FREE MANUFACTURING PROCESS TEMPLATE

Process Compliance Checklist

Use this 60-point checklist to audit process requirements, controlled information, people, inputs, execution, safety, quality, records, deviations, change control, corrective action, and sustained performance.

Facility / process	Review date	Process owner	Auditor / reviewer

Internal manufacturing template. Apply current approved procedures, ISO 9001 requirements where applicable, customer requirements, applicable OSHA controls, process specifications, and site risk controls as controlling references.

1. Process ownership, scope, requirements, risks, and compliance criteria

1 **Confirm the process has a clearly defined purpose, scope, start point, end point, owner, responsible functions, and expected outputs.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Start by defining what the process is expected to achieve and which requirements control it. Audit against approved criteria, not against...

2 **Verify applicable customer, product, quality, safety, regulatory, engineering, environmental, and internal requirements affecting the process are identified and current.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Start by defining what the process is expected to achieve and which requirements control it. Audit against approved criteria, not against...

3 **Confirm measurable process requirements and acceptance criteria are defined for critical outputs, controls, handoffs, and compliance decisions.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Start by defining what the process is expected to achieve and which requirements control it. Audit against approved criteria, not against...

4 **Verify process risks, failure modes, hazards, and critical control points are assessed and reflected in operating controls, inspections, escalation, or contingency arrangements.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Start by defining what the process is expected to achieve and which requirements control it. Audit against approved criteria, not against...

5 **Check responsibilities and decision authority are clear for operators, supervisors, quality, maintenance, engineering, EHS, and other functions involved in the process.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Start by defining what the process is expected to achieve and which requirements control it. Audit against approved criteria, not against...

6 **Review previous audit findings, customer complaints, incidents, recurring defects, process escapes, overdue actions, and recent changes before selecting the audit sample.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Start by defining what the process is expected to achieve and which requirements control it. Audit against approved criteria, not against...

2. Controlled procedures, work instructions, forms, and point-of-use information

7 **Confirm current approved procedures, SOPs, work instructions, control plans, specifications, drawings, forms, and checklists are available for the audited process.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Compare the controlled master with what employees actually use. The process cannot be compliant if the current method, form, specification,...

8 **Verify documents at the point of use match the current controlled revision and are legible, accessible, and suitable for the people performing the work.** CRITICAL PROCESS

Compliant | Needs action | Critical — LIVE PHOTO | Add

Execution tip: Compare the controlled master with what employees actually use. The process cannot be compliant if the current method, form, specification,...

9 **Confirm obsolete, superseded, draft, uncontrolled, or locally modified instructions are removed or clearly prevented from unintended use.** CRITICAL PROCESS

Compliant | Needs action | Critical — LIVE PHOTO | Add

Execution tip: Compare the controlled master with what employees actually use. The process cannot be compliant if the current method, form, specification,...

10 **Verify required process limits, quality criteria, safety precautions, hold points, sampling requirements, and escalation rules are clearly documented.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Compare the controlled master with what employees actually use. The process cannot be compliant if the current method, form, specification,...

11 **Check linked documents, forms, electronic screens, reference samples, setup sheets, and system instructions are consistent with one another.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Compare the controlled master with what employees actually use. The process cannot be compliant if the current method, form, specification,...

12 **Confirm changes to controlled process information are reviewed, approved, communicated, and implemented through the organization's document or change-control process.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Compare the controlled master with what employees actually use. The process cannot be compliant if the current method, form, specification,...

3. People, training, competence, authorization, and role readiness

13 **Confirm employees performing the process are trained on the current approved method before independently carrying out assigned work.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Do not rely only on training records. Observe and question the people doing the work to verify they understand the process, limits, controls,...

14 **Verify competency records identify the employee, required process or task, training date, trainer or assessor, status, and any required refresher or requalification.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Do not rely only on training records. Observe and question the people doing the work to verify they understand the process, limits, controls,...

15 **Observe sampled employees and confirm their actual work sequence and decisions match the approved process requirements for critical steps.** CRITICAL PROCESS

Compliant | Needs action | Critical

LIVE PHOTO | Add

Execution tip: Do not rely only on training records. Observe and question the people doing the work to verify they understand the process, limits, controls,...

16 **Confirm employees understand critical quality requirements, process limits, safety hazards, prohibited practices, abnormal conditions, and stop or escalation criteria.** CRITICAL PROCESS

C | PC | NC | NA

Execution tip: Do not rely only on training records. Observe and question the people doing the work to verify they understand the process, limits, controls,...

17 **Verify authorization controls prevent unqualified personnel from changing protected settings, releasing product, approving deviations, or performing restricted technical work.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Do not rely only on training records. Observe and question the people doing the work to verify they understand the process, limits, controls,...

18 **Check staffing, supervision, workload, shift coverage, and access to support functions are adequate to maintain the defined process without routine shortcuts or uncontrolled workarounds.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Do not rely only on training records. Observe and question the people doing the work to verify they understand the process, limits, controls,...

4. Inputs, materials, equipment, utilities, tooling, and pre-process readiness

19 **Confirm raw materials, components, packaging, consumables, information, or other process inputs match the approved specification and required release status.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: A compliant process starts with compliant inputs. Verify the identity and status of materials, equipment, tooling, utilities, and measurement...

20 **Verify equipment, machines, fixtures, tooling, change parts, and work areas used for the process are suitable, identified, available, and in acceptable condition.** CRITICAL PROCESS

Compliant | Needs action | Critical

LIVE PHOTO | Add

Execution tip: A compliant process starts with compliant inputs. Verify the identity and status of materials, equipment, tooling, utilities, and measurement...

21 **Confirm required utilities such as electrical power, compressed air, water, steam, gas, vacuum, ventilation, extraction, temperature control, or other services are available within approved conditions.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: A compliant process starts with compliant inputs. Verify the identity and status of materials, equipment, tooling, utilities, and measurement...

22 **Verify measuring, monitoring, inspection, or test equipment required for the process is available and within calibration or verification status.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: A compliant process starts with compliant inputs. Verify the identity and status of materials, equipment, tooling, utilities, and measurement...

23 **Check pre-start, line-clearance, cleaning, setup, sanitation, maintenance-release, material-verification, or other readiness checks required by the process have been completed.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: A compliant process starts with compliant inputs. Verify the identity and status of materials, equipment, tooling, utilities, and measurement...

24 **Confirm damaged, contaminated, unidentified, obsolete, expired, quarantined, unreleased, or otherwise unsuitable inputs and equipment are prevented from unintended use.** CRITICAL PROCESS

Compliant | Needs action | Critical

LIVE PHOTO | Add

Execution tip: A compliant process starts with compliant inputs. Verify the identity and status of materials, equipment, tooling, utilities, and measurement...

5. Process execution, sequence, critical parameters, and operational discipline

25 Observe the process and confirm required activities are performed in the approved sequence without unauthorized omission, substitution, or reordering of critical steps.

CRITICAL | PROCESS

Compliant | Needs action | Critical

LIVE PHOTO | Add

Execution tip: Follow the actual process from start to finish. Focus on skipped steps, repeated manual corrections, parameter drift, unapproved adjustments,...

26 Verify critical parameters such as speed, time, temperature, pressure, torque, dimensions, concentration, quantity, flow, or other controlled conditions remain within approved limits.

CRITICAL | PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Follow the actual process from start to finish. Focus on skipped steps, repeated manual corrections, parameter drift, unapproved adjustments,...

27 Confirm specified tools, fixtures, recipes, machine programs, materials, methods, quantities, cycle conditions, and standard-work requirements are used consistently.

CRITICAL | PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Follow the actual process from start to finish. Focus on skipped steps, repeated manual corrections, parameter drift, unapproved adjustments,...

28 Check alarms, interlocks, sensors, counters, reject devices, error-proofing controls, and automated monitoring required by the process remain enabled and functional.

CRITICAL | PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Follow the actual process from start to finish. Focus on skipped steps, repeated manual corrections, parameter drift, unapproved adjustments,...

29 Verify adjustments outside normal operator authority are approved, documented, traceable, and performed only by authorized personnel.

CRITICAL | PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Follow the actual process from start to finish. Focus on skipped steps, repeated manual corrections, parameter drift, unapproved adjustments,...

30 Review recurring shortcuts, undocumented workarounds, excessive manual intervention, repeated resets, frequent parameter changes, or inconsistent methods as potential process-control weaknesses.

PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Follow the actual process from start to finish. Focus on skipped steps, repeated manual corrections, parameter drift, unapproved adjustments,...

6. Safety, machine controls, hazardous energy, PPE, and workplace conditions

31 Confirm machine guards, barriers, interlocks, emergency stops, and other required protective devices remain functional and in place during normal process operation.

CRITICAL | PROCESS

Compliant | Needs action | Critical

LIVE PHOTO | Add

Execution tip: Process compliance includes safe execution. If the normal method depends on bypassing a safeguard, defeating an interlock, or ignoring a...

32 Verify point-of-operation hazards, rotating parts, nip points, moving equipment, hot surfaces, pressure, chemicals, and other process hazards are adequately controlled.

CRITICAL | PROCESS

Compliant | Needs action | Critical

LIVE PHOTO | Add

Execution tip: Process compliance includes safe execution. If the normal method depends on bypassing a safeguard, defeating an interlock, or ignoring a...

33 Where servicing or maintenance exposes employees to unexpected energization, startup, or stored energy, confirm the approved hazardous-energy control procedure is followed.

CRITICAL | PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Process compliance includes safe execution. If the normal method depends on bypassing a safeguard, defeating an interlock, or ignoring a...

34 Verify required PPE is correctly selected, available, serviceable, and worn for the hazards present in the audited process.

CRITICAL | PROCESS

Compliant | Needs action | Critical

LIVE PHOTO | Add

Execution tip: Process compliance includes safe execution. If the normal method depends on bypassing a safeguard, defeating an interlock, or ignoring a...

35 Check required ventilation, extraction, housekeeping, spill control, ergonomics, access, lighting, noise controls, and other workplace conditions support safe process execution.

PROCESS

Compliant | Needs action | Critical

LIVE PHOTO | Add

Execution tip: Process compliance includes safe execution. If the normal method depends on bypassing a safeguard, defeating an interlock, or ignoring a...

36 If the process as performed requires a safeguard bypass, uncontrolled hazardous-energy exposure, or another critical safety violation, stop or contain the activity and escalate immediately.

CRITICAL | PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Process compliance includes safe execution. If the normal method depends on bypassing a safeguard, defeating an interlock, or ignoring a...

7. In-process quality, inspection, measurement, traceability, and product control

37 **Confirm required first-off, in-process, patrol, dimensional, visual, functional, weight, torque, leak, code, packaging, or other inspections occur at the defined stage and frequency.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Trace one live unit or batch through the process. Measurements, inspection results, material identity, process conditions, and disposition should...

38 **Verify inspection and measurement results are evaluated against the current approved specification, drawing, limit, defect standard, control plan, or reference sample.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Trace one live unit or batch through the process. Measurements, inspection results, material identity, process conditions, and disposition should...

39 **Confirm sampling quantity, location, frequency, method, and acceptance criteria match the approved process or quality plan.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Trace one live unit or batch through the process. Measurements, inspection results, material identity, process conditions, and disposition should...

40 **Verify traceability links in-process or finished output to required material lots, equipment, line, operator, shift, process stage, date, batch, or order information.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Trace one live unit or batch through the process. Measurements, inspection results, material identity, process conditions, and disposition should...

41 **Check failed, suspect, quarantined, rejected, reworked, or otherwise nonconforming output is identified, contained, segregated, and prevented from unintended release.** CRITICAL PROCESS

Compliant | Needs action | Critical

LIVE PHOTO | Add

Execution tip: Trace one live unit or batch through the process. Measurements, inspection results, material identity, process conditions, and disposition should...

42 **Confirm required reaction plans are followed when process or quality results exceed limits, including stop, containment, adjustment, inspection, escalation, or revalidation as applicable.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Trace one live unit or batch through the process. Measurements, inspection results, material identity, process conditions, and disposition should...

8. Records, data integrity, handoffs, reconciliation, and process evidence

43 **Confirm required process records are completed at the time work is performed and identify the product or job, date, shift, employee, equipment, and relevant process results.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Sample records from different shifts and employees. The evidence should be attributable, timely, complete, consistent with actual work, and...

44 **Verify manual and electronic records are legible, attributable, accurate, complete, protected from unauthorized alteration, and retained according to the approved record-control process.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Sample records from different shifts and employees. The evidence should be attributable, timely, complete, consistent with actual work, and...

45 **Check corrections preserve the original information and identify the person, date, and reason where required by the organization's data-integrity procedure.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Sample records from different shifts and employees. The evidence should be attributable, timely, complete, consistent with actual work, and...

46 **Confirm material usage, output quantity, scrap, rework, rejects, downtime, labels, inventory movements, or other required process quantities are reconciled where applicable.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Sample records from different shifts and employees. The evidence should be attributable, timely, complete, consistent with actual work, and...

47 **Verify handoffs between functions or process stages communicate the required status, restrictions, open issues, quality holds, maintenance needs, and special instructions.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Sample records from different shifts and employees. The evidence should be attributable, timely, complete, consistent with actual work, and...

48 **Confirm records, attachments, photos, electronic logs, inspection results, approvals, and corrective-action evidence remain linked to the correct process, batch, job, or transaction.** PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Sample records from different shifts and employees. The evidence should be attributable, timely, complete, consistent with actual work, and...

9. Deviations, nonconformance, process changes, abnormal conditions, and restart

49 **Confirm abnormal conditions such as alarms, breakdowns, utility loss, material defects, process drift, quality failures, or missing resources trigger the defined containment and escalation response.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Ask what happens when the process leaves its normal operating window. Employees should know when to stop, what can be adjusted, who...

50 **Verify employees stop or contain the process when conditions exceed their authorized limits rather than relying on undocumented workarounds.** CRITICAL PROCESS

C PC NC NA

Execution tip: Ask what happens when the process leaves its normal operating window. Employees should know when to stop, what can be adjusted, who...

51 **Check process deviations are formally documented with reason, scope, risk, authorization, duration, affected output, temporary controls, and required follow-up where applicable.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Ask what happens when the process leaves its normal operating window. Employees should know when to stop, what can be adjusted, who...

52 **Confirm changes to equipment, tooling, materials, software, recipes, parameters, layout, methods, specifications, or process sequence receive appropriate review before implementation.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Ask what happens when the process leaves its normal operating window. Employees should know when to stop, what can be adjusted, who...

53 **Verify significant process changes are validated, trialed, or otherwise verified as necessary and related documents, training, controls, and records are updated before full release.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Ask what happens when the process leaves its normal operating window. Employees should know when to stop, what can be adjusted, who...

54 **Confirm restart after a major abnormal event, breakdown, process change, or quality hold includes the required readiness checks, safeguard verification, setup confirmation, and product or process approval.** CRITICAL PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Ask what happens when the process leaves its normal operating window. Employees should know when to stop, what can be adjusted, who...

10. Performance review, audit findings, corrective action, effectiveness, and sign-off

55 **Confirm process performance is reviewed using relevant measures such as compliance rate, first-pass yield, defects, scrap, downtime, rework, customer complaints, cycle performance, and overdue actions.**

PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Close process findings only when evidence shows the process itself is more reliable. Trend repeat failures across products, shifts, equipment,...

56 **Assign every process-compliance finding to a named owner with risk level, due date, interim control, required evidence, and escalation route.**

PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Close process findings only when evidence shows the process itself is more reliable. Trend repeat failures across products, shifts, equipment,...

57 **For critical safety, quality, traceability, or customer-impact failures, verify immediate containment protects employees, equipment, product, customers, and the process before normal work continues.**

CRITICAL

PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Close process findings only when evidence shows the process itself is more reliable. Trend repeat failures across products, shifts, equipment,...

58 **Confirm corrective actions address underlying causes such as process design, equipment, materials, training, supervision, documentation, maintenance, measurement, supplier performance, or workload.**

PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Close process findings only when evidence shows the process itself is more reliable. Trend repeat failures across products, shifts, equipment,...

59 **Verify effectiveness through repeat observation, process results, inspection data, record review, audit follow-up, or other objective evidence rather than administrative closure alone.**

CRITICAL

PROCESS

Record / item	Current status	Owner	Evidence	Action

Execution tip: Close process findings only when evidence shows the process itself is more reliable. Trend repeat failures across products, shifts, equipment,...

60 **Record final compliance status, unresolved critical process risks, affected products or operations, follow-up actions, next review date, auditor, process owner, reviewer, date, and management approval.**

CRITICAL

PROCESS

FINAL STATUS | Enter

REVIEWER | Enter

APPROVAL | Enter

Execution tip: Close process findings only when evidence shows the process itself is more reliable. Trend repeat failures across products, shifts, equipment,...