

Software Validation



By [John E. Lincoln](#) Jan 7, 2013 6:31 am PST

[John E. Lincoln](#)



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...

This content is only available to IVT members.

Get help maintaining your knowledge in Software Validation. [Read More!](#)

If you are already a member and you do not have access to this article, [upgrade your membership](#).

Need help? [Read our FAQs](#).

Tags:

[Software Validation, Regulatory & Industry Guidance](#)



[John E. Lincoln](#)

John E. Lincoln, principal consultant, J. E. Lincoln and Associates LLC, assists companies in the design and implementation of complete 21 CFR 111, 210, 211, 820 and ISO 13485 quality management systems, fully CGMP-...

[View Author Bio](#)

Source URL: <http://www.ivtnetwork.com/article/software-validation>