

Medvacon Shares Best Practice for Computer System Validation

January 27, 2021 - (SPARTA, NJ) - One of the biggest mistakes companies make when starting a computer system validation (CSV) project is to not do the strategic planning necessary to ensure success. That is according to Ray Roggero, Managing Member and Operations Leader for Medvacon Life Sciences.

“The first step in any informatics project should always be a thorough workflow and business analysis,” said Roggero, who has extensive leadership and operations experience overseeing consulting regulatory compliance/engineering services and commercial services within the life sciences industry. “This process allows the development of clear and precise functional and user requirements that are tailored to your unique operating environment to a high degree of specificity and defined at a level that can be addressed through the new software. Without clear and precise requirements,” he continued, “CSV will not be able to adequately verify that the system is functioning as intended.

Roggero explains that CSV takes a lot of time and IT resources to accomplish, so it is wise to follow a GAMP 5 approach that utilizes a risk-based assessment on the system to determine required test cases and the optimal level of testing for each. “CSV efforts should concentrate on what is identified in the risk assessment for the critical elements of the system that affect quality assurance and regulatory compliance. Benefits of this risk-based approach to CSV include reduced cost, reduced business risk, and reduced duration of the validation efforts.”

Medvacon is a full-service Quality and Compliance consulting firm offering a suite of quality services such as: Quality Systems Implementation and Remediation; Computer System Validation; Process and Cleaning Validation; Equipment, Facility and Utility Qualification; Mock FDA Inspections and Audits; Project Management; and cGMP Training. These services help clients to ensure FDA Compliance and reduce compliance cost in the Life Sciences’ industry. The company provides experienced project administration, trouble-shooting, and/or training services, on-site, with local resources and senior management involvement to optimize flow and collaboration. Headquartered in Sparta, NJ, Medvacon also has offices in San Diego California. More information can be found at www.Medvacon.com.

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