Practical Use of Automated Tools in Computer System Compliance

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“Computer Validation Forum” discusses topics and issues associated with computer validation in order to provide useful resources for daily work applications. It brings information regarding regulatory requirements for the validation and qualification of computerized systems.

Reader questions, comments, and suggestions are required to fulfill the objective for this column. Case studies illustrating principles submitted by readers are welcome. Please send your comments to column coordinator Sharon Strause at sastrause@aol.com or to journal coordinating editor Susan Haigney at shaigney@advanstar.com

KEY POINTS
The following key points are discussed in this article:
• 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 such as enterprise resource planning, document management systems, laboratory information management systems, corrective action and preventive action, and so on
• Organizations should consider a formalized validation plan for each tool or set of tools to describe the risk, use, and validation or qualification requirements to maximize benefits
• The organization’s information technology (IT) strategic vision is one way to define how to identify, select, prioritize, plan, and implement automated tools for computer system validation. These IT initiatives can realize significant value by the adoption and integration with the computer system compliance process.

INTRODUCTION
For those of us working in US Food and Drug Administration-regulated industries, computer system validation (CSV) has been the long standing practice of establishing documented evidence that a specific process will produce, with a high degree of assurance, a product meeting its predetermined specifications and quality attributes. The FDA definition of validation rolls effortlessly off our tongues when those not familiar with the discipline ask. And, as we continue into a more detailed explanation of the validation lifecycle, the eyes of those who ask the question begin to glaze over as we cite regulatory references and enthusiastically dive deeper into the details of how validation is accomplished. Invariably, those discussions include
terms such as controlled processes, risk assessment, documented requirements, and documented testing results that typically are met by the manual methods of CSV. The outcome of a validated computer system is for the benefit of the organization’s use of an enabling technology in a regulated process. Typically, the organization or business unit is using technology to transform or improve manual or inefficient business processes. Yet, the process of CSV has historically been mostly manual and paper driven. However, the use of enabling technology in CSV projects can serve industry well as a way to achieve the validated state, while reducing the overall duration of validation with gains in efficiency. Careful consideration and purposeful application of the appropriate technology tools for your organization can help you gain greater control and streamline processes in a pragmatic, cost-effective manner.

**CSV EVOLUTION**

Historically, the validation process for computerized systems can be time consuming and, if not focused properly, can become an exercise in documentation. The pharmaceutical, biotech, and medical device industries have made great progress in reducing unnecessary or minimal value validation by adopting a risk-based approach to CSV. Most companies now recognize the value of using a risk-based approach as a means to identify the systems and system functions that fall under FDA predicate rules and are subject to validation requirements. The next major improvement for CSV is the adoption and implementation of enabling technology for use in the validation process. Automated tools supporting the management of requirements, configuration, change and documentation, as well as automated testing, can be leveraged if integrated into the validation process appropriately. The industry is traditionally risk-adverse, but the adoption of enabling technology for CSV is increasing as companies look to take advantage of the benefits it can offer.

Using automated tools to support the validation lifecycle is easier said than done. Other industries not subject to 21 CFR Part 11 have benefitted from using these tools to aid in the system development lifecycle for years. These industries, however, do not have concerns of electronic signatures, audit trail, qualification requirements, and formalized procedures. These additional requirements should not be seen as roadblocks to using automated tools in the CSV process, but they do need to be addressed. 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. The value of these automated tools is quite high considering the criticality, complexity, and volume of software components used in medical devices.

*GAMP 5, A Risk-Based Approach to Compliant GXP Computerized Systems*, released in March 2008, addresses automated testing. The current industry guide states, “Automated test execution tools can be used to improve test execution efficiency and effectiveness” (1). The guide continues, “Any use of automated test execution tools should be defined in the test strategy. Tools should be used in accordance with defined instructions and manuals as appropriate, and the tool should be held under Configuration Management. Commercial or established tools are normally considered to be GAMP Category 1.” GAMP 5 goes on to explain that if an automated testing tool is used on a GXP regulated system, it becomes subject to specification and verification based on risk. While GAMP 5 doesn’t focus on all types of automated tools, these principles should be applied when considering automated tools for GXP systems.

**APPROPRIATE USE OF AUTOMATED CSV TOOLS**

Automated tools are not the answer for all systems; the effort to qualify a tool used for validation of a smaller-scale system could actually be greater than performing and controlling the validation activities manually. Automated tools in CSV provide the most benefit for larger enterprise applications such as enterprise resource planning (ERP), document management systems (DMS), laboratory information management (LIMS), corrective action and preventative action (CAPA), and complaint handling. The validation effort for these types of systems can be significant as well as the on-going sustainment activities such as system maintenance and the introduction of changes via the change control process. For example, automated testing tools, such as HP Quality Center, provide a central repository for the qualification protocol test cases that can be easily reused in support of change control and offers functionality to easily capture and record test results. Defect management functions offered in automated testing software are another benefit to the validation process and allow for real-time view of status of defects, resolution activities, and results of retesting.
COMMERCIAL AUTOMATED CSV SOFTWARE
Automated testing software does present certain real challenges when used as part of the validation testing for regulated computer systems. HP Quality Center does not have built-in electronic signature capabilities. Life science companies can use a third-party software component to provide the capability or can consider the formal approval and control of test cases outside of the system—essentially a hybrid approach between automation and manual processes. Formalized procedures should also be established to define use of the tool in the validation process and detail any manual controls.

Another automated tool becoming more widely leveraged for ERP computer system validation and compliance is SAP's Solution Manager (2). The system is a centralized tool for supporting the SAP ERP software suite installation. Several components and functionality of Solution Manager are leveraged for the validation and on-going compliance of SAP. Solution Manager's functionality includes implementation and configuration information, change management, testing, and application support, among others. Taking advantage of the integrated functionality to support the compliance activities can provide big benefits to a life science company. For example, leveraging Solution Manager as a repository for application configuration provides the traceability to specifications. The change request component of Solution Manager, also known as ChaRM, links the change request, approval, test, and migration of the change through the SAP system landscape with its integration with the transport management system. SAP also offers adapters with third-party applications (3, 4), such as HP Quality Center, adding additional testing functionality. Full traceability between the change request and the production system build is realized. Life science companies recognize the business and compliance value of this tool and make plans early in the lifecycle of their SAP implementations to validate or qualify Solution Manager.

STRATEGY FOR USE OF AUTOMATED CSV TOOLS
Before an automated tool can be used in the CSV process or other compliance activities of a GXP-regulated system, planning and assessment of any tool should be considered. The functionality of the tool and its intended use will determine the extent of validation or qualification requirements. Organizations should consider a formalized validation plan for each tool or set of tools to describe the risk, use, and validation or qualification requirements. Operating procedures should also be in place to detail system administration, configuration management, and any other control processes.

As automated tools become more widely used, life science companies can take advantage of the benefits and leverage the technology for CSV and compliance. A pragmatic approach to integrating automated tools in the validation process should be taken. The effort to qualify a tool for validation of smaller-scale systems could be greater than the effort to validate manually. Identification and selection of enabling tools should be carefully considered. Companies need to have a clear vision of how these tools are used to sustain system compliance and provide benefit to the organization. A computer system compliance roadmap that complements the organization's IT strategic vision is one way to define how to identify, select, prioritize, plan, and implement automated tools for computer system validation. The compliance roadmap aligns with the IT strategic plan and offers a method to lay out the compliance activities and tools for computer system validation and operational controls for GXP systems. Organizations that involve members from the IT, business, and compliance groups will benefit from early assessment and planning for enabling tools for GXP systems. Many organizations already have a level of competency for automated tools used for supporting non-GXP systems.

CONCLUSION
Automated tools can have a real impact on computer system compliance and serve as a way to gain greater control and efficiencies. Life science companies should consider the various tools supporting the management of requirements, configuration, change control, documentation, and automated testing as real options. These IT initiatives can realize significant value by the adoption and integration within the computer system compliance process.

REFERENCES
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ARTICLE ACRONYM LISTING
CAPA Corrective Action and Preventive Action
CSV Computer System Validation
DMS Document Management Systems
ERP Enterprise Resource Planning
FDA US Food and Drug Administration
IT Information Technology
LIMS Laboratory Information Management Systems
RDM Requirements Definition Management