



**MLKC CONSULTING, LLC**

*Life Science Quality and Regulatory Experts*

## **Dietary Supplement GMP Compliance Checklist**

This checklist provides a step-by-step guide to ensuring compliance with FDA's Good Manufacturing Practices (GMP) for dietary supplements under 21 CFR Part 111. Following these best practices helps prevent regulatory violations, product recalls, and quality failures.

### **Use this checklist to:**

- Verify raw materials and ingredient quality before use
- Maintain detailed batch production records and testing data
- Implement contamination controls and cleaning validation procedures
- Ensure compliance with FDA labeling rules and avoid making unapproved claims
- Train employees on GMP requirements and conduct regular compliance audits

### **1. Ingredient Testing & Supplier Qualification**

- Verify ingredient identity, purity, strength, and composition.
- Require Certificates of Analysis (CoAs) from all suppliers.
- Conduct third-party contaminant testing (heavy metals, pesticides, microbes, allergens).
- Maintain a Supplier Qualification Program with audits.

### **2. Batch Production Records & Documentation**

- Maintain detailed batch production records (BPRs) for each product run.
- Ensure traceability of raw materials, manufacturing steps, and quality checks.
- Use electronic documentation systems (21 CFR Part 11 compliance).
- Conduct internal audits to verify accuracy and completeness.

### **3. Finished Product Testing & Quality Control**

- Perform analytical testing for potency, composition, and contaminants.
- Use stability studies to confirm expiration dates and shelf life.
- Implement a Quality Control (QC) review process before product release.

### **4. Contamination Prevention & Facility Sanitation**

- Establish strict sanitation SOPs and cleaning logs.
- Use segregated production areas to prevent cross-contamination.
- Conduct microbial and heavy metal testing on final products.

## **5. Labeling Compliance & Marketing Claims**

- Follow FDA dietary supplement labeling requirements (21 CFR Part 101).
- Ensure the Supplement Facts panel is formatted correctly.
- Include the FDA disclaimer for structure/function claims.
- Avoid making drug-like claims (e.g., 'treats arthritis').

## **6. Employee GMP Training & Compliance Monitoring**

- Train employees on GMP requirements and FDA regulations.
- Conduct refresher courses and compliance testing.
- Maintain employee training records for FDA inspections.

## **7. FDA Inspection Readiness & Post-Market Compliance**

- Monitor adverse events and report serious reactions to the FDA.
- Keep all compliance records up to date for FDA inspections.
- Perform periodic internal audits to ensure ongoing GMP compliance.

## **Pro Tip: Strengthening Dietary Supplement GMP Compliance**

- \* Conduct supplier audits to ensure raw material quality.
- \* Regularly review FDA warning letters to learn from common industry violations.
- \* Implement Corrective and Preventive Actions (CAPA) for compliance gaps.
- \* Maintain complete and accurate batch records to pass FDA inspections.

## **Need Expert Support for Dietary Supplement GMP Compliance?**

MLKC Consulting, LLC specializes in GMP audits, FDA compliance training, and dietary supplement manufacturing best practices. Contact us for expert guidance!

### **Contact us today for a Consultation!**

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