

Critical Documentation Requirements in Validation- 2008 Update

By **Gamal Amer, Ph.D.** May 26, 2013 2:15 pm EDT

Engineering design documents Operations and maintenance (O&M manuals) Construction and installation documents Commissioning documents Technical support documents for equipment, facilities, utilities, and manufacturing processes. The above documentation, which describes and characterizes the respective equipment, facilities, utilities, and processes, is used in the preparation of validation protocols; defines the acceptance criteria; and, helps in the preparation of standard operating procedures (SOPs)— all of which are essential to the comprehensive validation effort. Further, these documents...

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