ChecklistGuro

Control Plan Checklist

Process Definition & Documentation

Ensures the process is clearly defined and documented, forming the basis of the control plan.

Process Name

Write something...

Process Description (including flow)

Write something...

Process Location(s)

Write something...

Process Step Number(s)

Enter a number...

Equipment/Machines Used

Write something...

Process Flow Diagram (PFD)

Upload File

Raw Materials Used (and suppliers)

Write something...

Critical Process Parameters (CPP)

Identifies and validates the process parameters that directly influence product quality.

Temperature (during process X)

Enter a number...

Pressure (during process Y)

Enter a number...

Cycle Time (seconds)

Enter a number...

Material Type

- [ ] Material A
- [ ] Material B
- [ ] Material C

Feed Rate (units/minute)

Enter a number...

Equipment Status

- [ ] Operating
- [ ] Idle
- [ ] Maintenance

Justification for CPP Selection

Write something...

Control Methods & Procedures

Details the methods used to monitor and control CPPs, including inspection, measurement, and corrective actions.

Inspection Frequency for CPP X

- [ ] Continuous
- [ ] Hourly
- [ ] Shiftly
- [ ] Daily
- [ ] Weekly

Maximum Allowable Variation for CPP Y

Enter a number...

Detailed Procedure for Measuring CPP Z

Write something...

Equipment Used for CPP Measurement (e.g. Caliper, Gauge)

- [ ] Caliper
- [ ] Micrometer
- [ ] Gauge
- [ ] Other (Specify)

Methods for CPP Control

- [ ] Statistical Process Control (SPC)
- [ ] Automated Adjustment
- [ ] Operator Adjustment
- [ ] Preventative Maintenance

Date of Last Calibration for Measurement Equipment

Enter date...

Time of CPP Measurement

Measurement System Analysis (MSA)

Verifies the accuracy and reliability of measurement systems used to monitor CPPs.

Repeatability (r) Value

Enter a number...

Reproducibility (R) Value

Enter a number...

Equipment Variation (Ev) Value

Enter a number...

Operator Variation (Ov) Value

Enter a number...

Gauge Repeatability and Reproducibility (GR&R) %

Enter a number...

MSA Study Type Performed (e.g., PPAP, Gage R&R)

- [ ] PPAP
- [ ] Gage R&R
- [ ] Attribute Gage R&R
- [ ] Variable Gage R&R
- [ ] Length Study
- [ ] Other

Summary of MSA Study Findings and Conclusions

Write something...

MSA Study Result (Overall Assessment)

- [ ] Acceptable
- [ ] Needs Improvement
- [ ] Unacceptable

MSA Study Completion Date

Enter date...

Process Capability & Performance

Evaluates the process's ability to consistently meet specifications.

Process Cp (Current Process Capability)

Enter a number...

Process Cpk (Current Process Capability Index)

Enter a number...

Target Cp (Desired Process Capability)

Enter a number...

Target Cpk (Desired Process Capability Index)

Enter a number...

Date of Capability Study

Enter date...

Summary of Capability Study Results and Analysis

Write something...

Description of any actions taken to improve process capability.

Write something...

Number of Samples Used in Capability Study

Enter a number...

Is the process currently capable? (Based on target Cpk)

- [ ] Yes
- [ ] No
- [ ] Needs Further Investigation

Control Plan Implementation & Training

Confirms that the control plan is implemented correctly and that personnel are adequately trained.

Number of personnel trained on the Control Plan

Enter a number...

Date of most recent Control Plan training

Enter date...

Summary of Control Plan training content (key topics covered)

Write something...

Training Method Used (e.g., Classroom, Online, On-the-Job)

- [ ] Classroom
- [ ] Online
- [ ] On-the-Job
- [ ] Other

Departments Receiving Control Plan Training

- [ ] Production
- [ ] Quality
- [ ] Maintenance
- [ ] Engineering
- [ ] Other

Verification Method for Training Effectiveness (e.g., Quiz, Observation)

- [ ] Quiz
- [ ] Observation
- [ ] Practical Demonstration
- [ ] Other

Notes on any deviations from the planned training schedule or content.

Write something...

Control Plan Review & Updates

Ensures the control plan is periodically reviewed and updated based on performance data and changes to the process.

Last Control Plan Review Date

Enter date...

Frequency of Control Plan Review (in months)

Enter a number...

Summary of Review Findings & Changes

Write something...

Areas Reviewed During Update (Select all that apply)

- [ ] Process Parameters
- [ ] Measurement Systems
- [ ] Reaction Plans
- [ ] Training Procedures
- [ ] Equipment
- [ ] Materials
- [ ] Supplier Performance

Rationale for Changes Made (if applicable)

Write something...

Impact of Changes on Process Capability (e.g., Sigma Level - if applicable)

Enter a number...

Approval Status of Updated Control Plan

- [ ] Approved
- [ ] Rejected
- [ ] Pending Approval

Reviewer Signature

Reaction Plan (Corrective Action)

Details the steps to be taken when a CPP falls outside of acceptable limits.

Severity Level of Deviation

- [ ] Minor
- [ ] Moderate
- [ ] Major
- [ ] Critical

Detailed Description of Deviation

Write something...

Root Cause Analysis Documentation

Write something...

Corrective Action Proposed

Write something...

Date Corrective Action Implemented

Enter date...

Effectiveness Verification Method

Write something...

Effectiveness Verification Result (e.g., % improvement)

Enter a number...

Verification Result

- [ ] Meets Requirements
- [ ] Does Not Meet Requirements
- [ ] Requires Further Action

Additional Comments/Notes

Write something...

Signature of Person Implementing Correction

Record Keeping & Traceability

Ensures proper documentation of all data related to the control plan and traceability of products.

Date of Record Creation

Enter date...

Lot/Batch Number

Enter a number...

Operator Notes/Comments (any deviations from standard)

Write something...

Quantity Produced

Enter a number...

Record Status (e.g., Complete, Pending Review, Approved)

- [ ] Complete
- [ ] Pending Review
- [ ] Approved
- [ ] Rejected

Attach Supporting Documentation (e.g., Calibration Certificates, Inspection Reports)

Upload File

Method of Traceability (e.g., Serial Numbers, Barcodes, Batch Codes)

- [ ] Serial Numbers
- [ ] Barcodes
- [ ] Batch Codes
- [ ] Unique Identifiers
- [ ] Other

Description of Traceability Method and its Scope

Write something...