Contract Manufacturer Oversight Checklist

12-point oversight checklist for private label supplement brands (21 CFR 111)

Contract manufacturer oversight checks

- ☐ Facility name, address and FDA registration on file
- ☐ Current GMP certificate (and who issued it, and when)
- ☐ Named quality contact at the manufacturer, and a named person at your brand responsible for quality decisions (111.12(b): "You must identify who is responsible for your quality control operations")
- ☐ Signed quality agreement listing who tests, who releases and who handles complaints
- ☐ Written finished-product specification for your SKU (identity, strength, limits for contaminants)
- ☐ Label and packaging specification you approved
- ☐ How dietary ingredient identity is verified (method and example result)
- ☐ Master manufacturing record summary for your product
- ☐ Batch record for your first lot, reviewed by you
- ☐ Certificate of analysis for every lot, checked against your specification
- ☐ Your written release decision for every lot, dated and signed
- ☐ Records kept for at least 1 year past the shelf life date (if you use shelf life dating) or 2 years beyond distribution of the last batch (21 CFR 111.605)

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