|  |  |  |
| --- | --- | --- |
| **C:\Users\GMP003\Downloads\logo of cyclone.jpg** | **Paperless GMP Validation Report** | PROTOCOL NO.: |
| SUPERSEDE NO: |
| DATE: |

**Paperless GMP**

**Validation Report**

|  |  |
| --- | --- |
| **TITLE:** |  |
| **AUTHORING GROUP:** |  |
| **DATE:** |  |
| **SUPERSEDE PROTOCOL NO.:** |  |

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1. **Introduction**

Remark: this report template is not made for design qualification. Use your own report for design qualification.

This document contains the report of IQ/OQ/PQ of Paperless GMP system.

The Paperless GMP system (version x.y.z) was tested on the xxx test platform located in xxx, from the yyyy/mm/dd to the yyyy/mm/dd. The tests of the test phase (ref. software test plan) were executed with protocol ref. protocol and version of protocol.

Tester where:\_\_\_\_\_\_\_\_\_

Tests logs and data are located in…….

List and discuss all bugs, deviations, corrective actions, and resulting changes (especially bug fixes between IQ and OQ or PQ).

1. **Results**

Copy-paste the protocols and add a columns for results.

If protocols are long, it’s better to have a report for each phase of IQ/OQ/PQ

Otherwise IQ/OQ and PQ can be included in a single report, with sections like below:

1. **IQ Results**

|  |  |  |  |
| --- | --- | --- | --- |
| **Requirement** | **Inspection** | **Comment** | **Result** |
| Hardware prerequisites | Verify that PC has at least 4Gb RAM | Use OS control panel  No upper limit | OK |
| Network connexion | Verify that network connexion is at least 100Mb | Use OS control panel  No upper limit | OK |
| OS version | Verify that OS version is Windows 7 SP1 | Use OS control panel  Windows 8 not allowed | OK |
| Software Installation | Verify that software installation log doesn’t contain errors | Log is in directory //Path/to/Directory | OK |

1. **OQ Results**

Add results here (with matrix like below) or reference a report containing results of OQ tests.

|  |  |  |  |
| --- | --- | --- | --- |
| **Test ID** | **Test id** | **Overall result:** | **OK** |
| Test description | Small description |  |  |
| Verified Requirement | Either a req ID like SRS-REQ-001 or a textual sentence |  |  |
| Initial conditions | The state of software before test |  |  |
| Tests inputs | Input data mandatory for the test. Eg: input files name and location |  |  |
| Data collection actions | Recording and post processing of output data |  |  |
| Tests outputs | Output data files names and location, logs … | Give unique name out output data files. |  |
| Expected results and criteria | List here the results of test | And the criteria to evaluate the result |  |
| **Test procedure** |  |  |  |
| **Step number** | **Operator actions** | **Expected result and evaluation criteria** | **Result** |
| 1 | Start foo | Foo is started | OK |

1. **PQ Results**

Add results here or reference a report containing results of PQ tests.

1. **Conclusion**

The system is:

|  |  |
| --- | --- |
| **X** | Compliant |
|  | Compliant with reserves |
|  | Non compliant |

With requirements of quote input documents containing user requirements verified in IQ/OQ/PQ phase(s).