

Gamp 5: A Risk-based Approach to Compliant Gxp Computerized Systems (Fifth Edition). El Precio Es En Dolares

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GAMP ® 5 proporciona orientación de la industria pragmática y práctica para lograr sistemas computarizados compatibles aptos para el uso previsto de una manera eficiente y eficaz. Este documento técnico describe un enfoque flexible basado en el riesgo a los sistemas informáticos compatibles GxP regulados, basados en la especificación escalable y verificación. Señala que el futuro del cumplimiento de sistemas informáticos centrándose en principios detrás de las principales novedades de la industria como PQLI; ICH Q8, Q9, Q10, y ASTM E2500. Esta guía revolucionaria abarca todo el ciclo de vida de un sistema automatizado y su aplicabilidad a una amplia gama de sistemas de información, equipos de laboratorio, sistemas de producción integrados, e infraestructuras de TI. Contiene nueva información sobre la contratación externa, registro electrónico de lotes, aplicaciones de usuario final (por ejemplo, hojas de cálculo y bases de datos pequeñas), y la gestión de parches. Una innovación interesante es el CD que acompaña a la Guía. Proporciona materiales de apoyo, incluidas las diferencias entre GAMP ® 4 y GAMP ® 5, diagramas clave, plantillas, formularios, documentos de ejemplo, y la información de fondo. (CD es sólo para Windows compatible.)

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