

1. Record Nr.	UNINA9910785000603321
Titolo	Pharmaceutical manufacturing handbook : regulations and quality // [edited by] Shayne Cox Gad
Pubbl/distr/stampa	Hoboken, N.J. : , : Wiley-Interscience, , 2008 ©2008
ISBN	1-281-23752-3 9786611237523 0-470-25983-3 0-470-25982-5
Descrizione fisica	1 online resource (857 pages)
Collana	Pharmaceutical Development Series
Altri autori (Persone)	GadShayne C. <1948->
Disciplina	615.19 615/.19
Soggetti	Pharmaceutical technology - Quality control Pharmacy - Law and legislation - United States Drugs - Law and legislation - United States
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	PHARMACEUTICAL MANUFACTURING HANDBOOK Regulations and Quality; CONTRIBUTORS; CONTENTS; PREFACE; SECTION 1 GOOD MANUFACTURING PRACTICES (GMP) AND OTHER FDA GUIDELINES; 1.1 Good Manufacturing Practices (GMPs) and Related FDA Guidelines; 1.2 Enforcement of Current Good Manufacturing Practices; 1.3 Scale-Up and Postapproval Changes (SUPAC) Regulations; 1.4 GMP-Compliant Propagation of Human Multipotent Mesenchymal Stromal Cells; SECTION 2 INTERNATIONAL REGULATIONS OF GOOD MANUFACTURING PRACTICES 2.1 National GMP Regulations and Codes and International GMP Guides and Guildelines: Correspondences and Differences; SECTION 3 QUALITY; 3.1 Analytical and Computational Methods and Examples for Designing and Controlling Total Quality Management Pharmaceutical Manufacturing Systems; 3.2 Role of Quality Systems and Audits in Phatmaceutical Manufacturing Environment; 3.3 Creating and Managing a Quality Management System; 3.4 Quality Process Improvement;

SECTION 4 PROCESS ANALYTICAL TECHNOLOGY (PAT); 4.1 Case for Process Analytical Technology: Regulatory and Industrial Perspectives 4.2 Process Analytical Technology; 4.3 Chemical Imaging and Chemometrics: Useful Tools for Process Analytical Technology; SECTION 5 PERSONNEL; 5.1 Personnel Training in Pharmaceutical Manufacturing; SECTION 6 CONTAMINATION AND CONTAMINATION CONTROL; 6.1 Origin of Contamination; 6.2 Quantitation of Markers for Gram-Negative and Gram-Positive Endotoxins in Work Environment and as Contaminants in Pharmaceutical Products Using Gas Chromatography-Tandem Mass Spectrometry; 6.3 Microbiology of Nonsterile Pharmaceutical Manufacturing; SECTION 7 DRUG STABILITY 7.1 Stability and Shelf Life of Pharmaceutical Products; 7.2 Drug Stability; 7.3 Effect of Packaging on Stability of Drugs and Drug Products; 7.4 Pharmaceutical Product Stability; 7.5 Alternative Accelerated Methods for Studying Drug Stability: Variable-Parameter Kinetics; SECTION 8 VALIDATION; 8.1 Analytical Method Validation: Principles and Practices; 8.2 Analytical Method Validation and Quality Assurance; 8.3 Validation of Laboratory Instruments; 8.4 Pharmaceutical Manufacturing Validation Principles; INDEX

Sommario/riassunto

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines.

2. Record Nr.	UNINA9911018943603321
Autore	Gray Joanna, L. L .B.
Titolo	Implementing financial regulation : theory and practice / / Joanna Gray and Jenny Hamilton
Pubbl/distr/stampa	Chichester, England ; ; Hoboken, NJ, : John Wiley & Sons, c2006
ISBN	9786610449132 9781119207115 1119207118 9781280449130 1280449136 9780470869307 0470869305
Descrizione fisica	1 online resource (287 p.)
Collana	Wiley finance
Altri autori (Persone)	HamiltonJenny <1957->
Disciplina	346.41/082 346.4108
Soggetti	Financial services industry - Law and legislation - Great Britain Financial services industry - State supervision - Great Britain Financial services industry - Great Britain
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Implementing Financial Regulation; Contents; Preface; Acknowledgements; 1 Regulation in Context; 2 Aligning Risk and Regulation: FSA's Risk-Based Operating Framework; 3 Regulation within the Regulated Firm: Legislation and Rules; 4 Senior Management Regulation: Evidence and Practice Since N2; 5 The Wider Regulatory and Legal Context for Senior Management; 6 Regulation and the Emergence of the Financial Citizen; 7 An Illustrated Critique of Meta Regulation and Concluding Comments; Index
Sommario/riassunto	Now that the Financial Services and Markets Act 2000 has had a chance to bed itself down and the Financial Services Authority (FSA) is developing its new regulatory toolkit and modus operandi, financial regulation has moved on in interesting directions. This book takes a critical look at the principles and practices behind this regulation, as

well as the theory that is involved. This book goes further than a description of the laws that are currently out there, by analysing the impact and implications of the new financial regulations, making it a 'must-read' for law, finance an
