Software Validation

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Software Validation Regulatory Handbook
As a result, part of a SW V&V package usually includes a traceability matrix or similar to prove that each software requirement has been met in its design, development or selection (if commercial off-the-shelf), and addressed by test cases in the test protocols (often as IQ, Installation Qualification, OQ, Operation Qualification, or PQ, Performance Qualification, or their equivalents. Whereas code testing is more detailed and thorough, sw v&v to meet U.S FDA, ICU, EMA, et al, regulatory requirements is focused on safety and effectiveness, whether software is: In a device As...

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Software Validation, Regulatory & Industry Guidance

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