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# Computer Systems Validation: Quality Assurance, Risk Management, and Regulatory Compliance for Pharmaceutical and Healthcare Companies

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**Computer Systems Validation: Quality Assurance, Risk Management, and Regulatory Compliance for Pharmaceutical and Healthcare Companies**

Both pervasive and ubiquitous, computerized systems are now an integral component of every corporate strategy in pharmaceutical and healthcare companies. However, when technology is combined with high-risk public safety projects or the production and control of life-saving medicines or devices, it is necessary to ensure that it is reliable, quality assured, and validated. The most comprehensive guide on computer validation currently available, containing more than 200 illustrations and more than 100 tables, Computer Systems Validation helps you see the big picture.

The author reviews regulations and their development, organization responsibilities, validation life cycle based on GAMP4 Guide, strategic approaches to validation, electronic records and signatures, handling regulatory inspections, metrics, and opportunities for performance improvement. He presents practical examples and checklists throughout the book and explores the role of quality assurance and risk management as key components of pragmatic regulatory compliance. Covering methods that help you avoid duplicating effort among departments and business functions, the book demonstrates how you can use your investment in technology to improve business efficiency and gain the competitive edge.

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