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Nota di contenuto	Controlling regulatory costs -- Clear operation definitions of requirements -- Pre-regulatory audits -- Quality by design -- Outsourcing -- Electronic submissions -- Emea/fda coordination -- Managing FDA inspections -- Risk assessment -- Cases -- Cost containment analysis -- Managing regulation in times of chaos -- International regulation -- Cost contained regulatory compliance.
Sommario/riassunto	This book guides the reader through FDA regulation guidelines and outlines a comprehensive strategy for cost reduction in regulatory affairs and compliance. This book explains six strategies to cost-effectively comply with FDA regulations while maintaining product safety and improving public access through cost controls. It provides useful and practical guidance through industry case studies from pharmaceutical, biotech, and medical device industries.