Comprehensive Compliance Checklist for a Dietary Supplements Company

Quality Management System (QMS)

1. Documented Quality Policy and Objectives ☐ Yes ☐ No
2. Implementation of a Quality Manual in alignment with FDA 21 CFR Part 111 requirements ☐ Yes ☐ No
3. Defined roles and responsibilities for quality oversight ☐ Yes ☐ No
4. Periodic Management Reviews of the QMS ☐ Yes ☐ No
5. Change Control procedures in place and effectively managed ☐ Yes ☐ No

Good Manufacturing Practices (GMP)

6. Compliance with FDA 21 CFR Part 111 (Dietary Supplement GMPs) ☐ Yes ☐ No
7. Controlled manufacturing environment with sanitation procedures ☐ Yes ☐ No
8. Equipment calibration, qualification, and maintenance records ☐ Yes ☐ No
9. Batch production records and Master Manufacturing Records (MMRs) documented and reviewed ☐ Yes ☐ No
10. In-process and finished product testing protocols ☐ Yes ☐ No

Supplier and Raw Material Management

11. Supplier qualification and approval programs ☐ Yes ☐ No
12. Verification of raw material identity, purity, strength, and composition ☐ Yes ☐ No
13. Certificates of Analysis (COAs) for all raw materials ☐ Yes ☐ No
14. Vendor audits and performance evaluations ☐ Yes ☐ No
15. Proper storage and handling of raw materials ☐ Yes ☐ No

Product Testing and Quality Control

16. Identity testing of dietary ingredients ☐ Yes ☐ No
17. Microbial and heavy metal testing protocols ☐ Yes ☐ No
18. Product stability testing to support shelf-life claims ☐ Yes ☐ No
19. Retention of testing records and samples ☐ Yes ☐ No

20. Third-party laboratory qualification ☐ Yes ☐ No

Labeling and Claims Compliance

21. Compliance with FDA labeling regulations (21 CFR Part 101) ☐ Yes ☐ No
22. Verification of ingredient listings and daily values ☐ Yes ☐ No
23. Substantiation of structure/function claims ☐ Yes ☐ No
24. Warning statements as required by FDA ☐ Yes ☐ No
25. Review of marketing materials for compliance ☐ Yes ☐ No

Packaging and Distribution

26. Packaging procedures prevent contamination and mislabeling ☐ Yes ☐ No
27. Compliance with tamper-evident packaging requirements ☐ Yes ☐ No
28. Traceability of products through the supply chain ☐ Yes ☐ No
29. Distribution records maintained and reviewed ☐ Yes ☐ No
30. Recall procedures in place and tested ☐ Yes ☐ No

Training and Employee Competency

31. Documented training programs for all employees ☐ Yes ☐ No
32. Job-specific training and competency assessments ☐ Yes ☐ No
33. Regular GMP training for manufacturing and quality staff ☐ Yes ☐ No
34. Training records maintained and accessible ☐ Yes ☐ No

Internal and External Audits

35. Annual internal audit program covering all operational areas ☐ Yes ☐ No
36. Risk-based audit scheduling and execution ☐ Yes ☐ No
37. Corrective and Preventive Actions (CAPA) management post-audit ☐ Yes ☐ No
38. Supplier and vendor audit program established ☐ Yes ☐ No

Risk Management and Continuous Improvement

39. Implementation of risk assessment procedures for product safety ☐ Yes ☐ No
40. Monitoring of adverse event reports and customer feedback ☐ Yes ☐ No
41. Continuous improvement initiatives for manufacturing and quality processes ☐ Yes ☐ No
42. CAPA effectiveness checks ☐ Yes ☐ No

Regulatory Compliance and Reporting

43. Compliance with FDA, FTC, and state regulations for dietary supplements ☐ Yes ☐ No
44. Timely reporting of serious adverse events to FDA ☐ Yes ☐ No
45. Maintenance of product and facility registrations ☐ Yes ☐ No
46. Compliance with FDA inspections and audit responses ☐ Yes ☐ No

Environmental, Health, and Safety (EHS)

47. Compliance with OSHA and EPA regulations ☐ Yes ☐ No
48. Proper storage and handling of hazardous materials ☐ Yes ☐ No
49. Employee safety training programs ☐ Yes ☐ No
50. Emergency preparedness and response plans ☐ Yes ☐ No

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