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Nota di contenuto	Preface -- Introduction to the quality systems approach to CGMP compliance -- Preparing for the audit -- Auditing and data capture -- Organizing data and reporting the results -- Developing and implementing a corrective action plan -- Developing and implementing a verification plan -- Developing and implementing a monitoring plan -- A summary for establishing a CGMP laboratory audit system -- Appendixes -- Example audit checklists: laboratory subelements -- Example template for an audit summary report -- Glossary of CGMP and audit system terms -- FDA compliance program guidance manual 7356.002 "Drug manufacturing inspections" -- 21 Code of U.S Federal Regulations parts 210 and 211 current good manufacturing practice regulations.
Sommario/riassunto	The first systematic, hands-on auditing guide for today's pharmaceutical laboratoriesIn today's litigious environment, pharmaceutical laboratories are subject to ever stricter operational guidelines as mandated by the FDA, and must be able to establish and demonstrate sustainable operational practices that ensure compliance

with the current good manufacturing practice (CGMP) regulations. David Bliesner's Establishing a CGMP Laboratory Audit System: A Practical Guide is designed to provide laboratory supervisors and personnel with a step-by-step, hands-on audit system that they can rely