



GAMP 5: A Risk-based Approach to Compliant Gxp Computerized Systems

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The new GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems provides pragmatic and practical industry guidance that aims to achieve compliant computerized systems that are fit for intended use in an efficient and effective manner, while also enabling innovation and technological advance. The revised Guide describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification. A robust quality risk management process based on ICH Q9 principles is central to the approach. GAMP® 5 also contains new information on outsourcing, electronic batch recording, end user applications (such as spreadsheets and small database applications), and patch management.

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