Computer Systems and Computer Validation

By  Jan 13, 2013 2:54 pm PST
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I. Introduction For Pharmaceutical/Bio-Pharmaceutical or Vaccines products manufactured under a current good manufacturing practice (cGMP) environment, the intent of the Computer Systems/Computer Validation handbook is to outline the major regulatory guidelines by US Food and Drug Administration, European Medicines Agency (EMA) and other regulatory agencies. Moreover, the topic of discussions will include recommendations from the subject matter expert including examples of warning letters/citations, and advice on avoiding the warning letters/citations relating to not having your Computer...

Tags:
Computer & Software Validation, Regulatory & Industry Guidance


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<p>Allan Marinelli is currently the President of Quality Validation 360 Incorporated and has acquired over 24 years of experience (Well Balanced experience between Quality Assurance/Quality Systems and Validation...
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