

RevereIT LLC

Validation Summary Report

Version: 1.41

Validation Summary Report & SOP Development

Validation Report

When the validation project is completed a validation summary report should be generated by the system owner. The report documents the outcome of the validation project. The validation report should mirror the validation project plan and should include:

- A brief description of the system.
- Identification of the system and all software versions that were tested.
- Description of hardware used.
- Major project activities.
- Listing of test protocols, test results and conclusions.
- Statement on system status prior to release.
- List of all major or critical issues and deviations with risk assessment and corrective actions
- Statement that all tasks have been performed as defined in the project plan.
- Statement that validation has been performed according to the documented procedures.
- Listing of all deliverables.
- Final approval or rejection statement.
- The validation report should be reviewed, approved and signed by QA and the system owner.

Standard Operating Procedures

Validation activities should be performed according to written procedures. Generic procedures should be taken from the corporate SOP list. System specific procedures should be developed for the system to be validated. Procedures should be available under the same or a similar title as follows:

1. Training for GxP, 21 CFR Part 11 and Computer Validation
2. Risk Assessment for Systems Used in GxP Environments
3. Validation of Commercial Off-the-Shelf (COTS) Computer Systems
4. Validation of Macro Programs and Other Application Software
5. Risk-Based Validation of Computer Systems
6. Development of User Requirement Specifications for Computers
7. Quality Assessment of Software and Computer System Suppliers
8. Auditing Software Suppliers: Preparation, Conduct, Follow-up
9. Development and Maintenance of Test Scripts for Equipment Hardware, Software and Systems
10. Handling of Problems with Software and Computer Systems.
11. Data Back-Up and Restore
12. Disaster Recovery of Computer Systems
13. Archiving and Retrieval of GMP Data and Other Documents
14. Access Control to Computer Systems and Data
15. Configuration Management and Version Control of Software
16. Change Control of Software and Computer Systems
17. Revalidation of Software and Computer Systems
18. Retention and Archiving of Electronic Records
19. Retirement of Computer Systems
20. Review of Computer Systems
21. Auditing Computer Systems

Please contact Mr. A Gupta at 603-889-3000 X 107 for more details.