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Nota di contenuto	Introduction to the quality systems based approach to CGMP compliance -- Components of the laboratory managerial and administrative systems sub element (MS) -- Components of the laboratory documentation practices and standard operating procedures sub element (OP) -- Components of the laboratory equipment sub element (Le) -- Components of the laboratory facilities sub element (LF) -- Components of the method validation and method transfer sub element (MV) -- Components of the laboratory computer systems sub element (LC) -- Components of the laboratory investigations sub element (Li) -- Components of the laboratory data governance and data integrity sub element (DI) -- Components of the stability program sub element (SB) -- Components of the general laboratory compliance practices sub element (CP) -- Summary for establishing and maintaining a laboratory control system.
Sommario/riassunto	"This book provides the basis for operating a CGMP compliant Laboratory Control System (LCS) implemented in QC and R&D laboratories. Improving an organizations chances for withstanding Regulatory scrutiny and enhancing operational efficiency. The book focuses both on the operational aspects of the original seven LCS sub elements, but expands the LCS to encompass three additional sub

elements. Resulting in the following chapters in the book: Laboratory Managerial and Administrative Systems; Laboratory Documentation Practices and Standard Operating Procedures; Laboratory Equipment Qualification and Calibration; Laboratory Facilities; Methods Validation and Technology Transfer; Laboratory Computer Systems; Laboratory Investigations; Data Governance and Data Integrity; Stability Program; and General Laboratory Compliance Practices. Each chapter describes the critical functions of the LCS sub element so the reader understands what is expected from the FDA and Global Regulatory Agencies. In addition, each chapter includes link to tools, templates, checklists and Global Regulatory Agencies' guidance. All of these tools and templates will be provided electronically for easy application by the end-user in their own laboratories. It is the inclusion of these practical tools that makes this text unique. It would require untold man hours if one were to develop these checklists and example-templates on one's own"--