



THE CONTRACT MANUFACTURING & CO-PACKING GUIDE

Your customer's spec. Your plant. One record.

Responsibilities, specs, changeovers and release, by product type

A practical evaluation guide for contract manufacturers, co-packers and the brand owners who use them: who is responsible for what, how customer specifications, changes and supplied materials are controlled, and what evidence each customer should be able to see.



DRUGS

FOOD

SUPPLEMENTS

PEOPLE DECIDE RELEASE

U.S. focus with an EU note / October 2026

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

INSIDE THE GUIDE

One customer lot, start to finish.

Contract manufacturing is an operating model, not a regulation. The product decides which rules apply; the agreement decides who does what. This guide follows one customer lot and shows what the record should hold.

01 / FRAME

pp. 03–04

Which rules, which product

Why a drug quality agreement, food co-packing and supplement work are not the same, and what the FDA guidance covers.

02 / DECIDE

pp. 05–06

Who is responsible

A responsibility matrix, customer assurances in food, and why brand owners stay responsible.

03 / CONTROL

pp. 07–08

Specs, changes, materials

Customer-approved specification revisions, change approvals and customer-supplied material.

04 / MAKE

pp. 09–10

Changeovers, make and test

Line clearance between customers, weighing and steps against the customer's spec, results.

05 / RELEASE

pp. 11–12

Release and evidence

Your decision and the customer's step, lot genealogy, CoAs, complaints and recalls.

06 / APPLY

pp. 13–18

V5 fit, worksheets, sources

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

Who it is for. Quality, technical and customer-service leads at contract manufacturers and co-packers, operations and planning managers running shared lines, and brand-owner quality teams who audit them.

How to read it. Operational pages end with a teal Where V5 fits panel. Everything above it is regulation and practice. Statements cite numbered sources, and the source pages say which are law and which are guidance.

WHERE V5 FITS

V5 records the specifications, changes, materials, production, testing, release and shipping work your procedures and agreements define. It does not write agreements, approve changes for a customer, release product or decide recalls. Those decisions stay with named people.

FRAME / 01

One model, many rulebooks.

The same contract can cover very different products. Start every customer relationship by writing down what the product is, and therefore which rules apply to each party.

PRODUCT	MAIN RULES	SRC
Human or animal drugs	CGMP, 21 CFR 210/211; quality agreements guidance	[1][2][3]
Food (co-packing)	CGMP and preventive controls, 21 CFR 117	[4]
Dietary supplements	Supplement CGMP, 21 CFR 111	[5][6]
Foods on the Traceability List	Extra traceability records, 21 CFR 1 Subpart S	[7]
EU medicines	EU GMP Part I, Chapter 7 (outsourced activities)	[8]
Cosmetics, chemicals, devices	Their own rules; not covered in depth here	—

Classify each product

Record the product type for each customer item. A supplement and a food made on the same line follow different rules.

Guidance is not law

FDA's quality agreement guidance is its current thinking for drugs. It is useful practice elsewhere, but it does not bind a food co-packer [1].

Agreements do not move duties

A contract decides who does a task. It does not remove a party's own legal duties under the rules that apply to it [1][3].

FIVE QUESTIONS BEFORE YOU QUOTE

What is it, and where is it sold?

Product type and market decide the rules for both parties.

Who releases?

Your quality decision, the customer's, or both in sequence.

Who owns the spec and formula?

And who may change them, with what notice.

Who talks to regulators?

Complaints, recalls and inspections: who leads, who supports.

Who supplies which materials?

Bought by you, nominated, or supplied by the customer.

Write it before the first lot

Answers belong in the agreement, not in a sales email.

WHERE V5 FITS

Product master data in V5 can carry the customer, product type and your regulatory notes, so records, labels and reports follow the right template. V5 does not classify products or decide which rules apply.

Sources: [1], [2], [3], [4], [5], [6], [7], [8] (linked on pages 17–18)

FRAME / 02

Drugs: the quality agreement.

For drugs, FDA treats a contract facility as an extension of the owner's own facility (21 CFR 200.10(b)), and the owner's quality unit approves or rejects product made under contract (211.22(a)) [2][3].

WHAT THE 2016 GUIDANCE SAYS [1]

Owners and contracted facilities each remain responsible for CGMP. A written quality agreement should define each party's manufacturing activities, so both know who does what. It does not transfer the owner's responsibility. (Paraphrased; read the guidance.)

Typical contents

Purpose and scope, definitions, how disputes are resolved, and each party's responsibilities, including quality-unit contacts and how they communicate [1].

Change control

How changes to materials, processes, equipment, specifications or sites are proposed, assessed, approved and communicated, and when the owner must agree first [1].

Records and release

Who keeps which records, who reviews batch records, and who performs final release. Under 211.22(a) the owner's quality unit approves or rejects [1][2].

PRACTICAL GAPS TO CHECK IN ANY AGREEMENT

Change thresholds

Which changes need the owner's approval first, and which only notice.

Subcontracting

Whether the facility may use a sub-contractor, such as a test lab, and how the owner is told [1].

Contacts and escalation

Named quality contacts at both parties and how fast deviations are shared.

In the EU, Chapter 7 of EU GMP sets out the contract giver's and contract acceptor's duties for outsourced activities, with a written contract that covers how the Qualified Person certifies batches [8].

WHERE V5 FITS

V5 records which party performed each step, keeps the change history and approvals on controlled revisions, and holds the batch for a named reviewer. It does not draft or interpret your quality agreement.

Sources: [1], [2], [3], [8] (linked on pages 17–18)

DECIDE / 01

Who decides what.

Write one matrix per customer. Most disputes, and many audit findings, start where nobody wrote down who owns a decision. The split below is illustrative: example roles, not a template to copy.

DECISION	BRAND OWNER	CONTRACTOR	EXAMPLE ROLE
Product specification	Approves	Proposes, applies	Brand QA lead
Change to spec or process	Approves if agreed	Assesses, proposes	Brand QA lead
Material supplier choice	May nominate	Qualifies, monitors	Site QA manager
Customer-supplied material	Supplies, CoA	Receives, tests, holds	Site QA manager
Line clearance, cleaning	Audits	Performs, records	Site production lead
Batch record review	Reviews if agreed	Reviews	Site QA reviewer
Final release (drugs)	Approves or rejects	Reviews own work	Owner quality unit
Complaints	Receives, decides	Investigates site	Brand QA lead
Recall decision	Leads market action	Supports, trace data	Brand recall lead

Name people, not companies. For each line, record the role at each party and their contact. A matrix that says only 'customer' fails at 2 a.m. on a deviation.

HOW TO BUILD YOUR MATRIX

Start from the agreement

List every decision the agreement mentions, then the ones it does not.

One owner per line

Others may review or be told; only one role decides.

Test it on a deviation

Walk a real past deviation through the matrix and see where it stalls.

WHERE V5 FITS

V5 can route approvals to named roles, show who signed each step, and record a customer's decision by the person who made it. Who must approve what comes from your agreement; V5 does not approve anything on a customer's behalf.

Sources: [1], [2] (linked on pages 17–18)

DECIDE / 02

Food and supplements: different mechanics.

Food co-packing and supplement contract work do not use the drug quality agreement model in law, but they still need written responsibilities [4][5].

Food: relying on your customer

Under 21 CFR 117.136, a manufacturer may skip a preventive control when its customer controls the hazard, but only if it discloses that the food is 'not processed to control [hazard]' and obtains the written assurances 117.137 describes [4].

Food: supply-chain program

When a hazard in a raw material is controlled before receipt, Part 117 Subpart G sets supply-chain controls, including for materials a customer supplies [4].

Supplements: Part 111

Part 111 applies to firms that manufacture, package, label or hold supplements, and Subpart G covers product received for packaging or labeling [5][6].

Brand owners stay accountable

FDA has repeatedly said that a firm can contract out operations, not its responsibility for the product it sells. Write down who does each Part 111 task [5][6].

	DRUGS	FOOD	SUPPLEMENTS
Main U.S. rules	21 CFR 210/211	21 CFR 117	21 CFR 111
Written split of duties	Quality agreement (guidance)	Contract; 117.137 assurances	Contract; your procedures
Who approves product	Owner's quality unit	As agreed; both have duties	As agreed; both have duties

TRACEABILITY LIST FOODS

If a customer's food is on FDA's Food Traceability List, Subpart S adds key data elements for critical tracking events. Check the current compliance date before planning [7].

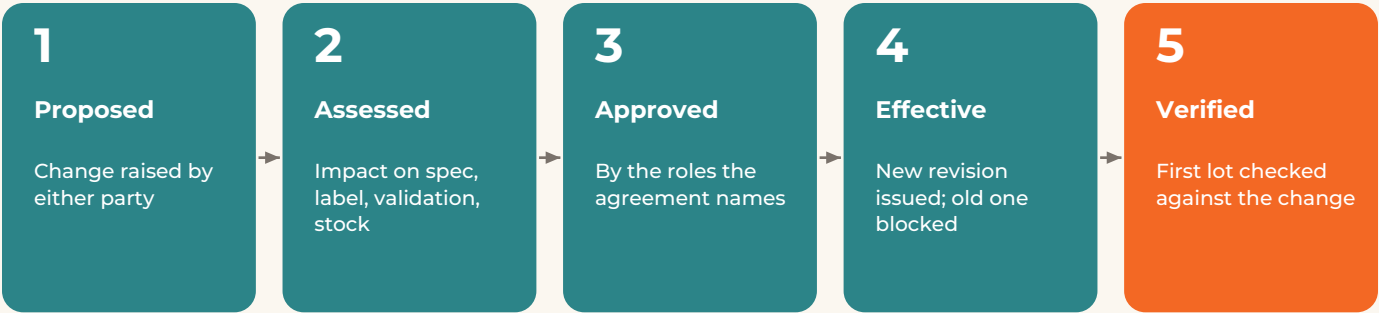
WHERE V5 FITS

V5 can store written assurances and supplier documents against the customer and material, and record traceability events by lot. It does not judge whether an assurance is adequate.

CONTROL / 01

The customer's latest approved version.

The most common contract-manufacturing failure is simple: the floor runs an old revision. A controlled specification has one current version, a history, and a recorded approval.



One source of truth

Keep the customer's specification, formula, pack instructions and label artwork as linked controlled revisions, not attachments in email.

Stock on hand

A change can strand labels, packaging or customer-supplied material. Decide its disposition as part of the change.

Who approves

Record each approval by a named person at each party, with the date the new revision takes effect.

REVISION	APPROVAL	STATUS	USE
Rev B	Superseded 14 Sep	Kept for history	Not for new work
Rev C	Customer approved 14 Sep	Effective 21 Sep	Current
Rev D	Proposed: new pack size	Impact assessment open	Not approved

Example: what a planner should see for one customer specification. Dates and revisions are illustrative.

WHERE V5 FITS

V5 document control and change control record the impact assessment, approvals and effective revision; formulas use two-signature approvals; work orders are issued from the approved revision. Customer specifications can capture how the pack must read.

CONTROL / 02

Their materials, kept apart.

Brand owners often supply key ingredients, actives, fragrances or printed packaging. Treat ownership as a property of the lot, not a note on a pallet.



Identify the owner

Record which customer owns each lot at receipt, with their lot number and documents, so it can only be issued to that customer's work.

Accept, don't assume

Agree what you test on receipt and what you rely on from the customer's CoA. Record the decision either way.

Account for every unit

Reconcile issued, used, wasted and returned quantities per customer. Brand owners ask, especially for actives and printed labels.

STATUS	MEANING	ISSUE?
Pending	Received, not yet accepted	HOLD
Released for use	Accepted; issue to this customer only	OK
Rejected or returned	Disposition recorded with the customer	OPEN

RECONCILIATION EXAMPLE	QUANTITY	NOTE
Received	20.0 kg	Customer lot BO-F-2207
Issued to lots CM-4471, 4472	19.7 kg	Scanned at weighing
Wasted (spill, recorded)	0.1 kg	Recorded per procedure
Returned to customer	0.2 kg	Returned with record

WHERE V5 FITS

V5 receiving records supplier and internal lots, documents and status, blocks issue of pending lots, and reconciles usage by lot. How you record customer ownership (for example as supplier or lot attribute) is set during configuration; ask to see it in a demo.

MAKE / 01

Clear the line between customers.

Shared lines are the commercial point of contract manufacturing and its biggest risk: the previous customer's product, labels or allergens reaching the next run.



Remove

Every material, label, carton and document from the previous run leaves the line and is reconciled.

Clean and verify

Clean to the procedure for that changeover, including allergen or cross-contact steps, and have a second person verify.

First-off check

Check the first labels, codes and packs against the new customer's current spec before running.

ALLERGENS AND CROSS-CONTACT

Sequence the schedule

Plan runs so changeovers from allergen-containing to allergen-free product get the full clean.

Verify the clean

Use the check your procedure sets, such as visual inspection or a test, and record the result.

Labels follow the spec

Allergen statements come from the customer's current label revision, checked at first-off.

WHERE V5 FITS

V5 step sequences put line-clearance steps on the kiosk with sign-off by the person who did them; label and lot scans catch the wrong customer's material; scheduling shows changeovers so allergen and cleaning sequences can be planned.

Sources: [2], [4], [5] (linked on pages 17–18)

MAKE / 02

Make and test to the customer's spec.

During the run, the record should show that each weight, step and result was checked against the customer's current limits, not a generic house standard.



Weigh to the formula

Scan the lot, use a calibrated scale, check the tolerance. Out-of-tolerance entries are flagged before the step closes.

Steps in order

Critical steps and times are recorded as they happen, with the equipment used.

Customer's tests

In-process and finished tests, sample counts and limits come from the agreed specification; pending results stay visible.

Deviations

Anything outside the spec raises a deviation the customer can be told about, as the agreement says.

RECORD LINE, LOT CM-4471	TARGET	ACTUAL	STATUS
Fragrance BO-F-2207 (customer)	4.00 kg	4.01 kg	In tolerance
Emollient base lot RM-7781	180.0 kg	180.2 kg	In tolerance
Mix 20 min at set speed	20 min	20 min	Done
pH, viscosity, fill weight	Customer limits	Recorded	OK
Micro, per agreement	Customer limits	Pending	HOLD

WHERE V5 FITS

V5 weigh and dispense checks the scale, tolerance and lot; step sequences enforce order; LIMS sample plans and results are recorded per lot; deviations and their review stay linked to the lot.

RELEASE / 01

Your decision, and the customer's step.

Release is where responsibilities must be clearest. Record who decided, what they reviewed and, where the agreement says so, the customer's own decision.



Contractor review

Your quality reviewer confirms results, deviations, labels and reconciliation, and records a decision.

Customer disposition

For drugs, the owner's quality unit approves or rejects (211.22(a)) [2]. In other sectors, the agreement decides whether the customer reviews first.

No silent release

A lot with a pending result or open deviation stays on hold until a named person decides.



Example release sequence. Drugs: the owner's quality unit must approve or reject (211.22(a)). Other sectors: a customer step only where the agreement requires it. No agreement removes a legal duty.

NOTHING IS RELEASED AUTOMATICALLY

Software can show that a record is complete. It should not decide that a lot is acceptable, and it should never record a customer's approval that the customer did not give.

WHERE V5 FITS

The V5 QC release queue shows each lot's results, deviations and checks and records the decision with an e-signature. A customer's decision can be recorded by the named person who made it. V5 does not release product or approve on anyone's behalf.

Sources: [1], [2] (linked on pages 17–18)

RELEASE / 02

Show a brand owner their lot, fast.

Customers audit, ask for CoAs, raise complaints and sometimes recall. Each request is faster when the lot record already links everything.



Lot genealogy

From customer-supplied and bought lots to finished pallets and shipments, both ways.

Customer documents

CoA, batch record, deviation summary and trace report for one customer, without other customers' data.

Complaints and recalls

Investigate on the site side and give the brand owner the facts. The brand owner usually leads market action; each regulated party keeps its own legal duties, whatever the agreement says.

Confidentiality cuts both ways. A co-packer holds several brands' formulas and volumes. Any sharing, portal or report must show a customer only their own records.



One customer-supplied lot traced forward to the shipment, and back. A mock recall should produce this list, including consignees.

WHAT A BRAND OWNER USUALLY ASKS FOR

Per lot

CoA, batch record summary, deviations.

Per audit

Training, calibration, cleaning, complaints.

Per incident

Genealogy, shipments, timeline.

WHERE V5 FITS

V5 lot trace, mock recall and shareable reports produce customer evidence; regulated reports include batch records and CoAs; a white-labelled, read-only customer portal for orders, lot trace, CoAs and pack documents is available on supporting plans.

Sources: [4], [7] (linked on pages 17–18)

APPLY / 01

Where V5 fits, and where it does not.

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

TASK	V5 KEEPS THE RECORD	PEOPLE DECIDE
Customer specification	Controlled revisions, two-signature formulas	Spec content, approval
Change	Change control, impact, approvals	Whether to change
Customer material	Receiving, lot status, reconciliation	Acceptance testing
Changeover	Step sequence, sign-off, scans	Cleaning method
Make	Weigh & dispense, steps, equipment	Limits and tolerances
Test	LIMS sample plans, results, OOS	Methods, judgement
Deviation	Structured deviations, CAPA	Root cause, disposition
Release	QC release queue, e-signature	The release decision
Evidence	Lot trace, reports, customer portal*	What to share
Recall	Mock recall, shipments by lot	Recall decision

***Plan-dependent:** customer portal and other capabilities depend on plan; IQ/OQ and validation support are Enterprise only, scoped in the accepted quote or statement of work. **Coming soon, not available today:** AI demand and yield forecasting and process anomaly detection.

WHERE V5 FITS

Nothing in V5 approves a change for a customer, releases a lot or starts a recall. It keeps the evidence connected so the people who make those decisions can see it.

WORKSHEET 01

Responsibility check for one customer.

Use with one real customer agreement. Tick what is written down today, not what everyone assumes.

	WRITTEN	PARTLY	NOT WRITTEN
Product type and rules Recorded for every item you make for this customer	☐	☐	☐
Specification approver Named role at the customer, with a deputy	☐	☐	☐
Change approval Which changes need the customer's prior approval	☐	☐	☐
Customer-supplied material Who tests, what the CoA covers, how it is reconciled	☐	☐	☐
Supplier choice Who selects and who qualifies material suppliers	☐	☐	☐
Line clearance Procedure and verifier for changeovers to this customer	☐	☐	☐
Deviations Which ones the customer must hear about, and how fast	☐	☐	☐
Release Who reviews, who decides, where the customer's step sits	☐	☐	☐
Complaints and recall Who investigates, who decides, who contacts regulators	☐	☐	☐
Records Who keeps which records, for how long, in what form	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Questions for any software demo.

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

	SHOWN	PARTLY	NOT SHOWN
Old revision Try to schedule a superseded spec revision; show the block.	☐	☐	☐
Change approval Raise a change; show assessment, approvals and effective date.	☐	☐	☐
Customer material Try to issue customer A's lot to customer B's order.	☐	☐	☐
Line clearance Show signed clearance steps and the second-person check.	☐	☐	☐
Wrong label Scan the previous customer's label at first-off; show the result.	☐	☐	☐
Pending result Try to release with a result still pending.	☐	☐	☐
Customer's step Record a customer review by a named person; show the signature.	☐	☐	☐
Customer evidence Produce one customer's CoA and trace with no other data.	☐	☐	☐
Mock recall From one customer-supplied lot, list shipments, timed.	☐	☐	☐
Audit trail Show who changed a value, when and why.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

A fair evaluation in four weeks.

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

WEEK 1

Pick one customer product and the five questions that matter most. Load its spec, materials and responsibilities.

WEEK 2

Run a lot end to end with test data: receipt of customer material, changeover, make, test, release review.

WEEK 3

Break it on purpose: old revision, wrong customer's lot, wrong label, pending result.

WEEK 4

Produce customer evidence and a timed mock recall. Review with QA, operations, customer service and IT.

Rules for the evaluation. Use test data only, never a customer's real formula without their consent. Keep current records and release live until a validated change is approved. Record what was shown, not what was promised.

ASK V5

"We make [product types] for [number] brand owners on [number] lines. Our hardest moment is [e.g. changeovers between customers]. Which workflows should we evaluate first?"

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

WHERE V5 FITS

Try V5 with one product in a trial workspace using test data. The assistant answers questions about features and plans; it does not give regulatory or contractual advice.

SOURCES

Keep the evidence close.

Primary sources behind this guide, checked 2 October 2026. Click a title to open the publisher's page.

- | | | |
|-----|---|---------------------------|
| [1] | <u>U.S. FDA, Contract Manufacturing Arrangements for Drugs: Quality Agreements (guidance, Nov 2016)</u>
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contract-manufacturing-arrangements-for-drugs-quality-agreements-guidance-nov-2016 | FDA GUIDANCE (NONBINDING) |
| [2] | <u>U.S. eCFR, 21 CFR Part 211: CGMP for finished pharmaceuticals (211.22 quality control unit)</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211 | BINDING U.S. REGULATION |
| [3] | <u>U.S. eCFR, 21 CFR 200.10: contract facilities as an extension of the manufacturer</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-200/subpart-A-200.10 | BINDING U.S. REGULATION |
| [4] | <u>U.S. eCFR, 21 CFR Part 117: CGMP and preventive controls for human food</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117 | BINDING U.S. REGULATION |
| [5] | <u>U.S. eCFR, 21 CFR Part 111: CGMP for dietary supplements</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-111 | BINDING U.S. REGULATION |
| [6] | <u>U.S. FDA, Small Entity Compliance Guide: dietary supplement CGMP (Part 111)</u>
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-dietary-supplement-cgmp-part-111 | FDA GUIDANCE (NONBINDING) |
| [7] | <u>U.S. eCFR, 21 CFR Part 1 Subpart S: additional traceability records for certain foods</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-1/subpart-S | BINDING U.S. REGULATION |
| [8] | <u>European Commission, EudraLex Volume 4 (EU GMP), Part I Chapter 7: outsourced activities</u>
https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en | EU GMP GUIDELINE |

SOURCES

Sources, continued.

[9] [U.S. eCFR, 21 CFR Part 11: electronic records and electronic signatures](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11)

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11>

How to read the status labels. Binding regulations are law in the United States for the products they cover. FDA guidance is FDA's current thinking and does not bind you; alternative approaches can satisfy the law. EU GMP is the EU's guideline for medicines.

SCOPE AND LIMITS

This guide is practical orientation for evaluating contract manufacturing and co-packing operations and software. It is not legal, regulatory or contractual advice and does not list every requirement that applies to you. The FDA quality agreements guidance applies to drugs; food and supplement work follow their own regulations, and cosmetics, chemicals and devices are not covered in depth. Regulatory text was checked on 2 October 2026; confirm the current text before relying on it. 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 write agreements, approve changes for a customer, release product or decide recalls, is not validated for your use until you validate it, and does not by itself make you compliant. Photography is illustrative; customers, lots and results are worked examples, not customer data.



Your customer's spec. Your plant. One record.

See contract manufacturing workflows at v5ultimate.com · October 2026