Pharmaceutical Computer Systems Validation: Quality Assurance, Risk Management and Regulatory Compliance

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Thoroughly revised to include the latest industry developments, the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice. To provide the current best practice and guidance on identifying and implementing improvements for computer systems, the text extensively reviews regulations of pharmaceuticals, healthcare products, blood processing, medical devices, clinical systems, and biotechnology. Ensuring that organizations transition smoothly to the new system, this guide explains how to implement the new GMP paradigm while maintaining continuity with current practices. In addition, all 24 case studies from the previous edition have been revised to reflect the new system.

Key topics in Pharmaceutical Computer Systems Validation, Second Edition include:

- GAMP5, ASTM 2500, EU GMP (Annex 11), and US GMP revisions to regulatory requirements for electronic records and signatures that should be published in 2008
- ICH Guidance Q8, Q9, and Q10 expectations
- FDA cGMPs for the 21st Century Initiative and associated guidance
- PIC/S Guidance on Good Practice for Computerized Systems in GxP Environments
- WK9864 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment
- the indirect developments from FDA/EU/Japan regulators and industry
- the role of QA department, and internal and external suppliers
- the integration of computer systems validation into single overall approach for wider system
- practical guidance on handling common high, medium, and low risk issues that can occur during the life cycle of a computer system
- managing outsource partners and handling legacy systems
- topical issues uncovered by regulatory authorities including US FDA

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