Computer System Verification and Validation in the Pharmaceutical Industry

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Abstract

Keywords: verification, validation, software quality control, software development, compliance, GxPThe verification and validation (V&V) are crucial parts of the software development life cycle in regulated areas. These processes assure and demonstrate that the checked computer system consistently produces results that meet specifications and quality requirements. During the development life cycle many requirements, tools and procedures must be applied not only for the sake of quality and safety conformance as well as customer satisfaction but also they must be in compliance with authorities' regulations. Another aspect is designing and using the resources efficiently where the strategy is based on risk assessments and defines the rules, activities and the delivered products. Thussoftware life cycle model should be understandable, completely documented, traceable and auditable. The development life cycle has a specification and design, furthermore a testing (qualification) stream. The V&V must be designed at the start of the project. Thus the validation plan is fundamental document that consists not only all project information (e.g. goal, scope, organization, time-lines) but defines compliance, quality requirements and deliverables. The relationships between the corresponding elements of process flows allow that the computerized system is specified, designed and finally tested. Traceability matrix is crucial among activities and documents because as a map, demonstrates the relationships between the elements of documents of development streams. Why is the V&V of computer system important for the Life Science Sector as well as the pharmaceutical industry? First of all, these are all law regulated which is often guided by government agencies. Thus the compliance-related requirements are very important elements. In addition the meaning of 'Computer System' is more than computer hardware and software. It also includes the controlled equipment or process and the operating environment as well.