RevereIT LLC

Computer Systems Validation – An Introduction

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COMPUTER SYSTEM VALIDATION (CSV)

Computer System Validation (CSV) in regulated operations provides confirmation by examination and provision of objective evidence that computer system validation specifications conform to user needs and intended users, and that all requirements can be consistently fulfilled.

Computer systems validation is not a one-time event. Validation should be considered as part of the complete life cycle of a computer system. This cycle includes the stages of planning, specification, programming, testing, commissioning, documentation, operation, monitoring and modifying.

Validation starts when a user department has a need for a new computer system. The department then considers how the system will solve an existing problem. For an existing computer system, validation starts when a system owner is given the task of bringing the system into a validated state.

Validation ends only when the system is retired. At this point all important quality data should be successfully moved to a new system. Important steps in between these two processes include planning of the validation, defining user requirements, defining functional specifications, defining design specifications, maintaining validation during development, procuring vendor assessment for purchased systems, installation, initial and ongoing testing and change control. Computer systems should be validated during the entire life of the system. The complexity and the extended period of time involved in the computer validation process is often broken down into life cycle phases for clear organization.

Computer system validation is a part of the design validation for a finished device, but is not separately defined in the Quality System regulation. In practice, computer system validation activities may occur both during, as well as at the end of the software development life cycle to ensure that all requirements have been fulfilled.

Drug and medical device manufacturing in the modern world relies increasingly on computerized systems. Being highly regulated industries, ensuring quality and accuracy of data is paramount; and thus, Computer System Validation (CSV) is necessary to assure that critical processes are functioning properly.

FDA: Examples of Computer systems

- Automatic manufacturing apparatus
- Control systems
- Laboratory data capture devices
- Automated laboratory equipment
- Manufacturing execution systems
- Laboratory, clinical or manufacturing database systems (LIMS, CTMS, Documentum)

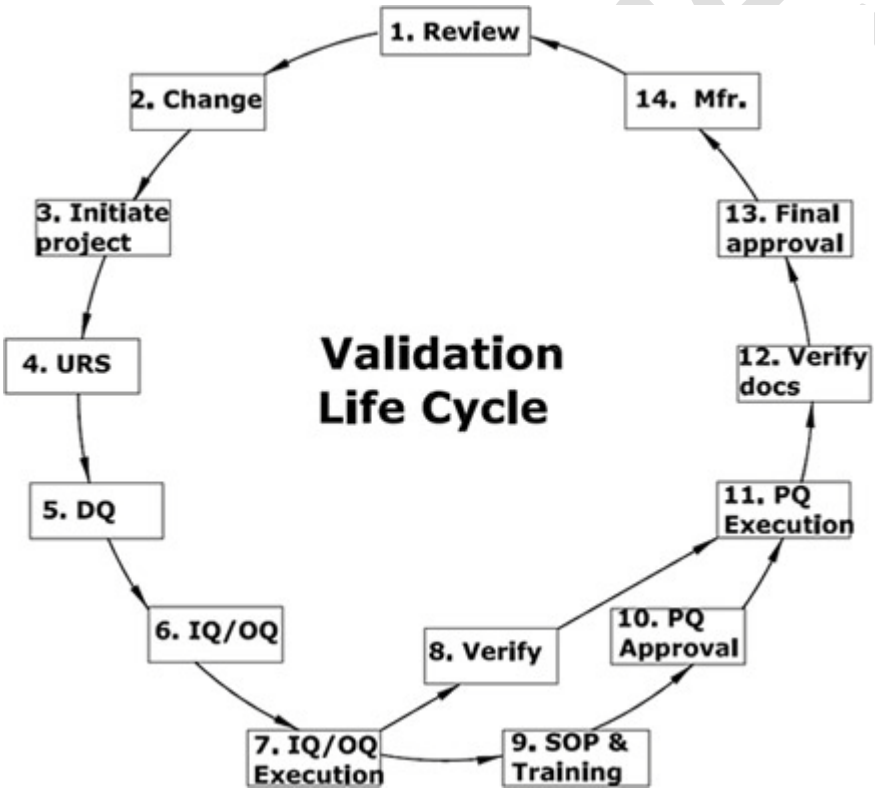
Basic Requirements

Computer system validation requires, first, that you obtain or design a process that can consistently conform to requirements; and then that you run studies demonstrating that this is the case. Both tasks can be performed with the aid of the right statistical tools. Briefly put, the requirements are:

a. Development of a validation plan
b. Utilization of Standard Operating Procedures (SOPs)
c. Documented Training on SOPs
d. Development of detailed specifications
e. Development of a test plan and/or test scripts

Both the FDA and ISO 13485:2003 require computer system validation.

Validation Life Cycle



Benefits of Computer System Validation

- Validation of software can increase the reliability and usability of the systems. This will result in decreased failure rates, fewer recalls and a decrease in the need for corrective actions. It satisfies the very important criteria of leading to less risk for patients and users, and reduces the liability of the manufacturers.
- Validation is also a critical tool for assuring the quality of device software and software automated operations.
- Validation reduces long-term costs by making it easier and less expensive to reliably modify software and revalidate software changes.
- Establishing comprehensive software validation processes can help reduce the long-term cost of software because it reduces the cost of validation for subsequent releases of the software.

Failures of CSV: Without adequate planning and preparation, computer system validation can encounter several problems, eventually leading to failure of the process. Problems include:

1. Inadequate documentation of plans
2. Inadequate definition of what constitutes the computer system
3. Inadequate definition of expected results
4. Inadequate specification of software
5. Software that does not meet its specifications
6. Unavailable source code for software

CSV Challenges: Computer system validation can come up against several challenges, including the risk of system failure, restrictive company policies and increasingly stringent regulatory requirements. Another significant issue is when users need to take action to balance the risk vs. cost equation after risk categories are defined.