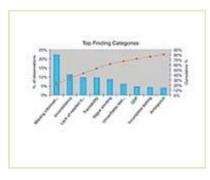
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The Nine Most Common Computer Validation Problems—Identify Frequent Deficiencies to Accelerate Your Validation Projects

By Frank Houston May 22, 2013 12:17 pm EDT



The following analysis is based on validation work performed for a large US Food and Drug Administration-regulated company. The goal was to bring the company's software validation evidence up to the level of FDA's current expectations as well as those of the client's own independent auditor. Our efforts yielded 1,720 observations. As part of a "lessons learned" review, these observations were grouped into 22 different categories. The documents that most frequently contained the observations were identified. The results, in the author's experience, are typical of the...

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