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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 19. Case Study 1: Computerized Analytical Laboratory Systems; Chapter

20. Case Study 2: Chromatography Data Systems; Chapter 21. Case Study 3: Laboratory Information Management Systems; Chapter 22. Case Study 4: Clinical Systems
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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
