BatchBuddy

21 CFR Part 111

Compliance Checklist

For Supplement Contract Manufacturers

Purpose	Self-assessment before FDA inspection or client audit
Regulation	21 CFR Part 111 — Current Good Manufacturing Practice, Dietary Supplements
Audience	Contract manufacturers producing for multiple supplement brands
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HOW TO USE THIS CHECKLIST

21 CFR Part 111 Compliance Self-Assessment

This checklist covers every major subpart of 21 CFR Part 111 — the Current Good Manufacturing Practice regulation for dietary supplements. Use it to assess your facility's compliance posture before an FDA inspection, a third-party GMP audit, or a client qualification review. Each item is rated: ✓ **Compliant**, ■ **Gap**, or ✗ **Not in place**.

SUBPART B — PERSONNEL QUALIFICATIONS (§111.8–§111.16)

§ Ref	Requirement	Priority	Status
§111.8	Written job descriptions exist for every position involved in manufacturing, packaging, labeling, or holding	**High**	■ Compliant ■ Gap ■ Not in place
§111.10	Personnel performing operations that may affect product quality are qualified through education, training, or experience	**High**	■ Compliant ■ Gap ■ Not in place
§111.12	Supervisor for each shift has education, training, or experience to supervise manufacturing operations	**High**	■ Compliant ■ Gap ■ Not in place
§111.14	Written procedures for hygienic practices, health condition exclusions, and re-entry after illness are in place	**Medium**	■ Compliant ■ Gap ■ Not in place
§111.16	Training records are current, accessible, and signed by each employee and their supervisor	**High**	■ Compliant ■ Gap ■ Not in place

SUBPART C — PHYSICAL PLANT & GROUNDS (§111.20–§111.30)

§ Ref	Requirement	Priority	Status
§111.20	Physical plant is of suitable size, construction, and design to facilitate cleaning, maintenance, and operations	**Medium**	■ Compliant ■ Gap ■ Not in place
§111.22	Written cleaning procedures for physical plant exist and are followed	**Medium**	■ Compliant ■ Gap ■ Not in place
§111.24	Plumbing, sewage, toilet, and handwashing facilities are adequate and in good repair	**Low**	■ Compliant ■ Gap ■ Not in place
§111.26	Water supply is adequate, safe, and sanitary where water contacts components or equipment	**Medium**	■ Compliant ■ Gap ■ Not in place
§111.30	Pest control procedures are documented and implemented	**Medium**	■ Compliant ■ Gap ■ Not in place

SUBPART E — EQUIPMENT & UTENSILS (§111.27–§111.35)

§ Ref	Requirement	Priority	Status
§111.27	Equipment and utensils used in manufacturing are of appropriate design, materials, and workmanship	**Medium**	■ Compliant ■ Gap ■ Not in place
§111.30	Written equipment cleaning and sanitizing procedures exist and are followed; records are maintained	**High**	■ Compliant ■ Gap ■ Not in place
§111.35	Calibration of instruments and controls used in manufacturing is documented; out-of-calibration events are investigated	**High**	■ Compliant ■ Gap ■ Not in place

SUBPART F — PRODUCTION & PROCESS CONTROLS (§111.55–§111.87)

§ Ref	Requirement	Priority	Status
§111.55	Master manufacturing records (MMRs) exist for every product produced	**High**	■ Compliant ■ Gap ■ Not in place
§111.60	Batch production records (BPRs) are completed for every batch; records link to the MMR	**High**	■ Compliant ■ Gap ■ Not in place
§111.65	In-process specifications are established and documented in the MMR	**High**	■ Compliant ■ Gap ■ Not in place
§111.70	Finished product specifications exist for every product; batch records verify compliance	**High**	■ Compliant ■ Gap ■ Not in place
§111.75	Before-use and after-use cleaning records for manufacturing equipment are maintained	**Medium**	■ Compliant ■ Gap ■ Not in place
§111.77	Actual yields are calculated and compared to theoretical yields; significant deviations are investigated	**High**	■ Compliant ■ Gap ■ Not in place
§111.80	Laboratory testing of finished products is completed per specifications before release	**High**	■ Compliant ■ Gap ■ Not in place

§ Ref	Requirement	Priority	Status
§111.87	Reserve samples are retained per regulation; storage conditions are documented	**Medium**	■ Compliant ■ Gap ■ Not in place

SUBPART G — PRODUCTION & PROCESS CONTROLS — MULTI-BRAND (§111.55)

§ Ref	Requirement	Priority	Status
CM-1	Separate MMRs exist for each client brand's product programs	**High**	■ Compliant ■ Gap ■ Not in place
CM-2	Client-specific finished product specifications are maintained and verified against each BPR	**High**	■ Compliant ■ Gap ■ Not in place
CM-3	Client COA expectations and delivery formats are documented and followed	**High**	■ Compliant ■ Gap ■ Not in place
CM-4	Records can be produced by client program without exposing other client data	**High**	■ Compliant ■ Gap ■ Not in place

SUBPART H — REQUIREMENT FOR LABORATORY CONTROLS (§111.303–§111.330)

§ Ref	Requirement	Priority	Status
§111.303	Laboratory controls include scientifically valid methods for each component and finished product specification	**High**	■ Compliant ■ Gap ■ Not in place
§111.310	Identity testing is performed on all incoming dietary ingredients from each lot received	**High**	■ Compliant ■ Gap ■ Not in place
§111.315	Identity testing of finished products is completed before release	**High**	■ Compliant ■ Gap ■ Not in place
§111.320	Out-of-specification (OOS) results trigger a formal investigation per written procedure	**High**	■ Compliant ■ Gap ■ Not in place
§111.325	Reserve samples are identified by lot number and stored to support investigation of complaints	**Medium**	■ Compliant ■ Gap ■ Not in place

SUBPART J — PRODUCTION & PROCESS CONTROLS — RECORDS (§111.475–§111.490)

§ Ref	Requirement	Priority	Status
§111.475	Records are kept as original records, true copies, or electronic records that comply with 21 CFR Part 11	**High**	■ Compliant ■ Gap ■ Not in place
§111.480	Records are accessible and retrievable within a reasonable time during an FDA inspection	**High**	■ Compliant ■ Gap ■ Not in place
§111.485	Records are retained for at least one year past the expiration date, or two years past the manufacture date	**High**	■ Compliant ■ Gap ■ Not in place
§111.490	Electronic records have appropriate controls per 21 CFR Part 11 (audit trail, e-signatures, access controls)	**High**	■ Compliant ■ Gap ■ Not in place

SUBPART M — HOLDING & DISTRIBUTING (§111.453–§111.470)

§ Ref	Requirement	Priority	Status
§111.453	Written procedures for holding and distributing components, in-process materials, and finished products exist	Medium	■ Compliant ■ Gap ■ Not in place
§111.455	First-in-first-out (FIFO) or first-expired-first-out (FEFO) practices are documented and followed	High	■ Compliant ■ Gap ■ Not in place
§111.460	Rejected components and finished products are clearly identified and controlled to prevent use	High	■ Compliant ■ Gap ■ Not in place
§111.465	Distribution records link each finished goods lot to customer(s) receiving it	High	■ Compliant ■ Gap ■ Not in place

SUBPART O — CONSUMER COMPLAINTS (§111.553–§111.570)

§ Ref	Requirement	Priority	Status
§111.553	Written consumer complaint handling procedure exists	High	■ Compliant ■ Gap ■ Not in place
§111.560	All complaints are evaluated by qualified personnel; serious adverse events are escalated per MoCRA/DSHEA	High	■ Compliant ■ Gap ■ Not in place
§111.570	Complaint records are maintained and include investigation outcome and any CAPA action taken	High	■ Compliant ■ Gap ■ Not in place

90-DAY INSPECTION READINESS PLAN

Priority action sequence for contract manufacturers

Days 1–30: Foundation · HIGH PRIORITY

• Audit all MMRs — verify each client program has a complete, current MMR

• Audit BPR completeness — identify any lots with missing steps, unsigned checkpoints, or reconstruction

• Verify identity testing records for all dietary ingredients received in the past 12 months

• Confirm all calibration records are current; schedule any overdue calibrations

• Enroll BatchBuddy and begin digital BPR capture for new production batches

Days 31–60: Documentation · MEDIUM PRIORITY

• Import historical BPRs and COAs into BatchBuddy; link to lot records

• Build out CAPA records for any open deviations or pending investigations

• Verify training records for all personnel touching production operations

• Run first bidirectional recall simulation; document gaps found and corrective actions taken

• Review and update finished product specifications for all active client programs

Days 61–90: Verification · COMPLETE & VERIFY

- Conduct internal mock inspection using FDA EIR audit checklist
- Run second recall simulation; verify full trace coverage across all brand programs
- Verify all BPRs from the past 6 months are complete, signed, and searchable
- Confirm COA chain of custody is intact from supplier through finished goods for every lot
- Document inspection readiness in BatchBuddy; generate locked compliance summary report