

	<b>Paperless GMP Validation Report</b>	PROTOCOL NO.:
		SUPERSEDE NO:
		DATE:

# Paperless GMP Validation Report

<b>TITLE:</b>	
<b>AUTHORING GROUP:</b>	
<b>DATE:</b>	
<b>SUPERSEDE PROTOCOL NO.:</b>	

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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).

## 2. 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:

### A. 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

## B. 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

## C. PQ Results

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

### 3. Conclusion

The system is:

<b>X</b>	Compliant
	Compliant with reserves
	Non compliant

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