configured. Lab & QC creates sampling and test requests. Certificate values can be read from a PDF or photo and shown for a person to confirm; AI extraction never releases a lot.

Sources: [1] (linked on pages 33–35)

FLOW / 04

Prove identity before you use it.

Mislabelled or substituted botanicals and adulterated ingredients are long-standing sector risks. Part 111 answers with a firm rule for dietary ingredients.



At least one appropriate identity test or examination, by you, before use. Exception only through an FDA-granted petition under 111.75(a)(1)(ii) [1].

Confirm identity and other specifications by your own tests or examinations, or by relying on a qualified supplier's CoA under 111.75(a)(2) [1].

Appropriate means fit

The test has to be capable of telling your ingredient from a likely substitute or adulterant. For a botanical extract that can mean more than one technique.

Per lot, not per supplier

Identity is checked before each lot is used. A long relationship with a supplier is not a test.

Keep the evidence

Method, sample, result, analyst and reviewer belong on the record, tied to the lot that was used in each batch.

WHERE V5 FITS

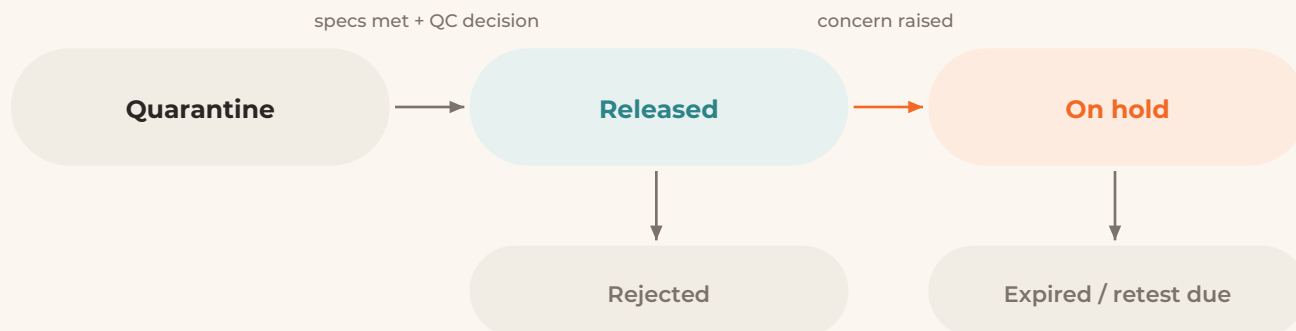
Each lot can carry its identity test plan and result. Scanning a lot at dispensing that has no approved identity result can be blocked according to your workspace rules. V5 records the result; it does not choose or validate the test method.

Sources: [1] (linked on pages 33–35)

FLOW / 05

Status, storage and shelf life.

Only released material of the right identity should reach a scoop. Probiotics, oils and some vitamins are sensitive to heat and moisture, so storage conditions matter as much as dates.



Status is a QC decision

Material moves out of quarantine on a recorded decision against specifications [1]. The record should say who changed status, when and why.

Hold to condition

Part 111 has requirements for holding components and finished product under conditions that protect against contamination and deterioration [1]. Keep system locations matching the shelf.

Shelf life is a claim

If you put a best-before or expiry date on the label, you should have data to support it. Track ingredient expiry and retest dates in the record, not in someone's head.

WHERE V5 FITS

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

Sources: [1] (linked on pages 33–35)

FLOW / 06

The master record is the promise.

The master manufacturing record turns the label into instructions. Part 111 is unusually specific about what it must contain.

111.210: THE MMR MUST INCLUDE [1]

- Product name and strength of each dietary ingredient per batch size
- A complete list of components
- The weight or measure of each component
- Each ingredient declared on the Supplement Facts and ingredient list
- Any intentional overage of a dietary ingredient
- Theoretical yield at each control point, with limits that trigger a deviation investigation
- Packaging description and a representative label
- Written instructions, including specifications at each control point

WORKED OVERAGE EXAMPLE

Label claim: 100 µg vitamin K2 per capsule. Your stability data shows some loss over shelf life, so MMR-22 states an intentional overage of 20%, giving 120 µg per capsule at manufacture. The overage, its reason and its supporting data belong on the record.

QC approves every change

111.123(a)(1): QC reviews and approves all master manufacturing records and modifications [1].

One batch, one record

111.255: a batch production record every time, accurately following the master record, with each step performed [1].

Justify every overage

Tie each overage to stability data and review it when the data changes.

WHERE V5 FITS

Formulas, master records and instructions are kept under revision with approval, including declared ingredients, overages and theoretical yields. An existing batch sheet or MMR can be uploaded and drafted into V5 for your team to check and approve; nothing goes live until approved.

Sources: [1] (linked on pages 33–35)

FLOW / 07

Weigh the right lot, the right amount.

Micro-ingredients such as vitamin D3, B12 or selenium may be milligrams in a large blend. A small weighing error can put a batch far from its label.

Released material only

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

Weigh to the record

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

Premixes and potency

Where a premix or assay value changes the quantity, show the calculation and inputs, checked like any other value.

Label what you dispense

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



Complete information. 111.255(b) requires the batch production record to include complete information relating to the production and control of each batch [1]. Weighings, checks and the identity of who did them are the core of it.

WHERE V5 FITS

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

Sources: [1] (linked on pages 33–35)

FLOW / 08

Blend, fill, press: watch the process.

Blending, encapsulation, tableting, powder filling and gummy depositing each have points where a batch can quietly go wrong. Part 111 asks you to watch them.



Monitor control points

111.75(b): monitor in-process points, steps or stages where control is needed, to check specifications and detect deviations or unanticipated occurrences [1].

Equipment and lines

111.260(b): the batch record includes the identity of equipment and processing lines used [1]. Cleaning status belongs with it.

Yield at each stage

Compare actual with the theoretical yields in the master record. Results outside your limits trigger investigation and material review [1].

Contamination and mix-ups

Allergen-containing ingredients, shared equipment and similar-looking products need changeover and cleaning controls you can show.

WHERE V5 FITS

Operators follow approved steps on the kiosk with scanning, values against limits, photos and signatures. Fill-weight and blend checks are recorded against limits, equipment cleaning status is checked at the step, and yield reconciliation is part of the batch report.

Sources: [1] (linked on pages 33–35)

DECIDE / 01

Test the finished batch, honestly.

The finished batch must meet its specifications. Part 111 lets you verify that through a sound statistical plan, so the plan itself becomes evidence.



DK-0418 • FINISHED BATCH (WORKED EXAMPLE)	
Identity • vitamin K2 (HPLC)	Complies
Strength • D3, % of claim	112%
Strength • K2, % of claim	118%
Disintegration	Complies
Microbial limits	Awaiting review
Heavy metals	In progress

Statistical or every batch

111.75(c): for a subset of batches chosen by a sound statistical sampling plan, or every batch, verify identity, purity, strength, composition and contaminant limits [1].

Overage reads high

With a declared overage, strength above 100% of claim is expected. Your limits should say how high is acceptable.

WHERE V5 FITS

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

Sources: [1] (linked on pages 33–35)

DECIDE / 02

A person decides. The record shows why.

Releasing a batch for distribution is a quality control judgement. The system's job is to put a complete record, with its open items, in front of the right person.



Review the whole record

111.123(a)(2): QC reviews and approves all batch production-related records [1], including packaging and labelling.

Review by exception

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

Open means open

An unfinished material review or pending result should be visible on the record and stop release unless your approved procedure says otherwise.

WORKED EXAMPLE: REVIEW SUMMARY FOR DK-0418

Master record	MMR-22 rev 4, in force on manufacture date	OK
Component lots	7 lots; 2 dietary ingredients identity-tested	OK
In-process	Blend uniformity in limits; fill weight drift	DV-118
Yield	97.2% of theoretical, inside MMR limits	OK
Labels	Issued 12,400 · used 12,180 · returned 200 · destroyed 20	OK
Finished tests	Microbial limits awaiting review	OPEN

WHERE V5 FITS

The QC review queue shows each electronic batch record with exceptions first: out-of-limit values, open deviations, pending results, label discrepancies and missing signatures. Part 11 electronic signatures are available where your plan includes them. V5 never approves a batch by itself.

DECIDE / 03

When something does not go to plan.

Fill weight drifts high on one encapsulation station during DK-0418. Part 111 names exactly when a material review and disposition decision are required.

1

Record and contain

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

2

Material review

QC reviews: a specification not met, a deviation from the MMR, or an unanticipated occurrence [1].

3

Decide disposition

Release, reprocess, or reject, with the reasoning and who decided recorded.

4

Extend and link

Ask which other batches share the cause; link to the batch, CAPA and any change.

What the regulation says. 111.113(a) requires quality control personnel to conduct a material review and make a disposition decision when a specification established under 111.70 is not met, when a batch deviates from the master manufacturing record, including any step not completed, and when an unanticipated occurrence adulterates or may lead to adulteration of the product [1]. Out-of-specification laboratory results follow the same principle: investigate before deciding, do not keep retesting until a passing result appears.

WHERE V5 FITS

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

Sources: [1] (linked on pages 33–35)

DECIDE / 04

Complaints, adverse events, and the fix.

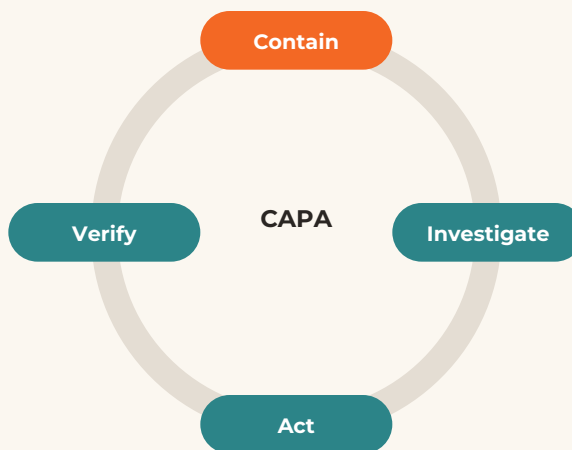
A consumer reports feeling unwell, or a capsule looks wrong. Two different obligations may start at once: a GMP complaint record, and a serious adverse event report.

PRODUCT COMPLAINT (PART 111)

111.570 requires a written record of every product complaint related to good manufacturing practice, with the person who performed each requirement documenting it at the time [1]. QC reviews complaints that may involve a failure to meet specifications or other GMP requirements, and decides whether to investigate.

SERIOUS ADVERSE EVENT (SEC. 761)

The responsible person named on the label must submit serious adverse event reports to FDA no later than 15 business days after receipt, and keep records related to each report for 6 years [3][4]. FDA's Q&A guidance explains how it interprets 'serious' and what records to keep [3].



Feed CAPA from every source

Complaints, material reviews, OOS results, supplier issues, audit findings and trends are all inputs. Link them so a repeat is visible.

Agree effectiveness first

Decide in advance what evidence will show the action worked, and review it.

Keep the two duties apart

A complaint record does not decide reportability. People trained in sec. 761 decide whether an event is serious.

WHERE V5 FITS

Complaints can be logged, linked to the batch and lots, and routed to CAPA with root-cause workflow and effectiveness checks. V5 does not decide whether an event is a serious adverse event and does not submit reports to FDA; those stay with your responsible person.

Sources: [1], [3], [4] (linked on pages 33–35)

DECIDE / 05

Trained on the current revision.

If an operator signed an encapsulation step on MMR-22 rev 4 without training on rev 4, the batch record needs explaining.

Qualified people

111.12(a) and (c): qualified employees, each with the education, training or experience to do their job [1].

Training records

111.14(b)(2): document training, including the date, the type of training and the people trained [1].

Separate the roles

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

EXAMPLE COMPETENCE AND PERMISSION MATRIX

	MMR-22 rev 4	Weigh check	Identity method	Disposition
Dispensary op.	Trained	Trained	—	Not permitted
Encapsulation op.	Trained	Retraining due	—	Not permitted
QC analyst	—	—	Trained	Not permitted
QC reviewer	—	—	—	Trained

Hygiene is training too. Part 111 includes personnel hygiene and protective clothing requirements to protect against contamination [1]. Gowning, hand hygiene and illness reporting are things to train, check and record, not only to post on a wall.

WHERE V5 FITS

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

Sources: [1] (linked on pages 33–35)

SUSTAIN / 01

Clean, calibrated, ready.

Scales, blenders, encapsulators, tablet presses and lab instruments are part of every batch's story. Their state on the day belongs in the record.



Suitable and maintained

111.27(a): equipment and utensils of appropriate design, construction and workmanship, suitable for use and able to be cleaned and maintained, including equipment used to measure [1].

Calibrate what measures

Part 111 expects instruments and controls used in manufacturing or testing to be calibrated and checked, with records [1]. Scales are the obvious first.

Look back when it fails

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

WHERE V5 FITS

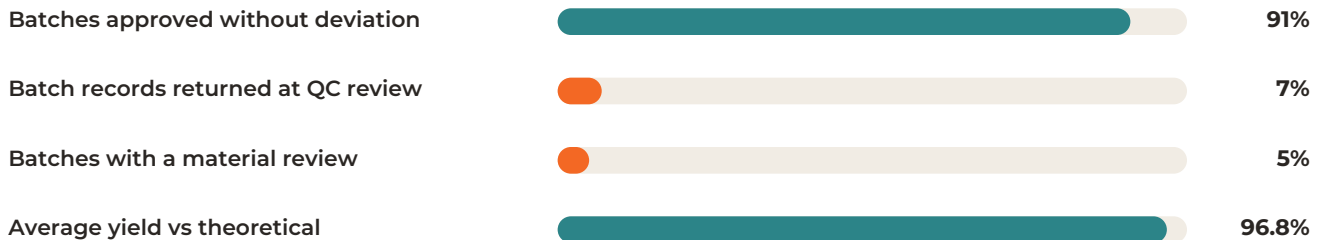
Each instrument and machine can have an equipment record with calibration schedules, tolerance checks, certificates, planned maintenance and use history. Out-of-calibration devices can be blocked at the kiosk, and the batches that used them can be found. Predictive failure analytics are not offered today.

Sources: [1] (linked on pages 33–35)

SUSTAIN / 02

Measure right first time, not just output.

In supplements the costliest batch is one that is made, bottled and labelled, then held for a failed test or a label discrepancy. Measure where time and quality are lost.

WORKED EXAMPLE · ONE QUARTER · ONE PRODUCT FAMILY

Overage is cost

An overage that is larger than your stability data needs is ingredient money spent every batch. Review it with the data, not by habit.

Time to disposition

Days from bottling to release tie up stock. Find which test or review step holds batches.

Equipment losses

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

WHERE V5 FITS

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

SUSTAIN / 03

Right label, reconciled.

A supplement's label carries its legal identity, its Supplement Facts and often its claims. Label mix-ups are a classic cause of recalls, so labels are controlled materials.



Control issuance and reconcile

111.410(b): control the issuance and use of packaging and labels and reconcile any discrepancies. An exemption applies to cut or rolled labels with 100% electronic examination [1].

Examine before use

111.410(c): before packaging and labelling, examine packaging and labels for each batch to confirm they conform to the master record [1].

Lot number on every lot

111.415(f): assign a batch, lot or control number to each lot of packaged and labelled product [1].

Supplement Facts

21 CFR 101.36 sets the U.S. Supplement Facts format and content [2]; in the EU, Directive 2002/46/EC and Regulation 1169/2011 apply [9][12].

Claims are outside the batch record, but not outside the business. Structure/function and health claims, notifications and substantiation follow their own rules in each market. Keep the approved artwork revision linked to the master record so production prints what regulatory approved.

WHERE V5 FITS

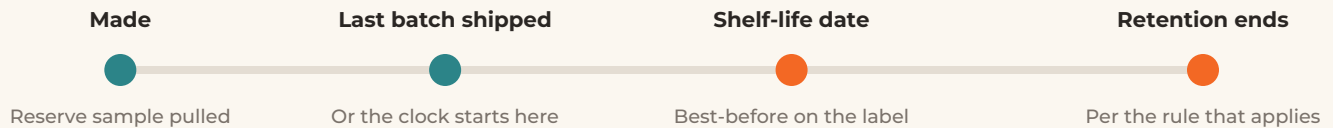
Packaging work orders record line clearance, component lots and label counts. Label design and printing use data from the record, with GS1-128 barcodes on configured printers. The approved artwork revision is linked to the master record and printed on the batch record. V5 does not write or substantiate label claims.

Sources: [1], [2], [9], [12] (linked on pages 33–35)

SUSTAIN / 04

Keep a sample. Keep the records.

Two years after a batch ships, a complaint arrives. Reserve samples and retained records are how you answer it with evidence rather than memory.



Reserve samples

111.83: collect and hold reserve samples of each lot of packaged and labelled supplement you distribute, in the same container-closure system, identified with the lot number [1].

How long

Hold them for 1 year past the shelf-life date if shelf-life dating is used, or 2 years from distribution of the last batch associated with the sample [1].

Records

111.605: keep required records for 1 year past the shelf-life date, or 2 years beyond distribution of the last batch; electronic records must comply with Part 11 [1][7].

Adverse event records are separate. Records related to serious adverse event reports are kept for 6 years under sec. 761 [4]. Set retention per record type, not one rule for everything.

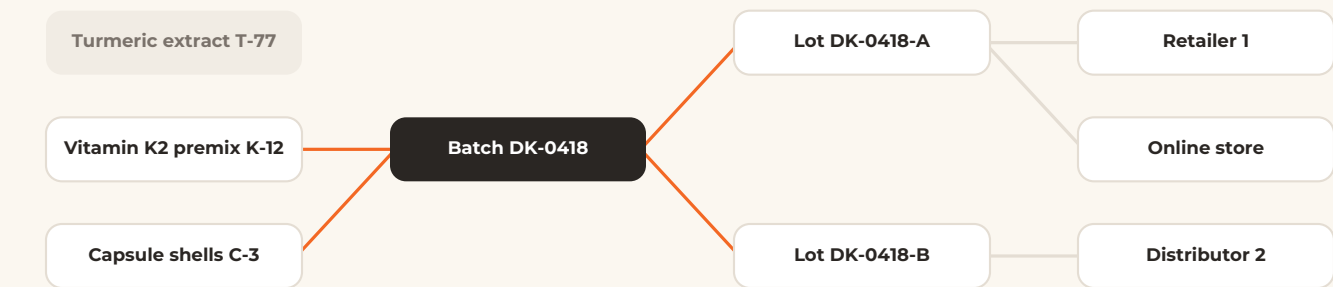
WHERE V5 FITS

Reserve samples can be logged against the lot with location and retention date, and records stay linked to the batch. Retention periods are set in your procedures; check that your configuration and backups meet them.

Sources: [1], [4], [7] (linked on pages 33–35)

Trace both ways, in minutes.

A botanical lot is suspected of adulteration, or a customer reports the wrong product in a bottle. The questions are the same: which batches, which lots, which customers.



T-77 was not used in DK-0418, so the trace shows it is outside this batch's scope.

Distribution records

111.475(b)(2): make and keep records of product distribution [1].

EU one step each way

Regulation 178/2002 Art. 18 requires traceability one step back and one step forward; Art. 19 covers withdrawal and informing authorities [10].

Recalls

21 CFR Part 7 Subpart C sets FDA's recall policy, including strategy and effectiveness checks [8]. Rehearse a mock recall and time it.

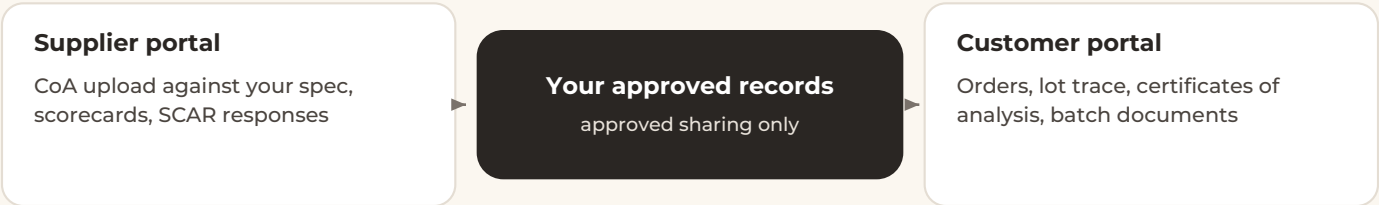
WHERE V5 FITS

Lots and batches link at receipt, dispensing, manufacture, packaging and shipment, so genealogy can be followed forward from an ingredient lot or backward from a complaint, and recall scope listed from those links. Recall and authority-notification decisions stay with your quality team.

SUSTAIN / 06

Share the right records, safely.

Brand owners want certificates, batch summaries and change notices from their contract manufacturer. Ingredient suppliers send CoAs and answer SCARs. Each should see only what you approve.



Brand owner and maker

Agree in a quality agreement who approves release, who receives which records, how fast, and who handles complaints and adverse event information.

Certificates for retailers

Retailers and marketplaces often ask for CoAs and test summaries. Share the approved version, linked to the lot they bought.

Supplier evidence

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

A SHARING POLICY TO AGREE BEFORE ANYONE LOGS IN

Certificate of analysis	After QC disposition	Customer
Batch documentation summary	As the quality agreement defines	Brand owner
Lot trace for their shipments	On request or always on	Customer
Open deviations and material reviews	Not by portal; agreed notification	Quality contacts
Supplier CoAs and SCAR replies	Reviewed before they count	Your QC

WHERE V5 FITS

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

SUSTAIN / 07

Trustworthy records. Honest AI.

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

Electronic records

111.605(c): all electronic records required by Part 111 must comply with 21 CFR Part 11 [1][7].

Original or true copy

111.605(b): records kept as originals, true copies or electronic records [1]. Know which is your record of truth.

Validate for intended use

Part 11 expects validation of systems that create and keep these records [7]. Scale the effort to the risk of each use.

AI CAN HELP

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

AI NEVER

- Approves, rejects or releases a batch
- Signs a record or approves a test result
- Decides adverse event reportability
- Writes or substantiates label claims
- Predicts failures today (forecasting is coming soon)

WHERE V5 FITS

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

Sources: [1], [7] (linked on pages 33–35)

APPLY / 01

Evidence map.

A one-page check that every theme an investigator may ask about has an owner and a record. Section numbers refer to 21 CFR Part 111 [1]; adapt them for other markets.

THEME	TYPICAL EVIDENCE	WHERE IT LIVES IN V5	OWNER
Personnel (111.12–14)	QC named, training records	Roles, skills matrix	Managers
Equipment (111.27)	Suitability, cleaning, calibration	Equipment, calibration	Engineering
Specifications (111.70)	Component to finished specs	Specifications	QC
Identity (111.75(a)(1))	Identity test per ingredient lot	Lab & QC, lots	QC
CoA reliance (111.75(a)(2))	Supplier qualification, re-checks	Suppliers, scorecards	QC + purchasing
In-process (111.75(b))	Monitoring results, deviations	Kiosk steps	Production
Finished batch (111.75(c))	Sampling plan, results	LIMS, Lab & QC	QC
Reserve samples (111.83)	Samples logged, retained	Lots, locations	QC
Material review (111.113)	Review and disposition record	Deviations, review queue	QC
QC records (111.123)	MMR and batch record approval	Formulas, eBMR	QC
Receiving (111.155)	Container checks, quarantine	Receiving, status	Warehouse
MMR (111.210)	Approved, complete MMR	Formulas, instructions	QC + production
Labels (111.410–415)	Issuance, reconciliation, lot no.	Packaging, labels	Packaging
Distribution (111.475)	Shipment records	Genealogy, shipments	Logistics
Complaints (111.570)	Complaint records, QC review	Complaints, CAPA	QC

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

WORKSHEET 01

Is your batch record ready for QC review?

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

	YES	PARTLY	NO
Master record revision The batch record shows which MMR and revision it was made to.	☐	☐	☐
Identity evidence Every dietary ingredient lot used has its own identity test result.	☐	☐	☐
Components traced Every component lot, its status at use and its quantity is recorded.	☐	☐	☐
Weighings checked Each weighing shows the scale, the result and who checked it.	☐	☐	☐
Equipment recorded Equipment and lines used are identified; cleaning and calibration valid.	☐	☐	☐
In-process monitored Control-point results are recorded against specifications.	☐	☐	☐
Yield reconciled Actual yields compared with theoretical; outside-limit results reviewed.	☐	☐	☐
Labels reconciled Labels issued, used and returned balance, or the discrepancy is reviewed.	☐	☐	☐
Finished batch Specified tests complete, reviewed and linked, or covered by the sampling plan.	☐	☐	☐
Decision identity The record shows who reviewed and who decided disposition, with date.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Is your CoA reliance earned?

For each component you accept on a supplier's certificate, check the five conditions of 111.75(a)(2) [1]. Use one row per supplier and material.

	YES	PARTLY	NO
Not a dietary ingredient The component is not a dietary ingredient, which needs its own identity test.	☐	☐	☐
Qualified by confirmation You confirmed the supplier's results with your own tests before relying on them.	☐	☐	☐
CoA content Certificates describe method, limits and actual results, not just 'complies'.	☐	☐	☐
Qualification documented How the supplier was qualified is written down and findable.	☐	☐	☐
Periodic re-confirmation You re-test at a defined interval, and the last one is on file.	☐	☐	☐
QC approval QC reviewed and approved the qualification and re-qualification basis.	☐	☐	☐
Identity still confirmed Identity of the component is still confirmed for each receipt.	☐	☐	☐
Change notification The supplier must tell you about changes in source, process or site.	☐	☐	☐
Performance feedback Rejections, complaints and late CoAs feed back into the supplier's status.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 03

Ask to see it work.

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

	SHOWN	PARTLY	NOT SHOWN
No identity result Scan a dietary ingredient lot without an identity result at dispensing; show what happens.	☐	☐	☐
Quarantined lot Scan a quarantined or expired lot and show the step stop.	☐	☐	☐
Out of tolerance Weigh a micro-ingredient outside tolerance and show the response and record.	☐	☐	☐
Untrained operator Show an operator not trained on the revision being stopped, if configured.	☐	☐	☐
Yield outside limits Enter a yield outside the MMR limits and show material review starting.	☐	☐	☐
Label discrepancy Enter label counts that do not reconcile; show it on the review queue.	☐	☐	☐
OOS result Enter a finished batch result outside specification and show the workflow.	☐	☐	☐
Review by exception Show a batch record with exceptions first, then sign it.	☐	☐	☐
Trace From an ingredient lot, list every batch, lot and customer; then the reverse.	☐	☐	☐
Export Export a complete batch record and its audit trail for an investigator.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

Roll out in phases.

Start where value is visible and risk is contained. Validate electronic records for their intended use as you go [7].

PHASE 1
Foundations

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

PHASE 2
Materials

Specifications, approved suppliers and CoA reliance, receiving with quarantine, identity testing, status and expiry.

PHASE 3
Batch record

Master records with overages and yields, dispensing and kiosk execution for one product family, run in parallel.

PHASE 4
Decide

Finished batch testing, material review, complaints, CAPA and QC disposition signatures, after validation.

PHASE 5
Connect

Labels and reconciliation, reserve samples, genealogy and distribution, mock recalls, portals, right-first-time review.

Validation runs through every phase. Agree intended use, risk and test evidence before each phase goes live. V5 offers a validation pack where your plan includes it; your validation remains yours.

Sources: [7] (linked on pages 33–35)

WORKSHEET 04

Find your first improvement.

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

	E	P	G
Specifications Every component and product has current, approved specs	☐	☐	☐
Supplier and CoA reliance Qualified, documented, re-confirmed	☐	☐	☐
Identity testing One appropriate test per dietary ingredient lot	☐	☐	☐
Goods-in and status Container checks, quarantine, blocking at the scan	☐	☐	☐
Master records Complete per 111.210, QC-approved revisions	☐	☐	☐
Dispensing Checked weighings, labelled containers	☐	☐	☐
In-process and yield Monitored control points, yields reconciled	☐	☐	☐
Finished batch testing Sound sampling plan, complete results	☐	☐	☐
Material review and CAPA Triggers recognised, reasoning recorded	☐	☐	☐
Labels Examined, issued, reconciled, lot-coded	☐	☐	☐
Complaints and adverse events Two duties, clear owners	☐	☐	☐
Trace and recall Both ways, mock recall timed	☐	☐	☐

NOTES AND OWNERS

APPLY / 03

A fair evaluation in four weeks.

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

WEEK 1

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

WEEK 2

Run a batch end to end with test data: receipt, identity test, dispensing, steps, results, labels and review.

WEEK 3

Break it on purpose: no identity result, expired lot, micro-ingredient out of tolerance, untrained operator, label miscount.

WEEK 4

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

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

ASK V5

“We make [capsules / tablets / powders / gummies] for [markets] under [21 CFR 111 / EU food supplement rules / both]. Our hardest moment is [e.g. identity testing every botanical lot]. Which workflows should we evaluate first?”

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

WHERE V5 FITS

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

SOURCES

Keep the evidence close.

Primary sources behind this guide, checked October 2026. Click a title to open the publisher's page.

- | | | |
|-----|---|----------------------------|
| [1] | U.S. eCFR, 21 CFR Part 111: CGMP for dietary supplements | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-111 | |
| [2] | U.S. eCFR, 21 CFR 101.36: nutrition labeling of dietary supplements | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-C... | |
| [3] | U.S. FDA, Q&A on adverse event reporting for dietary supplements (rev. 2013) | FDA GUIDANCE (NON-BINDING) |
| | https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidan... | |
| [4] | 21 U.S.C. 379aa-1 (FD&C Act sec. 761): serious adverse event reporting | BINDING U.S. STATUTE |
| | https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section379... | |
| [5] | U.S. eCFR, 21 CFR 190.6: new dietary ingredient notification | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-190/subpart-B... | |
| [6] | U.S. eCFR, 21 CFR Part 117 (incl. 117.5(e) supplement exemption) | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117 | |
| [7] | U.S. eCFR, 21 CFR Part 11: Electronic Records; Electronic Signatures | BINDING U.S. REGULATION |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11 | |
| [8] | U.S. eCFR, 21 CFR Part 7: Enforcement Policy (recalls, Subpart C) | U.S. REGULATION / POLICY |
| | https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7 | |
| [9] | Directive 2002/46/EC: food supplements (EU) | BINDING EU DIRECTIVE |
| | https://eur-lex.europa.eu/eli/dir/2002/46/oj | |

SOURCES

Sources, continued.

[10] Regulation (EC) 178/2002: General Food Law (EU)

BINDING EU REGULATION

<https://eur-lex.europa.eu/eli/reg/2002/178/oj>**[11] Regulation (EC) 852/2004: hygiene of foodstuffs (EU)**

BINDING EU REGULATION

<https://eur-lex.europa.eu/eli/reg/2004/852/oj>**[12] Regulation (EU) 1169/2011: food information to consumers**

BINDING EU REGULATION

<https://eur-lex.europa.eu/eli/reg/2011/1169/oj>**[13] Canada, Natural Health Products Regulations (SOR/2003-196)**

BINDING CANADIAN REGULATION

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/>**[14] Codex Alimentarius, Committee on Food Hygiene (CXC 1-1969)**

VOLUNTARY INTERNATIONAL

<https://codex.fao.org/codex-committees/general-subject-committees/CCFH/about>**[15] Health Canada, GMP guide for natural health products (GUI-0158 v4, 4 Sep 2025)**

HEALTH CANADA GUIDANCE

<https://www.canada.ca/en/health-canada/services/drugs-health-products/complianc...>**[16] TGA, Manufacturing listed medicines**

TGA GUIDANCE

<https://www.tga.gov.au/products/medicines/listed-medicines/manufacturing>**[17] TGA, Manufacturing registered complementary medicines**

TGA GUIDANCE

<https://www.tga.gov.au/products/medicines/registered-complementary-medicines/ma...>**[18] TGA, Listed complementary medicines overview**

TGA GUIDANCE

<https://www.tga.gov.au/products/medicines/listed-medicines/overview/listed-comp...>

SOURCES

Sources, continued.

[19] UK DHSC, Food supplements guidance

UK GOVERNMENT GUIDANCE

<https://www.gov.uk/government/publications/food-supplements-guidance/food-suppl...>**[20] UK, Guidance notes on legislation implementing Directive 2002/46/EC (GB and NI)**

UK GOVERNMENT GUIDANCE

<https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs/g...>**[21] European Commission, Food supplements overview**

EU COMMISSION PAGE

https://food.ec.europa.eu/food-safety/labelling-and-nutrition/food-supplements_en

How to read the status labels. Binding regulations and statutes are law in their jurisdiction. EU directives bind through each member state's national law, which can add rules. FDA Q&A guidance explains the agency's thinking but does not bind. Codex texts are voluntary international references.

SCOPE AND LIMITS

This guide is practical orientation for evaluating supplement production, laboratory, quality and traceability operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you; requirements depend on product, market and your role as manufacturer, packager, labeller, holder or brand owner. 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 set specifications, choose test methods, substantiate claims, decide reportability or release product, and does not by itself make you compliant. Photography is illustrative; batches, lots, results and charts are worked examples, not customer data.

**What the label says. What the batch proves.**[See supplement workflows at v5ultimate.com](https://v5ultimate.com) · Global edition · October 2026