



THE COSMETICS MANUFACTURING GUIDE

The right formula. Stable batches. Traceable jars.

From raw material to filled unit, complaint and recall

A capability and evaluation guide for skin care, hair care, colour cosmetics, toiletries and fragrance makers, brand owners and contract manufacturers who want formulas, phase records, bulk and micro results, fill checks and batch codes in one connected record.



GOOD MANUFACTURING PRACTICE

FORMULA REVISIONS

BATCH TO COMPLAINT

Global edition / October 2026

v5ultimate.com

Scope: practical orientation, not legal advice. Photos are staged; lots, formulas and numbers are worked examples.

INSIDE THE GUIDE

Drum to jar, phase by phase.

A cosmetic batch is made from many raw materials and packaging components, in phases, then held, tested, filled and coded. This guide follows one batch of face cream and shows what each handover must leave behind.

01 / FRAME

pp. 03–05

Rules, responsibility, one day

U.S. MoCRA, EU 1223/2009, Canada, ISO 22716; responsible person and product file; one batch day.

02 / MATERIALS

pp. 06–09

Specification to released drum

Raw materials and packaging specs, goods-in, water and status, formula revisions and ingredient lists.

03 / MAKE

pp. 10–16

Weigh, mix, test, fill

Dispensing, phases and emulsification, bulk testing, microbiology, bulk hold and filling, labels and batch codes, release.

04 / DECIDE

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Deviate, hear, improve

Deviations and out-of-spec, complaints and undesirable effects, CAPA, people and hygiene.

05 / SUSTAIN

pp. 21–26

Assets, trace, share

Cleaning and calibration, OEE and changeovers, trace and recall, a mock recall, portals, data and AI.

06 / APPLY

pp. 27–35

Evidence map, tools, sources

ISO 22716 evidence map, four worksheets, roadmap, four-week evaluation and eleven linked sources.

Who it is for. Quality and regulatory managers, production and filling leads, lab and microbiology teams, warehouse and purchasing, technical teams at brand owners and contract manufacturers, and anyone choosing a production and quality system for creams, lotions, shampoos, colour cosmetics or fragrances.

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.

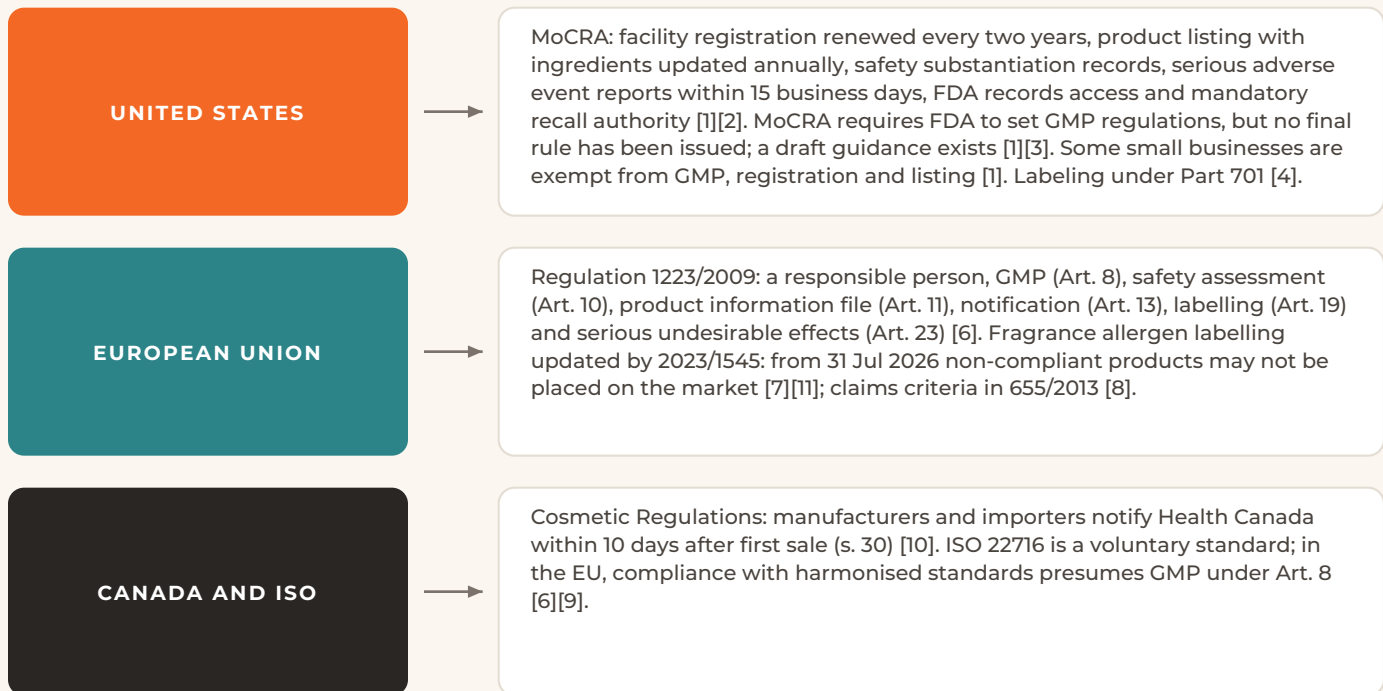
WHERE V5 FITS

V5 records the purchasing, weighing, mixing, testing, filling and quality work your procedures define. It does not assess product safety, write safety substantiation, decide whether an event is serious, approve claims or labels, release batches or decide recalls. Those stay with your qualified people.

FRAME / 01

Three regimes, one good practice.

Cosmetics law has changed fast. The U.S. now has MoCRA, the EU has long had a product regulation with a responsible person, and Canada requires notification. ISO 22716 is the shared practical language for good manufacturing practice.



Cosmetic or drug?

Sunscreens, anti-dandruff shampoos and some antiperspirants are drugs in the U.S. and follow drug GMP. Classify each product by intended use and market before you design its record.

Check the GMP status

MoCRA requires FDA to set GMP regulations [1]; no final rule yet, and the draft guidance is non-binding. Confirm FDA's status before relying on any date.

Write the scope down

Products, sites, markets, who is responsible person where, and which rules apply, kept as a controlled document.

WHERE V5 FITS

Keep scope, procedures and specifications as controlled documents with revisions, owners and review dates. V5 industry packs adjust wording, screens and reports for cosmetics work; they do not classify products or decide which rules apply.

Sources: [1], [2], [3], [4], [6], [7], [8], [9], [10], [11] (linked on pages 34–35)

FRAME / 02

Who answers for the product?

Each regime names someone responsible for a cosmetic on the market, and expects them to hold evidence. Much of that evidence is made on the production floor.

U.S. RESPONSIBLE PERSON

- Manufacturer, packer or distributor named on the label [1]
- Lists each product and its ingredients; updates yearly [2]
- Keeps records supporting safety substantiation [1]
- Reports serious adverse events in 15 business days [1][5]

EU RESPONSIBLE PERSON

- Established in the EU; designated for each product [6]
- Keeps the product information file, including GMP statement and safety report (Art. 11) [6]
- Notifies via the EU portal before placing on the market (Art. 13) [6]
- Notifies serious undesirable effects (Art. 23) [6]

CANADA

- Manufacturer or importer [10]
- Cosmetic notification within 10 days after first sale (s. 30) [10]
- Updates on changes, as the regulations set [10]
- Labelling under Canadian rules

WHAT PRODUCTION FEEDS INTO THE FILE

Formula and revision	Qualitative and quantitative composition
Raw material specs and certificates	Identity, purity, impurities of concern
Batch records	Evidence that GMP was followed (EU Art. 8, 11) [6]
Stability and micro results	Support shelf life and safety assessment
Complaints and undesirable effects	Feed safety review and reports

WHERE V5 FITS

Formulas, specifications, certificates, batch records and results can be found per product and exported for the person who compiles the product file or safety substantiation. V5 does not write the safety assessment, notify a portal or submit FDA listings.

Sources: [1], [2], [5], [6], [10] (linked on pages 34–35)

FRAME / 03

One batch day.

A worked example: batch CS-0457, hydrating face cream, formula revision 9, 500 kg, made after a tinted moisturiser in the same vessel. Follow it through every handover.

06:00	●	Vessel V-3 cleaned after the tinted batch; visual check and sign-off
06:40	●	Purified water point checked; daily scale and pH meter checks
07:00	●	Phases dispensed: water, oil and cool-down; every lot scanned
09:10	●	Water and oil phases heated to 75 °C
09:30	●	Phases combined; homogeniser speed and time recorded
10:40	●	Cooled to 40 °C; fragrance and preservative added
11:30	●	Bulk sample: appearance, odour, pH 5.6, viscosity; micro started
12:10	●	Bulk held in quarantine tote; filling waits for micro

One record grows

Cleaning, dispensing, phase temperatures, additions and bulk tests add to one batch record, so review starts complete.

Bulk is a lot too

The 500 kg in the tote has its own status, hold time and location before a single jar is filled.

Waiting is part of it

Micro results take days. The record should show what is pending and stop filling or release from running ahead.

WHERE V5 FITS

Work orders sit on the schedule with formula revision, vessel and line. Kiosk steps capture who did what, with which lots, equipment and values, and the batch record assembles as the batch runs.

Sources: [9] (linked on pages 34–35)

MATERIALS / 01

Specify materials and packaging alike.

A cosmetic is its raw materials and its pack. A preservative from a new source, or a pump with a different resin, can change stability and safety as surely as a formula change.

Raw materials

INCI name, grade, identity tests, impurities of concern, micro limits

Fragrances

Supplier composition data for allergen declarations [7]

Water

Your own spec and monitoring for purified water

Primary packaging

Material, compatibility, cleanliness, closures

Printed components

Approved artwork revision, codes area

Qualify suppliers

ISO 22716 expects purchasing based on reliable suppliers and agreed specifications, with checks at receipt [9]. Approve before use; requalify on schedule and on change.

Change notices

Ask suppliers to tell you about changes in source, process, site or composition. Feed them into change control and, where relevant, the safety assessor.

Restricted substances

EU Annexes list prohibited and restricted substances, colourants, preservatives and UV filters [6]. Keep the status of each ingredient with its specification.

WHERE V5 FITS

Approved supplier lists, qualification, scorecards and specifications for raw materials and packaging sit with purchasing and receiving, so an unapproved source is visible at goods-in. Suppliers can upload certificates and change notices through the supplier portal where configured; SCARs route back to them.

Sources: [6], [7], [9] (linked on pages 34–35)

MATERIALS / 02

Goods-in creates the first link.

Drums, totes, bags of powder and pallets of jars arrive with supplier lots. What is recorded at the dock starts every trace and every complaint investigation.



Quarantine first

Received materials are identified and held until checked and released by a person authorised to do so (ISO 22716 practice) [9].

Check, then accept

Seals, damage, labels against the order, certificate against the specification.

Sample and identify

A sampling plan per material; identity confirmed before release.

WORKED EXAMPLE: ONE RECEIPT

Item	Glycerin, 4 × 200 kg drums
Supplier / supplier lot	Approved supplier S-031 / GL-66140
Internal lot	RM-9081, linked to GL-66140
Certificate	Values read; reviewer confirmed against spec rev 3
Status	Quarantine until identity test passes

WHERE V5 FITS

Receiving records supplier, supplier lot, internal lot, quantity, expiry or retest date and condition against the purchase order. Certificate values can be read from a PDF or photo for a person to confirm; AI extraction never accepts a lot. Lots can start in quarantine where configured.

MATERIALS / 03

Water, status and retest dates.

Water is often the largest ingredient in a cream and a common source of microbial trouble. Every material, water included, needs a status people can see.

Quarantine

Awaiting checks or results

Released

Can be dispensed, FEFO

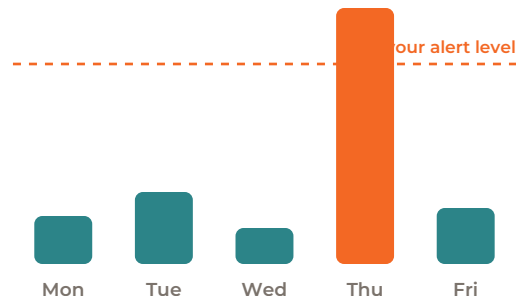
Retest due

Blocked until retested

Rejected / expired

Cannot be used

PURIFIED WATER · ONE WEEK (WORKED EXAMPLE)



Counts per mL at point of use; values and level are examples.

Monitor the system

Sample points, frequency, limits and action on excursions belong in your procedures. Record the result and what was done when Thursday's count rose.

Retest, not just expire

Many raw materials carry a retest date. A lot past it is blocked until retested and released again.

Opened containers

Partly used drums go back closed, labelled and with the same lot; opened-life rules apply where you set them.

WHERE V5 FITS

Lots carry status, location, expiry, retest and opened dates, with FEFO/FIFO picking. Scanning a quarantined, rejected or expired lot at the kiosk stops the step according to your workspace rules. Water results can be recorded in Lab & QC against your limits.

MATERIALS / 04

The formula is the source of truth.

Ingredient lists, allergen declarations, product listings and the product file all start from the formula. Keep one approved revision, and change it only through change control.

INGREDIENT (INCI)	% W/W	PHASE
Aqua	71.30	A
Glycerin	5.00	A
Caprylic/capric triglyceride	8.00	B
Cetearyl alcohol	4.00	B
Glyceryl stearate	3.00	B
Dimethicone	2.00	B
Niacinamide	4.00	C
Preservative system	1.00	C
Parfum (fragrance)	0.40	C
Other minors	1.30	C

Formula CS rev 9: worked example, not a product formula.

Order on the label

U.S. ingredient declaration is in descending order of predominance, with exceptions set in 701.3 [4]. EU Art. 19 sets its own ingredient list rules [6].

Fragrance allergens

EU Annex III labelling above 0.001% leave-on or 0.01% rinse-off. New rules apply to products placed on the market from 31 Jul 2026; earlier stock may be sold until 31 Jul 2028 [7][11]. Supplier composition data is the input.

Claims need evidence

EU claims follow common criteria (655/2013) [8]. Keep evidence linked to the product, not the brochure.

WHERE V5 FITS

Formulas and sub-formulas sit under revision with approval, phases, percentages scaled to batch size and ingredient data. Only the approved revision is issued to a work order. Ingredient list and label previews build from the formula; a person approves every label and claim.

MAKE / 01

Weigh each phase, scan each lot.

A preservative at 1 % or a fragrance at 0.4 % is easy to misweigh, double or forget. Dispensing is where formula accuracy is won or lost.



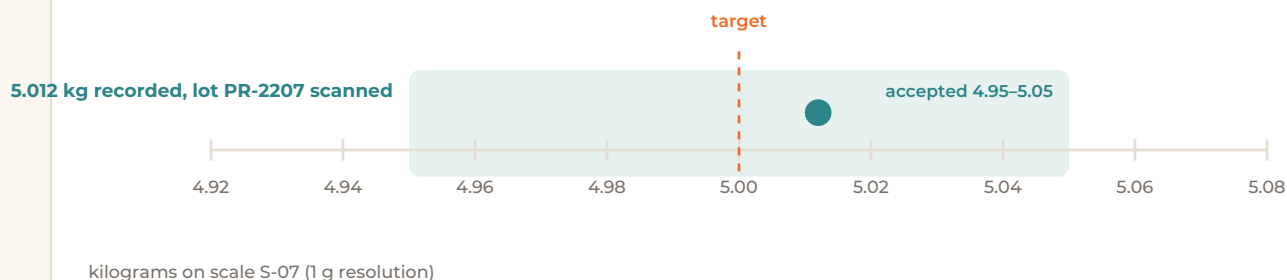
Right scale, checked

Assign scales by weight range; check them with test weights at the start of the shift.

Stage by phase

Dispensed materials are labelled with batch, phase, material, lot and weight, and kept together until charged.

PRESERVATIVE SYSTEM FOR CS-0457 · TARGET 5.00 kg, TOLERANCE ± 0.05 kg (WORKED EXAMPLE)



WHERE V5 FITS

Weigh & dispense guides each addition by formula quantity and tolerance, scans the lot and can block an out-of-tolerance or wrong-lot addition. Supported, configured scales send weights directly; otherwise the operator enters the value and their identity is recorded.

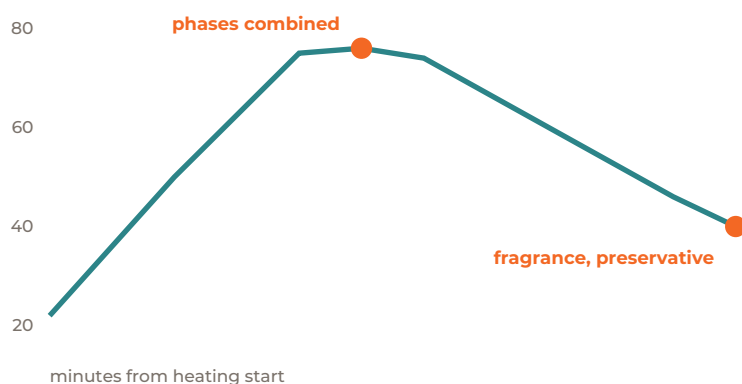
MAKE / 02

Heat, combine, cool, record it.

An emulsion is made by a sequence of temperatures, speeds and times. Two batches with the same ingredients can differ in texture and stability if those parameters drift.



CS-0457 · VESSEL V-3 TEMPERATURE (WORKED EXAMPLE)



Parameters are yours

Temperatures, speeds and times come from development and scale-up. Record actual values, not ticks.

Add heat-sensitive last

Fragrance and some preservatives go in below a set temperature. A step with a limit protects that.

Same vessel, same result

Record vessel and homogeniser used, so differences between equipment show up.

WHERE V5 FITS

Kiosk steps follow the formula's phase sequence with targets and limits for temperature, speed and time; an out-of-limit value can stop the step and open a deviation. Supported, configured sensors can send readings; otherwise operators enter values with their identity recorded.

MAKE / 03

Test the bulk against its spec.

Appearance, odour, colour, pH and viscosity tell you quickly whether the bulk is the product you meant to make. They are the gate before filling.

TEST	SPEC	RESULT
Appearance	White cream	Conforms
Odour	Matches std	Conforms
pH	5.2–6.0	5.6
Viscosity	Range in spec	In range
Micro	Your limits	Pending

Example specification. Methods, instruments and limits are yours.



Calibrated instruments

pH meters and viscometers need daily checks and periodic calibration; record them with the result they support.

Out of specification

A result outside spec opens an investigation, not a retest until it passes. ISO 22716 treats out-of-specification results as a defined process [9].

Keep a retained sample

Retain bulk or finished samples for the period your procedures set, to answer later complaints and stability questions.

WHERE V5 FITS

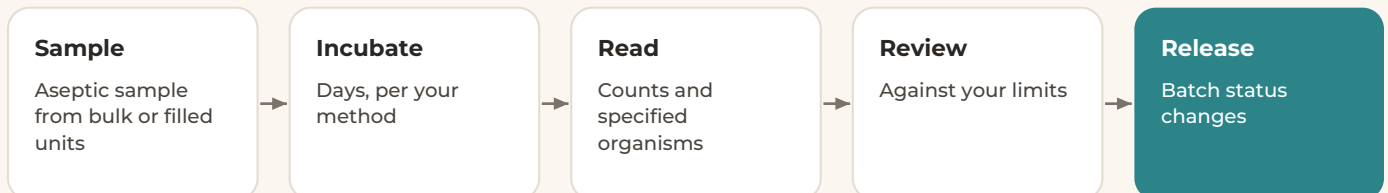
Lab & QC and LIMS hold specifications, sample plans and results with pending results keeping the batch on hold. Out-of-limit results can open a deviation or out-of-spec investigation. Analysts and reviewers sign; V5 does not approve results.

Sources: [9] (linked on pages 34–35)

MAKE / 04

Microbiology takes days. Plan for it.

Water-based products can support microbial growth. Micro testing of bulk or finished product, and the preservative system behind it, are central to cosmetic safety.



Fill at risk, release later

Some sites fill before micro results and hold filled stock in quarantine. Decide it in a procedure, and make the hold visible.

Preservative efficacy

Preservative challenge testing is a development and change-control question. Keep the evidence with the formula revision it supports.

Environment and people

Surfaces, air and hands in filling rooms can be monitored. Sites, frequencies and limits come from your own risk assessment.

WHERE V5 FITS

Micro samples and results sit in Lab & QC against your limits, linked to bulk, filled lots and the water point. Pending micro keeps batches and filled stock on hold until a person releases them.

MAKE / 05

Hold the bulk, fill to weight.

Between the vessel and the jar, bulk sits in a tote or tank. Hold time, line clearance and fill weight decide whether the 500 kg becomes the right 9,600 jars.



Bulk hold time

Within the time your stability data supports

Line clearance

No previous product, components or labels

Components

Jars, lids, labels: right lot and artwork

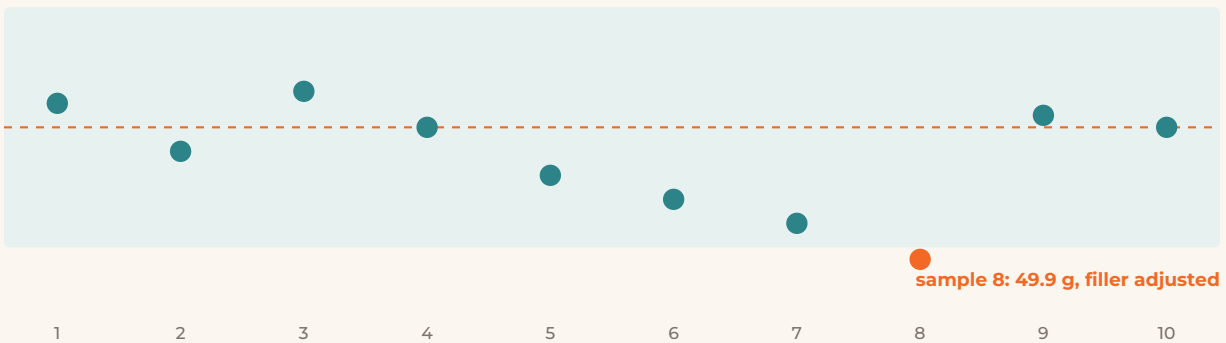
Fill weight

Samples at start and intervals

Seal and torque

Lids and pumps checked

FILL WEIGHTS, 50 mL JAR, FILLER 2 · TARGET 51.0 g ± 1.0 g (WORKED EXAMPLE)



WHERE V5 FITS

Filling runs as a work order linked to the bulk lot, with line clearance, component lot scans and timed fill-weight checks. Supported checkweighers can send results; a failed check can hold product. Bulk hold time is visible from the record.

MAKE / 06

Every unit carries its batch.

A batch code on each unit is what links a consumer's complaint to your record. Label content, artwork revision and code legibility deserve checks of their own.

EU label content

Art. 19 includes responsible person, nominal content, date of minimum durability or period after opening, precautions, batch number or reference, function and ingredient list [6].

U.S. labeling

Part 701 covers ingredient declaration and other labeling; MoCRA adds requirements such as contact information for adverse event reports [1][4].

Artwork is controlled

Labels and cartons are printed to an approved artwork revision; old stock is reconciled out on change.



LABEL AND CODE CHECKS ON CS-0457 (WORKED EXAMPLE)

Start	Label artwork rev 6 matches work order	OK
Start	Batch code CS-0457 and PAO symbol legible	OK
Every 30 min	Code legibility on 5 units	OK
13:50	Code smudged on 40 units after ribbon change	HOLD
End	Labels issued vs used vs returned reconciled	OK

WHERE V5 FITS

Label printing can use data from the batch record so codes and dates come from the record, not a keyboard. Code and label checks run as timed kiosk tasks, and component reconciliation can be recorded at line close. A person approves the artwork.

Sources: [1], [4], [6] (linked on pages 34–35)

MAKE / 07

Release is a person's decision.

Before a batch is released, someone authorised looks at the whole record: materials, process, results, deviations and packaging. The system can assemble it; it cannot decide.



RELEASE DECISION · CS-0457

Released by quality (named person, date, time, reason recorded)

40 smudged units reworked and re-inspected; deviation DV-118 closed before release.

Who may release

Name the roles authorised to release finished product, in writing, and make the system enforce it.

Contract manufacturing

Agree who releases: the manufacturer, the brand owner, or both in sequence. Put it in the quality agreement (ISO 22716 subcontracting) [9].

Release by exception

A review that starts from exceptions is faster and safer than reading 30 pages of ticks.

WHERE V5 FITS

A release review can show the full batch record with exceptions first, and only roles you authorise can record the decision. Electronic signatures are available where your plan includes them. V5 never releases a batch on its own.

Sources: [9] (linked on pages 34–35)

DECIDE / 01

When something goes off plan.

A temperature overshoot, a wrong-lot scan caught at the scale, a pH just outside spec. Each one needs recording, an impact assessment and a decision.

DEVIATION

A departure from an approved instruction or condition. ISO 22716 expects deviations to be justified, documented and assessed [9].

Example: the oil phase reached 79 °C against a 72–78 °C range for four minutes. Impact assessed with the formulator; batch continued; recorded and reviewed before release.

OUT-OF-SPECIFICATION RESULT

A test result outside its specification. Investigate the lab first, then the process, before deciding on the batch [9].

Example: pH 6.2 against 5.2–6.0. Meter check fails; recalibrated meter reads 5.7 on the same sample and a fresh one. The lab error is recorded; the original result stays in the record.

Record

At the moment it happens

Assess

Impact on this and other batches

Decide

Continue, rework, reject, by a person

Learn

Open CAPA when the cause may repeat

Never overwrite the first result. An investigation explains a result; it does not replace it. The original value, the investigation and the decision should all be visible to a reviewer.

WHERE V5 FITS

Out-of-limit values can open a deviation or out-of-spec investigation from the step, linked to the batch, equipment and people, with hold of affected lots. AI can suggest a classification or draft a summary for a person to edit. A person decides disposition.

Sources: [9] (linked on pages 34–35)

DECIDE / 02

Complaints and undesirable effects.

Most complaints are about a pump that sticks or a cream that separated. Some describe a reaction. Those need a different path, with legal clocks attached.

QUALITY COMPLAINT

- Pump, leak, separation, colour, odour
- Linked to batch code and its record
- Investigated; CAPA where the cause may repeat
- Answered to the consumer or customer

UNDESIRABLE OR ADVERSE EFFECT

- U.S.: serious adverse events reported to FDA within 15 business days, with the label; new information within 1 year also reported [1][5]
- EU: serious undesirable effects notified to the competent authority (Art. 23) [6]
- Severity decided by qualified people
- Records kept for the periods the law sets

U.S. DEFINITION OF A SERIOUS ADVERSE EVENT (SUMMARISED FROM FDA) [1]

An adverse event that results in death, a life-threatening experience, inpatient hospitalisation, persistent or significant disability, a congenital anomaly, an infection, or significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss or persistent alteration of appearance) other than as intended; or that requires medical or surgical intervention to prevent such an outcome.

WHERE V5 FITS

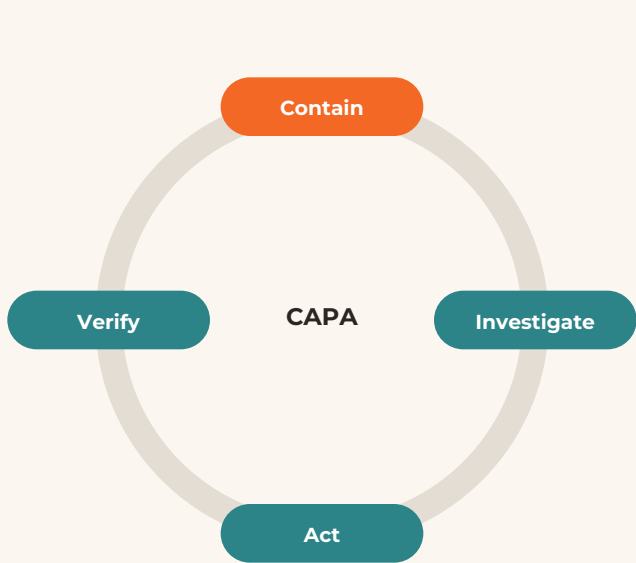
Complaints can be logged with batch code, linked to the batch record and other complaints, and routed to CAPA. A complaint can be flagged for safety review by a named person. V5 does not decide whether an event is serious and does not submit reports to FDA or EU authorities.

Sources: [1], [5], [6] (linked on pages 34–35)

DECIDE / 03

Fix the cause, prove it worked.

Corrective and preventive action turns individual problems into fewer problems. It works only if causes are found, actions are owned, and effectiveness is checked.



- Feed it from everywhere**
Complaints, deviations, out-of-spec results, audit findings, supplier issues, water excursions and trends.
- Root cause, not blame**
Ask why until you reach a cause you can act on: a procedure, a design, a supplier, a training gap.
- Agree effectiveness first**
Decide what evidence shows the action worked, and review it on a date.

WORKED EXAMPLE: A CAPA FROM THREE PUMP COMPLAINTS

Problem	Pumps on 3 batches of body lotion fail to prime
Cause found	New pump lot; actuator tolerance changed by supplier
Action	Incoming check added; SCAR to supplier; change notice clause
Effectiveness	No priming complaints over next 10 batches
Status	Closed after review

WHERE V5 FITS

CAPA records link to their sources, with root-cause workflow, owners, due dates and effectiveness checks. SCARs go to suppliers when the cause is upstream. AI can draft a summary for a person to edit; people own the decisions.

DECIDE / 04

Trained, clean, and permitted.

Gowning, hand hygiene and the right training for each step are part of the product. A filling-room operator who has not done the new line clearance SOP is a risk.

Training

ISO 22716 expects staff trained for their tasks, with training recorded and effectiveness considered [9].

Hygiene and health

Clothing, hand hygiene and reporting of illness or skin conditions, per your procedures [9].

Roles and permissions

Who may dispense, add fragrance, release a lot, approve a label. Write it down and enforce it.

EXAMPLE COMPETENCE AND PERMISSION MATRIX

	Formula rev 9	Line clearance SOP	Micro method	Batch release
Compounder	Trained	Trained	—	Not permitted
Filling operator	—	Retraining due	—	Not permitted
QC analyst	Trained	Trained	Trained	Not permitted
QA manager	Trained	Trained	Trained	Trained

Shared lines, many brands. Contract manufacturers run many customers' products on one line. Make brand-specific instructions visible at the step, in the operator's language, on a tablet that works with gloves.

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 decide who can record, verify, review or release.

Sources: [9] (linked on pages 34–35)

SUSTAIN / 01

Clean, calibrated, maintained.

Vessels, homogenisers, transfer lines and filler nozzles touch product. Thermometers, pH meters and scales decide whether records can be trusted.



Cleaning and sanitising

Validated or verified cleaning between batches and products, with status labels on equipment: dirty, clean, in use [9].

Calibrate what measures

Probes, meters and scales on a schedule, with daily checks. A failed calibration triggers a look-back at batches measured since the last good check.

Maintenance with care

Lubricants, tools and seals near product. Release equipment back to production with a cleaning check.

WHERE V5 FITS

Each vessel, filler and instrument can have an equipment record with cleaning status, calibration schedule, certificates, planned maintenance and use history. Out-of-calibration or uncleaned equipment can be blocked at the kiosk. Predictive failure analytics are not offered today.

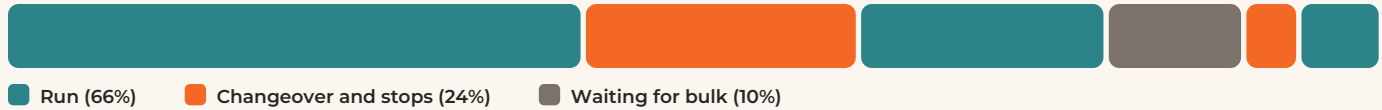
Sources: [9] (linked on pages 34–35)

SUSTAIN / 02

Where the filling line's day goes.

Cosmetics lines run many short orders: shades, sizes, brands. Changeovers, cleans and waiting for released bulk often outweigh speed.

FILLING LINE 2 · ONE 8-HOUR SHIFT (WORKED EXAMPLE)



WORKED OEE ARITHMETIC

Availability

66%

5.3 h run of 8 h planned

Performance

90%

actual vs ideal units per minute

Quality

99%

good units, first time

OEE

58.8% $0.66 \times 0.90 \times 0.99$

Sequence shades

Light to dark, unfragranced to fragranced: fewer full cleans, safer and faster.

Release bulk ahead

Waiting for bulk is usually waiting for a result or a review. Show that status on the filling work order.

Giveaway counts

Overfill above declared content is product given away. Track it with fill-weight data.

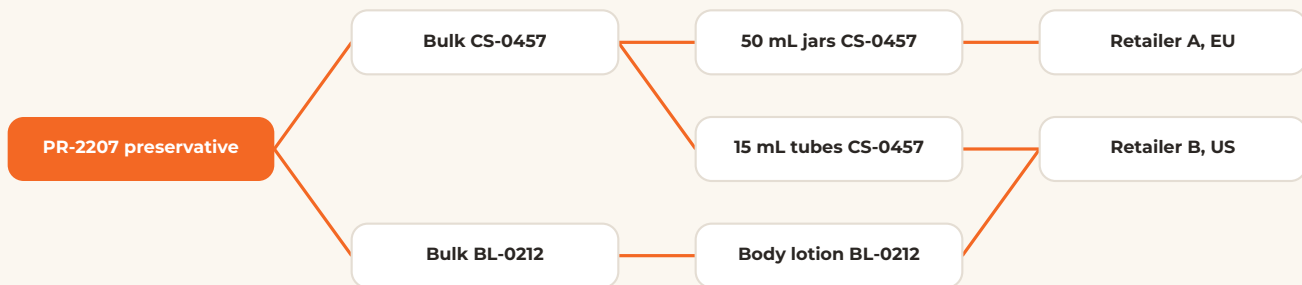
WHERE V5 FITS

Downtime reasons, changeovers, rejects and OEE come from events your team and supported connected machines 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 / 03

Trace both ways, then act.

A preservative supplier reports lot PR-2207 out of specification. Which bulk batches used it, which filled lots, which retailers and markets received them?



One bulk, many packs

A bulk batch can fill several sizes on different days. Each filled lot links back to its bulk and forward to customers.

U.S. recall authority

FDA can order a mandatory recall if a responsible person refuses a voluntary one and the conditions in the law are met [1].

EU corrective measures

Responsible persons act when a product is not in conformity, and inform authorities where it presents a risk (1223/2009) [6].

WHERE V5 FITS

Lots link at receipt, dispensing, bulk, filling and shipment, so genealogy can be followed forward from a raw material lot or back from a complaint, with customers and quantities listed. Recall and notification decisions stay with your team.

Sources: [1], [6] (linked on pages 34–35)

SUSTAIN / 04

Time a mock recall, unit by unit.

Pick a raw material lot nobody expects, start the clock, and see how long it takes to account for every kilogram of it and every unit it went into.

- 0:00 ● Start: PR-2207 named; QA lead opens the trace
- 0:05 ● Bulk batches found: CS-0457, BL-0212
- 0:13 ● Filled lots and unit counts per bulk
- 0:21 ● Customers and shipped quantities listed
- 0:28 ● Stock on site found and placed on hold
- 0:40 ● Balance: received vs used vs stock vs waste

BALANCE FOR PR-2207 (WORKED EXAMPLE)

Received	25.0 kg in 1 drum
Used in CS-0457	5.0 kg
Used in BL-0212	8.0 kg
In stock (held)	11.8 kg
Recorded waste / samples	0.2 kg
Unaccounted	0.0 kg

Times are an example of what to measure, not a benchmark. Include your customers: a trace that stops at your dock does not take a jar off a shelf.

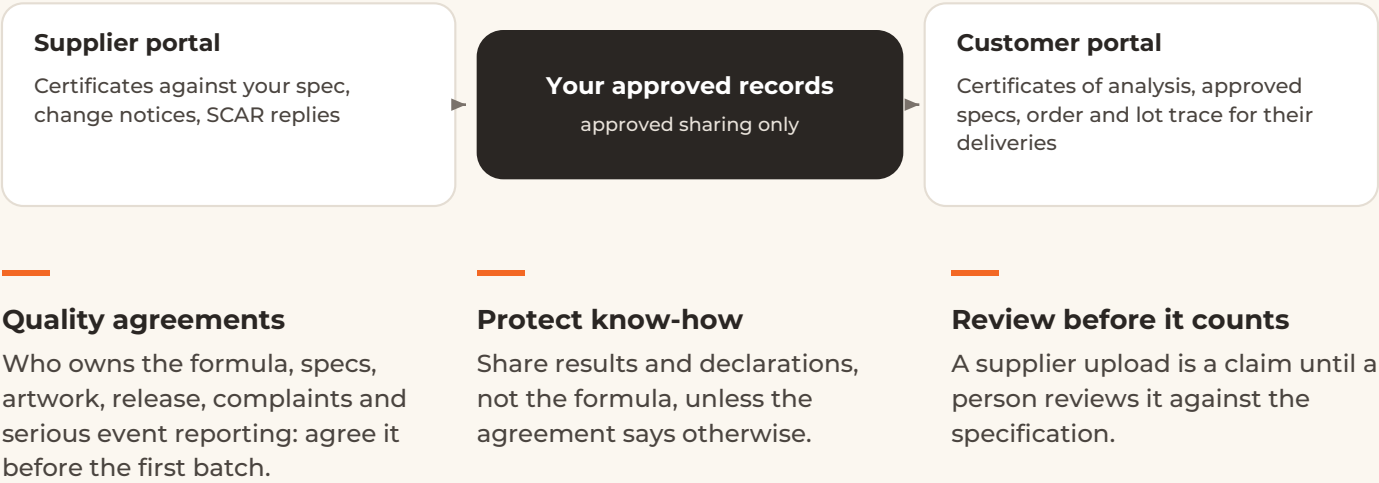
WHERE V5 FITS

Trace reports list bulk batches, filled lots, customers and quantities from a raw material or finished lot, and stock can be held from the trace. Mock recalls can be logged as exercises with times and findings that feed CAPA.

SUSTAIN / 05

Brand owners, suppliers, shared well.

Contract manufacturers share batch results and certificates with brand owners; brand owners share specifications and artwork. Suppliers send certificates and change notices. Each sees only what you approve.



A SHARING POLICY TO AGREE BEFORE ANYONE LOGS IN

Certificate of analysis	After release	Brand owner
Batch record summary	On request, agreed scope	Brand owner
Complaints on their product	Agreed timing	Brand owner QA
Formula details	Not by portal	Your R&D
Supplier certificates and SCARs	Reviewed before they count	Your QA

WHERE V5 FITS

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

SUSTAIN / 06

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.

Made at the time

Records written when the work is done, by the person who did it, are the core of good documentation practice [9].

Records access

MoCRA gives FDA access to certain records, including safety records, when conditions are met [1]. Know where yours are.

Keep the history

Changes to a recorded value should show who, when and why, with the original still visible.

AI CAN HELP

- Read supplier certificate values for a person to confirm
- Draft a formula or SOP from an uploaded sheet for approval
- Suggest a deviation classification or draft a summary
- Explain a batch's history in plain language
- Find records and screens faster

AI NEVER

- Assesses safety or writes safety substantiation
- Decides whether an adverse event is serious
- Approves a label, claim or artwork
- Releases a batch or decides a recall
- Predicts failures 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: [1], [9] (linked on pages 34–35)

APPLY / 01

Evidence map.

One page to check that every theme an auditor, brand owner or inspector may ask about has an owner and a record. Themes follow the structure of ISO 22716 [9]; map them to your own procedures.

THEME	TYPICAL EVIDENCE	WHERE IT LIVES IN V5	OWNER
Personnel	Roles, training, hygiene	Skills matrix, training	HR + QA
Premises	Zones, cleaning, pest control	Checklists, audits	Facilities
Equipment	Cleaning status, calibration	Equipment records	Engineering
Raw materials, packaging	Specs, receipt, release	Suppliers, receiving, LIMS	QA
Production	Batch record, parameters	Formulas, kiosk steps	Production
Finished products	Release, storage, shipment	Release review, shipments	QA
Quality control lab	Methods, results, samples	Lab & QC, LIMS	QC
Out of specification	Investigations	Deviations, LIMS	QC + QA
Subcontracting	Quality agreements	Document control	QA
Deviations	Records, assessments	Deviations	QA
Complaints and recalls	Log, links, mock recalls	Complaints, trace	QA
Change control	Requests, approvals	Change control, docs	QA
Internal audit	Plan, findings, CAPA	Audits, CAPA	QA
Documentation	Controlled documents	Document control	QA

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

WORKSHEET 01

Would yesterday's batch record pass?

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

	YES	PARTLY	NO
Formula revision The record shows the approved formula and revision made.	☐	☐	☐
Equipment clean Vessel and lines were cleaned and released before use, with sign-off.	☐	☐	☐
Every lot Each raw material lot used is recorded with quantity and status at use.	☐	☐	☐
Weights Each addition was within tolerance on a checked scale.	☐	☐	☐
Parameters Actual temperatures, speeds and times are recorded, not just ticks.	☐	☐	☐
Bulk results Bulk tests are recorded against the specification before filling.	☐	☐	☐
Micro Micro results are complete before release, or a documented hold exists.	☐	☐	☐
Fill and code Fill weights, codes and labels checked at the planned frequency.	☐	☐	☐
Deviations Every departure is recorded, assessed and closed before release.	☐	☐	☐
Release An authorised person recorded the release decision.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Ready for a serious complaint?

Walk through one real or invented complaint describing a reaction. Mark Yes, Partly or No.

	YES	PARTLY	NO
Intake Anyone who takes a call or email knows how to log it and escalate.	☐	☐	☐
Batch link The batch code on the unit finds the batch record in minutes.	☐	☐	☐
Label copy The label as sold can be produced (FDA asks for it with a report).	☐	☐	☐
Severity A named qualified person decides whether the event is serious.	☐	☐	☐
Clock The 15-business-day U.S. reporting clock and EU notification path are known.	☐	☐	☐
Follow-up New information within a year is captured and reported where required.	☐	☐	☐
Other batches Similar complaints on other batches are checked.	☐	☐	☐
Safety review The safety assessor or responsible person reviews the case.	☐	☐	☐
CAPA A CAPA is opened if a cause may repeat.	☐	☐	☐
Records Complaint and report records are kept for the period the law sets.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 03

Ask to see it work.

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

	SHOWN	PARTLY	NOT SHOWN
Old revision Try to issue a superseded formula revision to a work order.	☐	☐	☐
Quarantined lot Scan a quarantined raw material at dispensing; show the step stop.	☐	☐	☐
Tolerance Enter an out-of-tolerance preservative weight; show the block.	☐	☐	☐
Phase limit Record a temperature outside limits; show deviation and hold.	☐	☐	☐
Pending micro Try to release a batch with micro pending.	☐	☐	☐
Bulk to packs Fill one bulk into two sizes; trace both back to raw lots.	☐	☐	☐
Code check fail Record a failed code check; show which units are held.	☐	☐	☐
Complaint link Log a complaint by batch code; open the batch record.	☐	☐	☐
Trace From a raw material lot, list bulk, filled lots and customers.	☐	☐	☐
Audit trail Show who changed a recorded value, when and why.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

Roll out in phases.

Start where value is visible and risk is contained. Run paper and system in parallel until each phase is verified.

PHASE 1 Foundations

Scope, roles, document control for SOPs and specifications, training records, equipment register with cleaning and calibration.

PHASE 2 Materials

Raw material and packaging specs, approved suppliers, receiving with quarantine, sampling, retest dates, water monitoring.

PHASE 3 Make

Formulas under revision, dispensing, phase steps on one vessel, bulk testing; paper kept in parallel.

PHASE 4 Control

Filling, codes and labels, micro holds, deviations and out-of-spec, release review.

PHASE 5 Connect

Shipments and genealogy, mock recalls, complaints and CAPA, portals, OEE and loss review.

Tell brand owners early. If batch codes, certificate layouts or label printing will change, agree the switch date and a validation approach with each customer, and run the change through change control.

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, complaints or audit findings.

	E	P	G
Supplier approval Approved before use; requalified on change	☐	☐	☐
Receiving and quarantine Lots held until released	☐	☐	☐
Water Monitored; excursions acted on	☐	☐	☐
Formulas One approved revision; change control	☐	☐	☐
Dispensing Right scale, tolerance, lot scanned	☐	☐	☐
Process parameters Actual values, limits, deviations	☐	☐	☐
Bulk and micro Results before release; holds visible	☐	☐	☐
Filling and codes Weights, codes, labels, reconciliation	☐	☐	☐
Release Authorised person, exceptions first	☐	☐	☐
Cleaning and calibration Status, schedule, look-back	☐	☐	☐
Complaints and events Linked; serious path known	☐	☐	☐
Trace and recall Bulk to packs, both ways, 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 live records.

WEEK 1

Agree the product, the line and the five questions that matter most. Load one formula with phases, specs and checks.

WEEK 2

Run a batch end to end with test data: receipt, dispensing, phases, bulk test, micro hold, filling and release.

WEEK 3

Break it on purpose: old revision, quarantined lot, temperature excursion, pending micro, failed code check.

WEEK 4

Run a timed mock trace and a mock complaint. Review with production, QA, QC, warehouse and IT, and decide next steps.

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

ASK V5

“We make [creams / shampoos / colour cosmetics / fragrances] on [number] lines for [our brands / brand owners] in [markets]. Our hardest moment is [e.g. holding filled stock for micro results]. 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 formula in a trial workspace using test data. The assistant can answer questions about features and plans; it does not give regulatory advice.

SOURCES

Keep the evidence close.

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

- | | | |
|-----|---|-------------------------|
| [1] | <u>U.S. FDA, Modernization of Cosmetics Regulation Act of 2022 (MoCRA)</u>
https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetic... | FDA INFORMATION PAGE |
| [2] | <u>U.S. FDA, Registration and listing of cosmetic facilities and products</u>
https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-... | FDA INFORMATION PAGE |
| [3] | <u>U.S. FDA, Draft Guidance for Industry: Cosmetic Good Manufacturing Practices</u>
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-... | DRAFT FDA GUIDANCE |
| [4] | <u>U.S. eCFR, 21 CFR Part 701: cosmetic labeling</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-G/part-701 | BINDING U.S. REGULATION |
| [5] | <u>U.S. FDA, How to report a cosmetic product related complaint</u>
https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/how-report-cosme... | FDA INFORMATION PAGE |
| [6] | <u>Regulation (EC) 1223/2009 on cosmetic products (EU)</u>
https://eur-lex.europa.eu/eli/reg/2009/1223/oj | BINDING EU REGULATION |
| [7] | <u>Regulation (EU) 2023/1545: fragrance allergen labelling (EU)</u>
https://eur-lex.europa.eu/eli/reg/2023/1545/oj | BINDING EU REGULATION |
| [8] | <u>Regulation (EU) 655/2013: common criteria for cosmetic claims</u>
https://eur-lex.europa.eu/eli/reg/2013/655/oj | BINDING EU REGULATION |

SOURCES

Sources, continued.

[9] [ISO 22716:2007 Cosmetics: Good Manufacturing Practices](https://www.iso.org/standard/36437.html)

VOLUNTARY STANDARD

<https://www.iso.org/standard/36437.html>[10] [Canada, Cosmetic Regulations \(C.R.C., c. 869\)](https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._869/)

BINDING CANADIAN REGULATION

https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._869/[11] [European Commission, Fragrance allergens labelling](https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-products-...)

EUROPEAN COMMISSION PAGE

<https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-products-...>

How to read the status labels. Binding regulations are law in their jurisdiction. FDA web pages explain and announce; draft guidance is not binding and may change. ISO 22716 is a voluntary standard, though in the EU compliance with harmonised standards gives a presumption of GMP.

SCOPE AND LIMITS

This guide is practical orientation for evaluating cosmetics manufacturing operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you; requirements depend on product, classification, market and role. U.S. cosmetic GMP regulations had not been finalised when this guide was checked; confirm FDA's current status. 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 assess safety, decide whether events are serious, submit reports, listings or notifications, approve labels or claims, release batches or decide recalls, and does not by itself make you compliant. Photography is illustrative; batches, results and charts are worked examples, not customer data.



The right formula. Stable batches. Traceable jars.

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