

PQ Initiation—What, Why, How, and What Else?



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By

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The validation initiation document is a key document. It officially begins the validation. It likely will be the first document to be audited, reviewed, or otherwise consulted when the validation project is in progress. When the “how” component of the initiation, i.e., risk analysis and validation plan, is included in the initiation, it sets the tone for the future execution of the validation. The validation plan leads to subsequent validation documents. Protocols, studies, results, actions, and other work must be consistent with work prescribed in the validation plan. A thorough, complete, and concise validation initiation is key to a successful validation.

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