**Protocol Title**

**Equipment ID or Process**

**YEAR**

**Facility Name**

**Address**

|  |  |  |
| --- | --- | --- |
| **WRITTEN BY** | | |
| **Author** | **Title** | **Signature** |
|  |  |  |

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| --- | --- | --- |
| **APPROVALS** | | |
| **Approver** | **Title** | **Signature** |
|  |  |  |
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1. **Purpose**
   1. Define the purpose of validation activity
2. **Scope**
   1. Define the scope of validation activity including limitations or exclusions. Justify your approach.
3. **References**
   1. List any reference documents, include Standards, Regulations, your relevant SOPs, etc.
4. **System Overview**
   1. Short description of equipment or process to be validated
5. **Equipment and Materials**
   1. List all materials and instruments used for the validation. Include calibration dates, if applicable
6. **Definitions/abbreviations**
   1. List definitions or abbreviations relevant to final document
7. **Test Procedure**
   1. List the test procedures to be used
8. **Acceptance criteria**
   1. All test met the predetermined specification as outlined in the test description. Documentation of this protocol and supportive testing (if applicable) was completed and attached.
   2. The test will be considered fail if the actual test results are not reported. The failure of a step does not necessarily mean that execution of the protocol must be interrupted. However, all discrepancies must be resolved prior to the final sign approval of the executed protocol.
9. **Deviations**
   1. If any acceptance criteria are not met, . . .
10. **Test execution (Equipment)**
    1. **Installation Qualification (IQ)**

*Purpose: To document the unit and all subparts, to look for signs of damage or defect, to assure all parts are in working order and to assemble unity to working order.*

***Testing might require:***

* Equipment identification verification
* List of drawing/manuals or room design
* Purchase order verification
* Utility verification
* Software verification
* Component verification
* Calibration/certification verification
* Alarm testing
  1. **Operation Qualification (OQ)**

*Purpose: To assure the functionality of the unit is in working order.*

***Testing required for the OQ may include, but is not limited to:***

* Temperature mapping
* Environmental monitoring
* Sequence of operations
* Sterilization cycle development
* Procedure verification
  1. **Performance Qualification (PQ)**

*Purpose: To verify the unit operates as described and provides reliable readings, data or performance*

*Outline any testing which will provide documented evidence that the equipment under anticipated conditions produces results for predefined requirements.*

Objective: define

Test Procedure: explain

|  |  |  |
| --- | --- | --- |
| Expected Results | Results | Meets Acceptance Criteria (Y/N) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Test performed by/date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewed by/date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Test execution (Process Validation)**
   1. Type: New product or existing product verification
   2. Environment
   3. Sample Size based on Assurance Level and quantity products/year

Basic = 3, Medium = 13, Robust = 20

|  |  |  |  |
| --- | --- | --- | --- |
| **Sa** | **Pre: CFUs present** | **Post: CFUs present** | **Accept?** |
| 01 |  |  |  |
| 02 |  |  |  |
| 03 |  |  |  |

1. **List of Participants:**

|  |  |  |
| --- | --- | --- |
| Participant | Signature | Initials |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **Documentation:**
   1. Outline your documentation requirements here
   2. Attachments: Include any forms, charts, or printouts generated during the performance of this protocol

**Validation Final Report**

**Equipment ID or Process**

**YEAR**

**Facility Name**

**Address**

|  |  |  |
| --- | --- | --- |
| **WRITTEN BY** | | |
| **Author** | **Title** | **Signature** |
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| **APPROVALS** | | |
| **Approver** | **Title** | **Signature** |
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1. **Purpose**
   1. Repeat purpose
2. **Scope**
   1. Repeat scope
3. **Data Summary/Results**

|  |  |  |  |
| --- | --- | --- | --- |
| Tests performed | Acceptance Criteria | Results (or Range of Results) | Met Acceptance Criteria Yes/no |
| Test 1 name |  |  |  |
| Test 2 name |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Or:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sa** | **Pre: CFUs present** | **Post: CFUs present** | **Accept?** |
| 01 |  |  |  |
| 02 |  |  |  |
| 03 |  |  |  |

1. **Deviations** *(What didn’t work as expected? What were the results, cause, impact, and corrective made?)*
   1. **Deviation 1**

Description:

Cause:

Impact:

Corrective Action:

1. **Conclusions**
2. **Attachments**
   1. Executed Protocol
   2. Additional Attachments