Computer Systems and Computer Validation

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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...

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