1. Record Nr. UNINA9910459271703321

Titolo	Pharmaceutical computer systems validation : quality assurance, risk management and regulatory compliance / / edited by Guy Wingate
Pubbl/distr/stampa	New York : , : Informa Healthcare, , 2010
ISBN	0-429-13762-1 1-282-56102-2 9786612561023 1-4200-8895-5
Edizione	[2nd ed.]
Descrizione fisica	1 online resource (773 p.)
Altri autori (Persone)	WingateGuy
Disciplina	615.1068/4 615.10684
Soggetti	Pharmaceutical industry - Management Pharmaceutical industry - Data processing Health facilities - Risk management Risk management - Data processing Electronic books.
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Rev. ed. of: Computer systems validation / editor, Guy Wingate. Boca Raton, Fla. : Interpharm/CRC, c2004.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Front Cover; Foreword to the Second Edition; Foreword to the First Edition; Preface; Contributor Biographies; Abbreviations; Contents; Chapter 1. Introduction; Chapter 2. Organization and Management; Chapter 3. Supporting Processes; Chapter 4. Prospective Verification and Validation; Chapter 5. Project Initiation and Compliance Determination; Chapter 6. Requirements Capture and Supplier (Vendor) Selection; Chapter 7. Design and Development; Chapter 8. Coding, Configuration, and Build; Chapter 9. Development Testing; Chapter 10. User Qualification and Authorization to Use Chapter 11. Operation and MaintenanceChapter 12. Phaseout and Withdrawal; Chapter 13. Electronic Records and Electronic Signatures; Chapter 14. Regulatory Inspections; Chapter 15. Compliance Strategies; Chapter 16. Capabilities, Measures, and Performance; Chapter 17. Practical Troubleshooting; Chapter 18. Concluding Remarks; Chapter

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Chapter 32. Case Study 14: Marketing and Supply ApplicationsChapter 33. Case Study 15: IT Infrastructure and Associated Services; Chapter 34. Case Study 16: Internet/Intranet Applications; Chapter 35. Case Study 17: Medical Devices and Their Automated Manufacture; Chapter 36. Case Study 18: Blood Establishment Computer Systems; Chapter 37. Case Study 19: Process Analytical Technology; Chapter 38. Case Study 20: Computer Applications Supporting the Supply of Biotechnology Products; Glossary; Back Cover

Sommario/riassunto

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 w