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Titolo	Cost-contained regulatory compliance [[electronic resource] ] : for the pharmaceutical, biologics, and medical device industries // Sandy Weinberg
Pubbl/distr/stampa	Hoboken, N.J., : John Wiley & Sons, c2011
ISBN	1-118-00227-X 1-283-02560-4 9786613025609 0-470-93350-X 0-470-93351-8
Descrizione fisica	1 online resource (296 p.)
Disciplina	615.1068/1
Soggetti	Medical instruments and apparatus industry - United States - Cost control Medical instruments and apparatus - Inspection - United States Pharmaceutical industry - United States - Cost control Pharmaceutical industry - Inspection - United States
Lingua di pubblicazione	Inglese
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Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
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.

