



**Paperless GMP Final
Validation
Report**

PROTOCOL NO.:

SUPERSEDE NO.:

DATE:

**Paperless GMP
Final Validation Report**

TITLE:	
AUTHORING GROUP:	
DATE:	
SUPERSEDE PROTOCOL NO.:	



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1. Introduction

This report contains the results of the Validation Protocol of:

- Paperless GMP system,
- In version :
- Installed/ deployed on:

2. Paperless GMP System Description

<add here a brief description of the validated system.

A. Validation Documentation

List the number, title, revision, and date of all documents referenced in or used in the validation protocol. If this report is an update to the validation of an existing system, list the validation report that document is replacing as a reference document.

Example

The documentation of Paperless GMP validation comprises:

- Computer software validation procedure Vx.x
- Process Risk assessment report Vx.x
- IQ Validation protocol Vx.x
- OQ Validation protocol Vx.x
- PQ Validation protocol Vx.x
- Etc...

B. Hardware description

Target platform where the system was installed.

OR

For software could be installed “anywhere”, the HW and SW configuration prerequisites.



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C. Software version description

<add here the full version number of validated software, or any identifier which allows to identify without any doubt the version of validated software.>

D. Dependencies

Identification of 3rd party software: OS, drivers, ...

E. Storage of version

Describe here where is the master of the validated version.

Eg. In a software configuration management tool, on a shared directory, on a CDROM stored in Quality Department..

F. Residual problems

List residual anomalies or non-closed non-conformities,
Add justification proving that they don't impair the conformity of the process (es) where software is used.

G. Restrictions for use

Restrictions of use are possible when bugs or non-conformities are not closed.

3. Conclusion

The system is:

X	Compliant
	Compliant with reserves
	Non compliant



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With requirements of quote an input document containing user requirements and with normative and regulatory requirements quote applicable regulations and standards.

- **Compliant:** recorded results are compliant and anomalies are closed. Residual anomalies don't impair the conformity of the computerized system or of the process.
- **Compliant with reserves:** one or more recorded results are not compliant but the computerized system can be put in service with work around solutions. Provided that work around solutions are effective, residual anomalies don't impair the conformity of the computerized system or of the process.
- **Non-Compliant:** one or more recorded results are not compliant. Residual anomalies may impair the conformity of the computerized system or of the process.