ChecklistGuro

Sterilization Equipment Validation Checklist

Document Control & Planning

Ensuring proper documentation and planning is in place for the validation process.

Validation Protocol Number

Enter a number...

Protocol Creation Date

Enter date...

Protocol Review Date

Enter date...

Document Status (Draft/Approved/Revoked)

- [ ] Draft
- [ ] Approved
- [ ] Revoked

Document Scope & Objectives

Write something...

Approved Protocol Document (PDF)

Upload File

Validation Phase (Planning/Execution/Reporting)

- [ ] Planning
- [ ] Execution
- [ ] Reporting

Deviation Handling Procedure Reference

Write something...

Protocol Approver Signature

Equipment Identification & Description

Clearly identifying the sterilization equipment being validated and documenting its key characteristics.

Equipment Name

Write something...

Manufacturer

Write something...

Model Number

Write something...

Serial Number

Enter a number...

Detailed Equipment Description (including configuration)

Write something...

Capacity (e.g., number of trays)

Enter a number...

Cycle Type(s) Validated (e.g., Gravity, Steam Flush, Vacuum)

- [ ] Gravity
- [ ] Steam Flush
- [ ] Vacuum
- [ ] Other (Specify in Long Text)

Equipment Photos/Diagrams

Upload File

Any known modifications to the standard equipment configuration

Write something...

Personnel & Training

Verification of personnel involved in the validation process are appropriately trained and qualified.

Number of Personnel Involved in Validation

Enter a number...

Validation Personnel Roles

- [ ] Validation Lead
- [ ] Equipment Operator
- [ ] Quality Assurance
- [ ] Facility Management

Brief Description of Personnel Training (e.g., manufacturer training, SOP review)

Write something...

Date of Personnel Training

Enter date...

Attach Training Certificates/Records

Upload File

Competency Assessment Performed?

- [ ] Yes
- [ ] No

Details of Competency Assessment (if applicable)

Write something...

Signature of Validation Personnel (Confirmation of Training and Competency)

Validation Protocol Development

Review and approval of the validation protocol including acceptance criteria.

Protocol Purpose and Scope

Write something...

Reference Documents (e.g., SOPs, Manufacturer's Instructions)

Write something...

Number of Validation Runs

Enter a number...

Validation Method (e.g., Release, Non-release)

- [ ] Release
- [ ] Non-Release

Types of Indicators Used (e.g., Biological, Chemical)

- [ ] Biological Indicators
- [ ] Chemical Indicators
- [ ] Class 1 Chemical Indicators
- [ ] Class 1 Rapid Readout Indicators
- [ ] Class 2 Chemical Indicators

Date Protocol Prepared

Enter date...

Acceptance Criteria – Sterility Assurance Level (SAL)

- [ ] 10^-6
- [ ] 10^-3
- [ ] Other (Specify)

Specify 'Other' SAL, if applicable

Write something...

Prepared By

Pre-Validation Equipment Checks

Initial equipment checks to ensure proper function before commencing validation runs.

Equipment Serial Number

Enter a number...

Date of Last Preventative Maintenance

Enter date...

Time of Equipment Startup for Pre-Validation Check

Voltage Reading (Input)

Enter a number...

Pressure Reading (Initial)

Enter a number...

Equipment Cycle Type (e.g., Gravity, Steam Flush, Vacuum)

- [ ] Gravity
- [ ] Steam Flush
- [ ] Vacuum
- [ ] Other

Description of Pre-Validation Checks Performed

Write something...

Visual Inspection - Equipment Condition

- [ ] Excellent
- [ ] Good
- [ ] Fair
- [ ] Poor

Technician Signature - Pre-Validation Check Completion

Validation Runs – Biological Indicators (BIs)

Documentation and results of validation runs using biological indicators to assess sterilization efficacy.

BI Lot Number

Enter a number...

Date of BI Exposure

Enter date...

Time of BI Exposure

BI Incubation Temperature (°C)

Enter a number...

BI Incubation Time (hours)

Enter a number...

BI Result – Positive/Negative

- [ ] Positive
- [ ] Negative

BI Result Comments (e.g., unusual growth, etc.)

Write something...

Upload BI Result Image/Documentation

Upload File

BI Type (e.g., Spore Disc, Strip)

- [ ] Spore Disc
- [ ] Spore Strip
- [ ] Spore Suspension

Validation Runs – Chemical Indicators (CIs)

Documentation and results of validation runs using chemical indicators to verify process parameters.

Cycle Number

Enter a number...

Chemical Indicator Type Used (e.g., MSD, Dye, Integrator)

- [ ] MSD
- [ ] Dye
- [ ] Integrator
- [ ] Other (Specify in LONG_TEXT)

If 'Other' indicator type selected, please specify:

Write something...

Number of Chemical Indicators Used

Enter a number...

Indicator Placement (e.g., Inside, Outside, Top, Bottom)

- [ ] Inside
- [ ] Outside
- [ ] Top
- [ ] Bottom
- [ ] Other (Specify in LONG_TEXT)

If 'Other' indicator placement selected, please specify:

Write something...

Time Indicator Observed (Initial)

Time Indicator Observed (Final)

Photo/Scan of Chemical Indicator Post-Cycle

Upload File

Indicator Result (Based on Manufacturer Instructions)

- [ ] Passed
- [ ] Failed
- [ ] Uncertain/Unreadable

Data Analysis & Evaluation

Review and analysis of data collected during validation runs to determine compliance with acceptance criteria.

BI Spore Count (CFU/mL)

Enter a number...

Incubation Temperature (°C)

Enter a number...

Incubation Time (hours)

Enter a number...

BI Result (Positive/Negative)

- [ ] Positive
- [ ] Negative

CI Result (Passed/Failed)

- [ ] Passed
- [ ] Failed

Summary of Data Analysis

Write something...

Acceptance Criteria Met?

- [ ] Yes
- [ ] No

Detailed Explanation of Results and Justification (if applicable)

Write something...

Attach Raw Data Files (e.g., data logs, instrument printouts)

Upload File

Deviation Handling & Corrective Actions

Documentation of any deviations from the validation protocol and the implementation of corrective actions.

Description of Deviation

Write something...

Severity of Deviation (Minor, Moderate, Major)

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

Root Cause Analysis

Write something...

Corrective Action(s) Implemented

Write something...

Date Corrective Action Implemented

Enter date...

Effectiveness Verification of Corrective Action

Write something...

Verification Status (Satisfactory, Unsatisfactory)

- [ ] Satisfactory
- [ ] Unsatisfactory

Signature of Person Implementing Corrective Action

Validation Report & Documentation

Preparation and review of the final validation report, including all supporting documentation.

Report Summary & Conclusion

Write something...

Validation Protocol Document

Upload File

Raw Data Files (BI & CI Results)

Upload File

Number of Validation Cycles Completed

Enter a number...

Deviations Encountered (Select all that apply)

- [ ] None
- [ ] Parameter Out of Range
- [ ] Equipment Malfunction
- [ ] Documentation Error
- [ ] Other (Specify in Long Text)

Detailed Description of Deviations & Corrective Actions (If Applicable)

Write something...

Report Completion Date

Enter date...

Validation Lead Signature

Report Approval Status

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

Equipment Relocation/Maintenance/Repair Validation

Validation performed after equipment relocation, significant maintenance, or repair.

Description of Relocation/Maintenance/Repair Performed

Write something...

Reason for Relocation/Maintenance/Repair

- [ ] Routine Maintenance
- [ ] Equipment Repair
- [ ] Equipment Relocation
- [ ] Software Update
- [ ] Other (Specify in Long Text)

Date of Relocation/Maintenance/Repair

Enter date...

Time of Relocation/Maintenance/Repair (Start)

Cycle Number on Which Validation was Performed

Enter a number...

Pre-Relocation/Maintenance/Repair Equipment Log/Service Records

Upload File

Software Version (if applicable)

Detailed Description of Post-Maintenance/Repair Checks

Write something...

Technician Signature - Verification of Work Completion

Periodic Revalidation

Documentation of periodic revalidation activities to ensure continued sterilization effectiveness.

Date of Revalidation

Enter date...

Reason for Revalidation (e.g., Time-based, Equipment Modification, Deviation)

- [ ] Time-based (Scheduled)
- [ ] Equipment Modification
- [ ] Process Change
- [ ] Deviation Identified
- [ ] Other (Specify)

Brief Description of Revalidation Activities Performed

Write something...

Biological Indicator (BI) Records

Upload File

Chemical Indicator (CI) Records

Upload File

Number of BI Strips Used

Enter a number...

BI Results: All Positive/Negative?

- [ ] All Negative
- [ ] All Positive
- [ ] Mixed Results (Specify)

Explanation/Details of any Deviation from Expected Results (if applicable)

Write something...

Reviewer Signature