

Key Imaging Technology

A CRO's Challenge: Validating Leading-Edge Software for Imaging Clinical Studies

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The imaging modalities selected and employed for imaging trials are determined individually on a case-by-case basis for medical device and drug development programs. As this field of technology continues to develop and expand, the demand for standardization across platforms will continue to grow. Management control, system reliability, data integrity and auditable quality all need to be ensured through properly regulated computerized system validation (CSV), which encompasses not only elements of the computer system itself (i.e., hardware and software), but also the assigned work processes (i.e., equipment, people and standard operating procedures (SOP)).

Each component involved in supporting a work process represents a variable that requires specific attention for regulation by the Food and Drug Administration (FDA) and/or European Medicines Evaluation Agency (EMA); for instance, as software must have the capacity to display and manipulate image data without altering the image itself, this component must be validated before data is collected for regulatory submission. Likewise, user participation contains inherent risk for error; to reduce this, individuals must be trained in accordance with SOPs. Thus, each element becomes part of a collaborative validation effort. Before validation responsibilities can be delegated for performance qualification, installation qualification and operational qualification, a validation plan must be put into place. The plan will define respective roles and responsibilities in accordance with the specific work process. Organized and scheduled, typical validation packages will adhere to the schematic illustrated in Figure 1 (located on the back).

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Because *Guidance for Industry: Computerized Systems Used in Clinical Investigations* demands electronic source data be attributable, legible, contemporaneous, original and accurate, following the CSV plan is imperative to success. Your CSV plan should address:

- The processes assigned to the system for use in a specific study protocol
- Standard operating procedures and procedural controls
- Preservation of source documentation
- Internal security
- External security (access restrictions and cyber protection)
- System and access controls
- Audit or inspection events
- Training of personnel who use the system

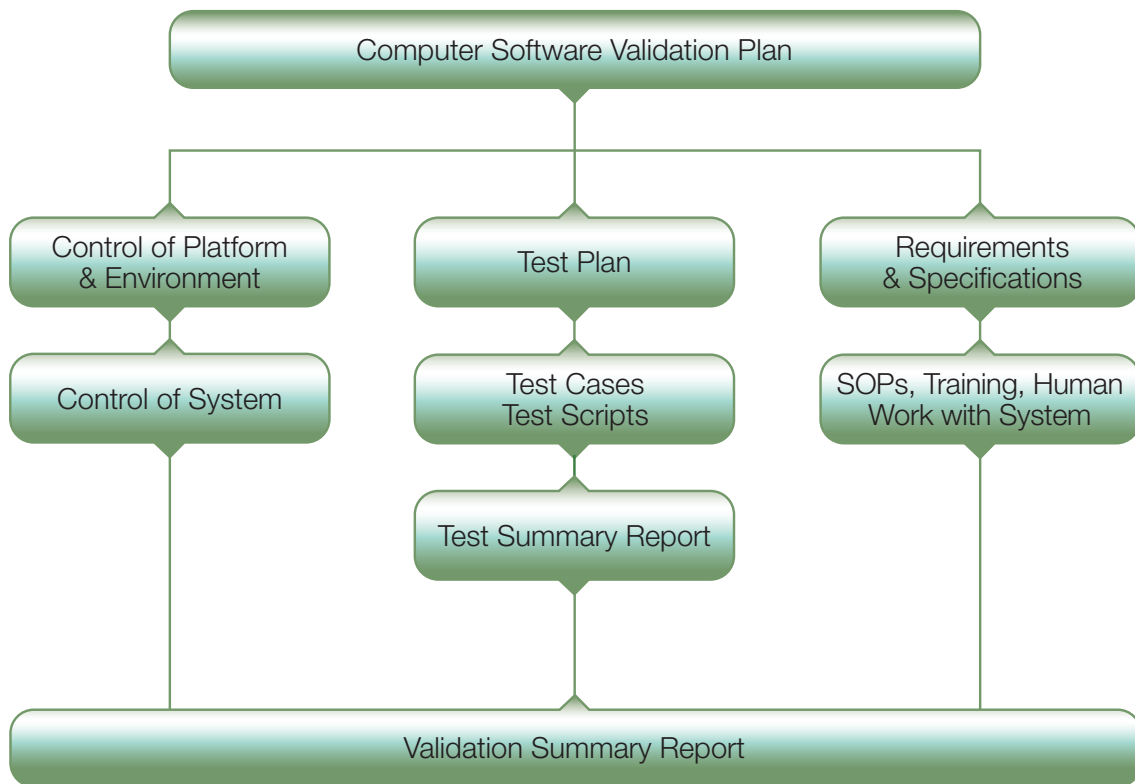


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Each element of the CSV plan determines a system of accountability and documentation. While the extent of validation necessary is determined by the system risk to data integrity, authenticity and confidentiality, as stipulated in the Code of Federal Regulations, 21 CFR Part 11, there must also be an independent review of the computerized system, which the CSV team named in the plan, prepares for through the CSV plan.

CSV prepares each operational component for use in a regulated work process. For an imaging CRO, testing a work process with the technology used protects data integrity. Whereas radiologic modalities are becoming more frequently integrated with development programs, CSV has become as vital as understanding the work process itself.

..... *Figure 1*



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