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GXP Talk: Questions 54 & 55

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QUESTION 54 In equipment qualification protocols, can we include documents or forms that will be used for recording data gathered during the execution of the protocol? ANSWER The regulatory requirement of equipment qualification and process validation is based on the Code of Federal Regulations (CFR) Title 21 Part 211.100(a), which requires procedures for production and process controls, and several statements in 21 CFR 211, which require that facilities and equipment be suitable for intended use. The US Food and Drug Administration 2011 Process Validation Guidance provides little detail regarding...