



A Risk-Based Approach to Operation of GxP Computerized Systems, A Companion Volume to GAMP 5 (GAMP G

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Regulated computerized systems should be maintained in a demonstrable state of control and in accordance with regulatory requirements. Recovery from a failure to maintain control of a regulated system during the operation phase can be both time-consuming and expensive, and increase the risk to data integrity, product quality, and patient safety. During the operational life of a GxP system regulators usually focus on the integrity, consistency, and completeness of controls required to maintain compliance. This Guide highlights the importance of the operation phase of the system lifecycle, when the return on investment for the significant time and resource expended in implementing new computerized systems can be achieved. The Guide will help regulated organizations achieve regulated computerized systems that are fit for intended use and compliant with applicable regulations and provides comprehensive guidance for maintaining control of regulated systems throughout their operational life, including to: Provide a better understanding of both the individual operational processes and the inter-relationships between them; Help organizations assign clear roles and responsibilities to required activities throughout the operation phase; Embed scalable risk-based approaches into the definition and management of those internal and external operational processes. When applied as intended, this Guide can provide detailed direction on the required control processes which form a substantial part of an appropriate Quality Management System (QMS).

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