

MANUFACTURING PROCESS AUDIT CHECKLIST

Facility / Plant Name		Audit Date	
Department / Area		Audit Type	
Lead Auditor		Audit No.	
Auditor(s)		Reference Standard	
Process Owner		Shift / Time	
Scope of Audit		Previous Audit Date	

Roles, Responsibilities, and Stakeholders

Score	Rating	Description	Action Required
<input checked="" type="checkbox"/> / C	Conforming	Requirement fully met, no gaps observed	None
M / MI	Minor NC	Partial compliance; gap unlikely to cause quality/safety issue	Corrective Action
X / MA	Major NC	Significant non-conformance; risk of product failure or unsafe condition	Immediate Action
N/A	Not Applicable	Item does not apply to this process	—
OFI	Opportunity	Observation for improvement, not a non-conformance	Optional

AUDIT CHECKLIST

#	Audit Item / Requirement	Status (C / MI / MA / N/A / OFI)	Observations / Evidence / Comments
1. PROCESS DOCUMENTATION & CONTROL			
1.1	Process flowcharts, SOPs, and work instructions are current, approved, and available at point of use		
1.2	Document revision history is maintained and changes are traceable		
1.3	A formal change control procedure is in place for updating process documentation		
1.4	Control Plan is available, reflects current process, and is aligned with FMEA		
1.5	FMEA (Failure Mode & Effects Analysis) is up-to-date and reviewed after process changes		
1.6	Process Flow Diagram corresponds to the actual production sequence		
1.7	Operators have acknowledged and signed off on applicable work instructions		
2. EQUIPMENT & FACILITIES			
<i>2a. Equipment Condition</i>			
2.1	All production equipment is in good working condition with no unauthorized modifications		
2.2	Preventive Maintenance (PM) schedule is documented and current for all critical equipment		
2.3	Last PM date and next PM date are posted on or near each machine		
2.4	Equipment calibration records are current and within established frequency		
2.5	Breakdown/repair history is logged; recurring failures are tracked and escalated		

<i>2b. Tooling & Fixtures</i>			
2.6	Tooling is identified, stored correctly, and in appropriate condition		
2.7	Tool change history and life-cycle records are maintained		
2.8	Fixtures are validated and carry proper identification markings		
3. SAFETY & ENVIRONMENT (EHS)			
3.1	Personal Protective Equipment (PPE) requirements are posted and observed by all workers		
3.2	Emergency exits, evacuation routes, and assembly points are clearly marked and unobstructed		
3.3	Fire extinguishers are accessible, tagged, and within inspection date		
3.4	Hazardous materials are properly labeled, stored, and accompanied by current Safety Data Sheets (SDS)		
3.5	Lockout/Tagout (LOTO) procedures are posted and staff are trained on their application		
3.6	Near-miss and incident reporting system is in place and records are accessible		
3.7	Ergonomic risks (lifting, repetitive motion, awkward postures) are identified and mitigated		
3.8	Housekeeping standards (5S) are maintained throughout the production area		
4. QUALITY MANAGEMENT			
<i>4a. Incoming Materials</i>			
4.1	Incoming inspection procedure is followed; acceptance criteria are defined		
4.2	Non-conforming incoming materials are segregated, labeled, and quarantined		
4.3	Material traceability (lot numbers, certificates of conformance) is maintained through production		

<i>4b. In-Process Quality</i>			
4.4	In-process inspection checkpoints are defined in the Control Plan and are being followed		
4.5	Statistical Process Control (SPC) charts are current, within control limits, and reviewed regularly		
4.6	First Article Inspection (FAI) records are available for new/changed parts		
4.7	Measurement equipment used at inspection stations is calibrated and identified		
<i>4b. In-Process Quality</i>			
4.4	In-process inspection checkpoints are defined in the Control Plan and are being followed		
4.5	Statistical Process Control (SPC) charts are current, within control limits, and reviewed regularly		
4.6	First Article Inspection (FAI) records are available for new/changed parts		
4.7	Measurement equipment used at inspection stations is calibrated and identified		
<i>4c. Non-Conforming Product</i>			
4.8	Non-conforming products are clearly identified, segregated from conforming product, and tagged		
4.9	Disposition decisions (rework, scrap, return) are documented and authorized		
4.10	Rework instructions are documented; reworked product is re-inspected before release		
4.11	Scrap rate data is tracked, trended, and reviewed in management meetings		

5. PRODUCTION OPERATIONS			
5.1	Production scheduling system is in use and production orders are readily accessible to operators		
5.2	Work-in-progress (WIP) is clearly identified with job/work order numbers and quantity		
5.3	Cycle times and takt times are defined; actual vs. target performance is monitored		
5.4	Line balancing or workload distribution has been assessed and optimized		
5.5	Set-up procedures and changeover instructions (SMED) are documented and followed		
5.6	Production output and downtime are recorded in real time or at shift end		
5.7	Traveler / router documents accompany work orders through each production stage		
6. MATERIALS & INVENTORY MANAGEMENT			
6.1	Raw materials and components are stored in designated locations with proper labeling		
6.2	FIFO (First-In, First-Out) or FEFO material rotation practice is followed		
6.3	Inventory levels are monitored; reorder points and min/max levels are defined		
6.4	Obsolete or expired materials are identified and removed from active stock		
6.5	Material handling methods prevent damage, contamination, or mix-up		
7. HUMAN RESOURCES & TRAINING			
7.1	Training matrix is current and covers all critical process operations and safety requirements		
7.2	New employee on-boarding includes process-specific orientation and verification of competency		

7.3	Cross-training plan exists to ensure process continuity during absences		
7.4	Operator certification records are documented and re-certification intervals are defined		
7.5	Awareness of quality policy, objectives, and customer requirements is confirmed among staff		
8. PACKAGING, LABELING & SHIPMENT			
8.1	Packaging specifications are documented and match customer or regulatory requirements		
8.2	Finished goods are correctly labeled with part number, revision, quantity, and lot/ batch ID		
8.3	Final inspection or sampling plan is completed prior to packaging and shipment		
8.4	Finished goods are stored in designated, organized locations and protected from damage		
8.5	Shipping records, packing slips, and COC/ COA documents are complete and accurate		
9. CORRECTIVE & PREVENTIVE ACTIONS (CAPA)			
9.1	Open CAPA items from previous audits have assigned owners and due dates		
9.2	CAPA effectiveness verification (re-audit / check) is performed after closure		
9.3	Root cause analysis method (5-Why, Fishbone, 8D) is documented for each major NC		
9.4	Lessons learned are captured and horizontally deployed to similar processes		
9.5	Customer complaints are tracked; containment and corrective actions are timely		

10. CONTINUOUS IMPROVEMENT & KEY PERFORMANCE INDICATORS				
10.1	Key production KPIs (OEE, yield, scrap rate, on-time delivery) are visible on the shop floor			
10.2	Improvement projects (Kaizen, Lean, Six Sigma) are active and documented			
10.3	Regular performance review meetings are scheduled with records of actions taken			
10.4	Suggestion / employee idea system is in place and ideas are reviewed promptly			
10.5	Benchmarking against industry standards or best practices is performed periodically			

AUDIT SUMMARY & SCORES

Section	Total Items	Conforming (C)	Non-Conformances	Score (%)
1. Process Documentation & Control				
2. Equipment & Facilities				
3. Safety & Environment				
4. Quality Management				
5. Production Operations				
6. Materials & Inventory				
7. Human Resources & Training				
8. Packaging & Shipment				
9. CAPA				
10. Continuous Improvement				
OVERALL TOTAL				

SIGNATURES & APPROVALS

Role	Name (Print)	Signature	Date
Lead Auditor			
Supporting Auditor			
Process Owner / Manager			
Quality Representative			
Facility Manager			

Contact us

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