

General GMP Audit - Industry Vetted

Template Information

Template ID	general-gmp-audit
Version	v1.0
Language	English (en)
Number of Check Items	70
Source	https://layeraudit.com
Revision Date	2026-10-27
Description	Description: Ensure your operations meet Good Manufacturing Practices (GMP) with this thorough audit template developed by our Industry Expert Partners. It guides you through key areas like PPE, hygiene, facility controls, equipment, raw material/supplier management, storage, production processes, quality, packaging, traceability, and staff training.

Audit Information (to be completed during audit)

Audit Date	
Auditor	
Area / Department	
Escort	

Instructions

1. This template contains 70 check items. Record results in the 'Checklist' worksheet.
2. The source does not define fixed pass/fail options. Fill in results according to your own criteria (e.g. Pass / Fail / N.A.).
3. Scores, conclusions and signatures are entered manually in the 'Scoring & Sign-off' worksheet.
4. For photos or other evidence, enter the evidence number in the 'Notes / Evidence No.' column and archive photos by number.
5. Check item numbers are renumbered consecutively. The mapping to the source rows is recorded in '编号对应表.xlsx' in the delivery package.

General GMP Audit - Industry Vetted — Checklist

No.	Section	Check Item	Result	Notes / Evidence No.
1	Personal Protective Equipment & Hygiene	Employees wear appropriate PPE, including gloves, hairnets, lab coats, and masks, in required areas.		
2	Personal Protective Equipment & Hygiene	PPE is clean, undamaged, and replaced or disposed of according to site procedures.		
3	Personal Protective Equipment & Hygiene	Handwashing stations are accessible, stocked with soap and disposable towels or air dryers, and clearly marked with signage.		
4	Personal Protective Equipment & Hygiene	Employees follow proper handwashing and sanitation protocols before entering production areas.		
5	Personal Protective Equipment & Hygiene	Gowning and de-gowning areas are designated, separated into clean and dirty zones, and properly maintained.		
6	Personal Protective Equipment & Hygiene	Jewelry, cosmetics, and personal items are not worn in restricted areas to prevent contamination.		
7	Personal Protective Equipment & Hygiene	Policies for illness reporting and exclusion from GMP areas are in place and enforced		
8	Cleaning & Sanitation	Cleaning procedures for production areas, equipment, and tools follow documented Standard Operating Procedures (SOPs).		
9	Cleaning & Sanitation	Cleaning chemicals are properly labeled, stored, and used according to manufacturer instructions.		
10	Cleaning & Sanitation	Cleaning logs are accurate, complete, and up to date.		
11	Cleaning & Sanitation	Sanitation verification methods, such as ATP testing and microbial swabs, are performed as required.		
12	Cleaning & Sanitation	Sanitation procedures prevent cross-contamination between cleaning tools used in different areas.		
13	Facility & Environmental Controls	Floors, walls, and ceilings are clean, free of damage, and maintained to prevent dust and debris accumulation.		
14	Facility & Environmental Controls	Lighting is sufficient and properly maintained in production, storage, and inspection areas.		
15	Facility & Environmental Controls	HVAC and ventilation systems regulate temperature, humidity, and air filtration effectively.		
16	Facility & Environmental Controls	Cross-contamination risks are minimized by proper segregation of production areas.		
17	Facility & Environmental Controls	Pest control measures are in place, monitored, and show no signs of infestation.		
18	Facility & Environmental Controls	Water, steam, and compressed air supplies meet purity and quality standards.		
19	Facility & Environmental Controls	Waste disposal systems are functional, properly used, and prevent contamination.		
20	Equipment & Maintenance	Production equipment is maintained on a documented schedule, with all maintenance records up to date.		
21	Equipment & Maintenance	Equipment calibration is performed at defined intervals, with traceable records.		
22	Equipment & Maintenance	Equipment surfaces in contact with product are made of non-reactive, non-toxic, and easy-to-clean materials.		
23	Equipment & Maintenance	Equipment changeovers are documented and performed according to validated procedures.		
24	Equipment & Maintenance	Preventive maintenance schedules are followed for tools and equipment and proper records are maintained		
25	Equipment & Maintenance	Tools and utensils are clean, properly stored, and in good condition.		
26	Equipment & Maintenance	Lubricants, coolants, and other chemicals used in equipment are GMP-compliant and properly labeled.		
27	Equipment & Maintenance	Cleaning and sanitation procedures are followed, with logs completed and verified.		
28	Purchasing	Suppliers are qualified and periodically evaluated for compliance with GMP standards.		
29	Purchasing	Purchase specifications for raw materials, components, and packaging materials are documented and verified.		

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No.	Section	Check Item	Result	Notes / Evidence No.
30	Purchasing	Supplier Certificates of Analysis (COAs) are received and reviewed for each shipment.		
31	Purchasing	Alternative suppliers are identified to prevent production disruptions.		
32	Purchasing	Incoming materials are inspected and approved before being used in production.		
33	Raw Material & Supplier Controls	Raw materials are received from approved suppliers and are accompanied by Certificates of Analysis (COAs).		
34	Raw Material & Supplier Controls	Incoming materials are quarantined until approved for use.		
35	Raw Material & Supplier Controls	Storage conditions for raw materials, including temperature and humidity controls, are maintained and monitored.		
36	Raw Material & Supplier Controls	Allergen-containing raw materials are segregated, labeled, and stored to prevent cross-contamination.		
37	Raw Material & Supplier Controls	FIFO (First-In, First-Out) or FEFO (First-Expired, First-Out) inventory management is followed.		
38	Raw Material & Supplier Controls	Material traceability systems allow tracking from supplier to finished product.		
39	Raw Material & Supplier Controls	Non-conforming materials are clearly identified, segregated, and documented.		
40	Storage & Warehousing	Finished products are stored under appropriate environmental conditions, including temperature and humidity controls.		
41	Storage & Warehousing	Storage areas are clean, organized, and free from potential contaminants.		
42	Storage & Warehousing	FIFO or FEFO inventory management practices are followed.		
43	Storage & Warehousing	Rejected, expired, or non-conforming materials are clearly labeled and segregated.		
44	Storage & Warehousing	Temperature monitoring systems are in place and calibrated to prevent excursions.		
45	Production Process Controls	Batch records are accurate, complete, and reviewed in real time.		
46	Production Process Controls	In-process checks, including weight, temperature, pH, and viscosity, are performed at defined intervals and documented.		
47	Production Process Controls	Line clearance procedures are followed before switching between different products.		
48	Production Process Controls	Product labeling and identification throughout the process are clear and compliant with specifications.		
49	Production Process Controls	Unauthorized materials, such as personal items and unapproved chemicals, are absent from production areas.		
50	Production Process Controls	Deviation management procedures are followed, with deviations investigated, documented, and corrective actions implemented.		
51	Quality Management	A formal Quality Management System (QMS) is in place, documented, and regularly reviewed.		
52	Quality Management	Standard Operating Procedures (SOPs) are current, easily accessible, and followed by employees.		
53	Quality Management	Non-conformances and corrective/preventive actions (CAPA) are documented and addressed effectively.		
54	Quality Management	Internal audits are performed on a regular schedule and findings are acted upon.		
55	Quality Management	Customer complaints and product deviations are investigated, documented, and resolved in a timely manner.		
56	Packaging & Labeling	Packaging materials are intact, clean, and comply with product specifications.		
57	Packaging & Labeling	Labels are applied correctly, legible, and match batch records.		
58	Packaging & Labeling	Label reconciliation procedures prevent mislabeling and excess labels are accounted for.		
59	Packaging & Labeling	Printed codes, such as lot numbers, expiration dates, and barcodes, are accurate and legible.		

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No.	Section	Check Item	Result	Notes / Evidence No.
60	Packaging & Labeling	Packaging equipment is properly maintained and calibrated to ensure consistency.		
61	Traceability & Recall Readiness	Batch records provide full traceability from raw materials to finished products.		
62	Traceability & Recall Readiness	Mock recall exercises are conducted regularly and documented.		
63	Traceability & Recall Readiness	Customer complaints and product deviations are recorded, investigated, and addressed.		
64	Traceability & Recall Readiness	Quarantine procedures for suspect or recalled products are in place and followed.		
65	Employee Training	Employees receive GMP training upon hiring and at regular intervals.		
66	Employee Training	Training records are up to date, documenting the date, topic, and trainer.		
67	Employee Training	Employees demonstrate understanding of GMP principles through observation and performance evaluations.		
68	Employee Training	Refresher training is provided for policy and procedural updates.		
69	Employee Training	Employees are aware of their roles in contamination prevention and product quality assurance.		
70	Employee Training	Training programs are evaluated and updated based on analysis of inspection and audit results and customer feedback		
	Sign Off	Additional notes		

General GMP Audit - Industry Vetted — Scoring & Sign-off

Sign-off

Inspector signature	
Supervisor signature	