Food Production FDA Compliance Checklist (US)

Quality Control | US

DATE	FACILITY	ASSESSOR
____ / ____ / _____		

CGMP (SUBPART B)

	OK	NOT OK
Personnel hygiene practices enforced *21 CFR 117.10*	○	○
Plant and grounds maintained	○	○
Equipment sanitary design and maintenance	○	○
Water supply safe and tested	○	○
Pest control program effective	○	○
Warehousing and distribution adequate	○	○

PREVENTIVE CONTROLS (SUBPART C)

	OK	NOT OK
Written food safety plan *21 CFR 117.126*	○	○
Hazard analysis — biological, chemical, physical	○	○
Process preventive controls with parameters	○	○
Sanitation preventive controls	○	○
Monitoring procedures documented	○	○
Corrective actions and corrections documented	○	○
Verification activities conducted	○	○
PCQI identified and qualified *Preventive Controls Qualified Individual*	○	○

ALLERGEN & LABELLING

	OK	NOT OK
Allergen control plan — Big 9 *FALCPA + sesame (2023)*	○	○
Cross-contact prevention controls	○	○
Label review and verification procedure	○	○
Labels compliant — ingredient and allergen	○	○
Supplier allergen statements on file	○	○

SUPPLY CHAIN & RECALL

	OK	NOT OK
Supply chain preventive controls / FSVP	○	○
Supplier approval programme	○	○
Traceability — one-up / one-back	○	○
Recall plan written and tested	○	○
FDA registration current	○	○

ASSESSMENT SUMMARY

Potential 483 observations identified _____

Priority corrective actions

Assessor signature _____

QA director sign-off _____

Notes

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