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Nota di contenuto	1. Introduction -- 2. Inspection trends -- 3. Electronic records life cycle -- 4. Electronic records related definitions -- 5. Electronic records handling : 21 CFR part 211 -- 6. Electronic records handling : EMA annex 11 -- 7. Relevant worldwide GMP regulations and guidelines -- 8. Trustworthy computer systems -- 9. MHRA guidance -- 10. Electronic records governance -- 11. Procedural controls for handling E-records -- 12. Electronic record controls : supporting processes -- 13. Electronic records controls : records retained by computer storage -- 14. Electronic record controls : during processing -- 15. Electronic record controls : while in transit -- 16. Electronic records and contract manufacturers -- 17. Electronic records and Cloud computing -- 18. Self-inspections -- 19. Electronic records remediation project -- 20. Summary.
Sommario/riassunto	Data integrity is fundamental in a pharmaceutical and medical devices quality system. This book provides practical information to enable compliance with data integrity, while highlighting and efficiently

integrating worldwide regulation into the subject. The ideas presented in this book are based on many years' experience in regulated industries in various computer systems development, maintenance, and quality functions. In addition to case studies, a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved.