

PQ Forum: PQ Documentation– Three Simple Rules



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Validation managers identified documentation problems as one of their most troubling problems. Documentation problems are prevalent at all stages of process qualification (i.e., plans, protocols, and results). Problems generally included the following: Incomplete and inadequate content Explanations that are not thorough or understandable Incorrect grammar and spelling. Documentation problems may have significant consequences including serious negative impressions on auditors. Three simple and memorable rules are proposed for validation documents: Clear, complete, concise, and consistent “Stand-alone”...

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