

Practical Use of Automated Tools in Computer System Compliance

May 15, 2013 8:00 am EDT

This discussion addresses the use of enabling technology in computer system validation (CSV) projects to most efficiently achieve the validated state in a pragmatic cost-effective manner. Requirements definition management (RDM) and automated testing software are used regularly for the validation and verification of embedded software in the design and development process for medical devices. GAMP 5 (March 2008) states that automated CSV testing tools can be used to improve test execution efficiency and effectiveness. Automated CSV tools provide the most benefit for larger enterprise applications...

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