BatchBuddy

Supplement Brand

21 CFR Part 111 Checklist

For Brand Owners & Dietary Supplement Companies

Purpose	Know your obligations as a supplement brand owner under 21 CFR Part 111 — whether you manufacture in-house or through a contract manufacturer
Audience	Supplement brand owners, brand managers, and quality leads at brands using contract manufacturers
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YOUR OBLIGATIONS AS A SUPPLEMENT BRAND OWNER

Why This Checklist Exists

The FDA is explicit: a brand that outsources manufacturing is still fully responsible for 21 CFR Part 111 cGMP compliance. This checklist helps supplement brand owners understand exactly what they're responsible for — and identify gaps before an FDA inspection, retailer qualification review, or recall forces the issue. Rate each item: ✓ **Have it**, ■ **Partial**, or ✗ **Gap**.

SECTION 1: FINISHED PRODUCT SPECIFICATIONS

Ref	Requirement	Priority	Status
SP-1	Written finished product specifications exist for every SKU you brand — identity, purity, strength, and composition	**High**	■ Have it ■ Partial ■ Gap
SP-2	Specifications are linked to your product name, version, and effective date — controlled like a formal document	**High**	■ Have it ■ Partial ■ Gap
SP-3	Every batch produced by your CM is verified against your finished product specifications before release under your label	**High**	■ Have it ■ Partial ■ Gap
SP-4	Out-of-specification results are investigated and documented — not just accepted or ignored	**High**	■ Have it ■ Partial ■ Gap
SP-5	Formula version history is controlled — you know which spec version governed each production lot	**Medium**	■ Have it ■ Partial ■ Gap

SECTION 2: COA REVIEW & SUPPLIER OVERSIGHT

Ref	Requirement	Priority	Status
COA-1	You receive and review a COA from your manufacturer for every lot produced under your label	**High**	■ Have it ■ Partial ■ Gap
COA-2	COAs are verified against your finished product specifications — not just filed	**High**	■ Have it ■ Partial ■ Gap
COA-3	Supplier COAs for raw ingredients are available to you for review — either directly or via your CM's records	**Medium**	■ Have it ■ Partial ■ Gap
COA-4	COA review is documented — you can show who reviewed it, when, and against which specification	**High**	■ Have it ■ Partial ■ Gap
COA-5	Out-of-spec COAs trigger a formal corrective action or rejection — not silent acceptance	**High**	■ Have it ■ Partial ■ Gap

SECTION 3: LOT-LEVEL TRACEABILITY

Ref	Requirement	Priority	Status
LOT-1	Every production lot can be linked back to the ingredient lots that went into it	**High**	■ Have it ■ Partial ■ Gap
LOT-2	Every production lot can be traced forward to every customer who received product from it	**High**	■ Have it ■ Partial ■ Gap
LOT-3	A full lot trace can be completed within 24 hours — without calling your CM and waiting	**High**	■ Have it ■ Partial ■ Gap
LOT-4	Lot numbers on finished product labels match your internal traceability records	**High**	■ Have it ■ Partial ■ Gap

SECTION 4: CAPA & OOS DOCUMENTATION

Ref	Requirement	Priority	Status
CAPA-1	A written procedure exists for investigating out-of-specification (OOS) results	**High**	■ Have it ■ Partial ■ Gap
CAPA-2	Corrective actions are documented with root cause, action taken, and effectiveness verification	**High**	■ Have it ■ Partial ■ Gap
CAPA-3	CAPA records are retained and searchable — not stored in email threads or shared drives	**High**	■ Have it ■ Partial ■ Gap
CAPA-4	Open CAPAs are tracked to closure — you have a live view of unresolved deviations	**Medium**	■ Have it ■ Partial ■ Gap

SECTION 5: RECALL READINESS

Ref	Requirement	Priority	Status
REC-1	A written recall procedure exists — not just a vague plan, but a documented procedure with assigned roles	**High**	■ Have it ■ Partial ■ Gap

Ref	Requirement	Priority	Status
REC-2	You can identify every customer who received product from any given lot within hours	**High**	■ Have it ■ Partial ■ Gap
REC-3	A recall simulation or mock recall has been run in the past 12 months — results documented	**High**	■ Have it ■ Partial ■ Gap
REC-4	Contact information for all distribution customers is current and accessible without hunting through emails	**Medium**	■ Have it ■ Partial ■ Gap

SECTION 6: AUDIT TRAIL & ELECTRONIC RECORDS

Ref	Requirement	Priority	Status
AT-1	All quality records are maintained in a tamper-evident system — not editable spreadsheets or Word docs	**High**	■ Have it ■ Partial ■ Gap
AT-2	Record changes are logged with who made them, when, and why — not silently overwritten	**High**	■ Have it ■ Partial ■ Gap
AT-3	Electronic records meet 21 CFR Part 11 requirements (or paper records are properly controlled)	**High**	■ Have it ■ Partial ■ Gap
AT-4	Records are retained for at least 1 year past the expiration date or 2 years past the manufacture date	**High**	■ Have it ■ Partial ■ Gap

SECTION 7: RETAILER QUALIFICATION READINESS

Ref	Requirement	Priority	Status
RQ-1	You can produce your GMP compliance documentation package within 24 hours of a retailer request	**High**	■ Have it ■ Partial ■ Gap
RQ-2	Third-party GMP audit report is current (within 12-24 months) or can be produced on request	**Medium**	■ Have it ■ Partial ■ Gap
RQ-3	Finished product specifications, COA examples, and lot traceability demo are ready to show a buyer	**High**	■ Have it ■ Partial ■ Gap
RQ-4	Quality agreement with your contract manufacturer is documented and signed	**Medium**	■ Have it ■ Partial ■ Gap

90-DAY COMPLIANCE ACTION PLAN FOR SUPPLEMENT BRANDS

Priority sequence for brand owners using contract manufacturers

Days 1–30: Specifications & Documentation Audit · HIGH PRIORITY

• Audit finished product specifications — verify every SKU has written specs for identity, purity, strength, composition

• Request batch records and COAs from your CM for the past 12 months — review and file systematically

• Identify any lots without traceable records; flag for investigation or documentation reconstruction

• Enroll BatchBuddy and begin importing COAs and linking them to lot records

Days 31–60: Traceability & CAPA · MEDIUM PRIORITY

• Build out lot traceability records for all active and recent production lots

• Document any open OOS results or deviations as formal CAPA records

• Run first lot trace exercise — verify forward and backward trace for your highest-volume SKU

• Confirm your CM has a written recall procedure and your brand has one that covers your distribution network

Days 61–90: Retailer Readiness & Verification · COMPLETE & VERIFY

• Run full bidirectional recall simulation; document results and close any traceability gaps

• Assemble retailer qualification documentation package — specs, COA examples, audit trail, recall procedure

• Confirm quality agreement with your CM is signed and current

• Generate locked BatchBuddy compliance summary — ready for FDA investigator or retail buyer review