Manufacturing Audit Checklist Template

1. Audit Overview

Audit Title

Manufacturing Process Audit

Organization

Company Name, Site, Department

Audit Type

☐ Internal Audit
☐ Supplier Audit
☐ Process Audit
☐ System Audit
☐ Customer / Certification Audit

Applicable Standards

☐ ISO 9001
☐ ISO 14001
☐ ISO 45001
☐ IATF 16949
☐ GMP / GxP
☐ Customer-Specific Requirements
☐ Local Regulatory Requirements

Audit Date(s)

From – To

Auditors

Name, Role, Qualification

Audited Area / Process

Production line, process step, department

Audit Objective

Verification of process conformity, effectiveness, and compliance with applicable standards and internal requirements.

Audit Scope

Processes, shifts, products, and interfaces included in the audit.

2. Audit Rating System

Assessment Result

- Conformity
- Minor Nonconformity
- Major Nonconformity
- Observation / Improvement Opportunity
- Not Applicable

Risk Classification (if applicable)

- Low
- Medium
- High
- Critical

3. Management & Governance

Audit Questions

- Are responsibilities and authorities for the audited process clearly defined?
- Are quality, safety, and operational objectives documented and communicated?
- Are management reviews performed and documented?
- Are audit results and KPIs reviewed by management?
- Are corrective actions tracked and verified for effectiveness?

Evidence

Policies, organizational charts, meeting minutes, KPIs

4. Documentation & Standardized Work

- Are approved procedures and work instructions available at point of use?
- Are documents version-controlled and up to date?
- Do documented procedures reflect actual shopfloor practice?
- Are deviations from standard work formally managed?
- Are training records aligned with current document versions?

Evidence
SOPs, work instructions, document control records, training matrix

5. Process Control & Execution

- Are process steps clearly defined and standardized?
- Are critical process parameters identified and controlled?
- Are monitoring and measurement methods defined?
- Are reaction plans available and known in case of deviation?
- Are process changes formally approved and documented?

Evidence
Process flow charts, control plans, parameter logs, change records

6. Quality Assurance & Product Conformity

- Are inspection and test plans defined and followed?
- Are acceptance criteria clearly specified?
- Is nonconforming product identified, segregated, and controlled?
- Are root cause analyses performed for quality issues?
- Are corrective and preventive actions effective?

Evidence
Inspection records, NCRs, CAPA reports, quality metrics

7. Equipment, Tools & Maintenance

- Is equipment suitable for intended use?
- Is preventive maintenance planned and executed?
- Are calibration and verification activities performed as required?
- Are equipment failures analyzed and addressed?
- Are safety devices functional and tested?

Evidence
Maintenance plans, calibration certificates, equipment logs

8. Materials, Logistics & Traceability

- Is material identification clear and consistent?
- Is traceability ensured across production stages?
- Are storage conditions defined and controlled?
- Are FIFO / FEFO principles applied where required?
- Are supplier materials verified upon receipt?

Evidence
Material labels, batch records, warehouse procedures

9. Health, Safety & Environment (HSE)

- Are risk assessments available and up to date?
- Are hazards identified and mitigated?
- Is PPE defined, available, and used?
- Are emergency procedures established and communicated?
- Are incidents and near-misses recorded and analyzed?

Evidence
Risk assessments, safety instructions, incident reports

10. Training & Competence

- Are competence requirements defined for each role?
- Are employees trained before performing tasks independently?
- Is training effectiveness evaluated?
- Are re-trainings conducted after changes?
- Are external qualifications verified where required?

Evidence
Training records, qualification certificates, competence matrix

11. Data Integrity & Records (critical for GMP / regulated industries)

- Are records complete, legible, and retrievable?
- Are entries traceable to individuals and dates?
- Are changes controlled and documented?
- Are digital systems access-controlled?
- Are data backups and retention rules defined?

Evidence
Records, system logs, access control lists

12. Audit Findings Summary

Finding No.	Description	Standard Reference	Severity	Risk Level

13. Corrective Action Plan

Finding No.	Root Cause	Corrective Action	Responsible	Due Date

14. Effectiveness Verification

- Has the corrective action been implemented?
- Has recurrence been prevented?
- Has the process risk been reduced?
- Is additional monitoring required?

Verification Result
Effective / Partially Effective / Not Effective

15. Audit Conclusion

Overall Assessment

- Audit objectives achieved
- Process capable and controlled
- Improvement actions required

Auditor Statement
The audit was conducted objectively and in accordance with the defined audit scope and applicable standards.

Signatures
Auditor | Audited Area Representative | Management