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Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references at the end of each chapters and index.
Nota di contenuto	Front Cover; Guide to Cell Therapy GxP; Copyright; Contents; List of Contributors; Foreword; Preface; 1 - Overview of the Development Program of a Cell-Based Medicine; 1. Introduction; 2. Key Pharmaceutical Factors to Consider in Early Development Stages; 3. TPP: Beginning with the End in Mind; 4. Stages of Drug Development; 5. Considering Stakeholders; 6. Product Lifecycle and Portfolio Management; 7. Performance Management and the Check Point Value; 8. Conclusions; References; Glossary; List of Acronyms and Abbreviations 1. Introduction 2. Types of Cell-Based Advanced Therapy Medicinal Products and their Safety Considerations 3. Regulations and Nonclinical Studies 4. Nonclinical Assessment-The Risk-Based Approach 5. The Requirement for Good Laboratory Practice 6. General Study Design Considerations 7. Specific Nonclinical Safety Considerations 8. Conclusions; References; Glossary; List of Acronyms and Abbreviations 4 - Good Manufacturing Practice Compliance in the Manufacture of Cell-Based Medicines 1. Outline of the Chapter 2. Quality Management 3. Documentation 4. Qualification and Validation 5. Premises and Equipment 6. Personnel and Hygiene 7. Manufacturing 8. Quality Control 9. Inspections, Audits, Complaints, Recalls, and

Returns; 10. Conclusion; Acknowledgment; References; List of Abbreviations; 5 - Good Clinical Practice in Nonprofit Institutions; 1. Introduction; 2. The Elements of GCP Compliance; 3. The Clinical Trial Protocol; 4. The Investigator's Brochure; 5. The Informed Consent; 6. Essential Documents for Clinical Trial; 7. Clinical Trial Files; 8. Sponsor Study Audit and Inspections; 9. Conclusion; References; Glossary; List of Acronyms and Abbreviations
6 - Compatibility of GxP with Existing Cell Therapy Quality Standards1. Quality Standards in Cell Therapy; 2. Adaptation of Existing Standards to GxP; 3. Impact of GxP Implementation; 4. Quality by Design; 5. Recommendations for Optimizing Integration of QA Systems; 6. Conclusions; References; Glossary; List of Abbreviations; Index

Sommario/riassunto

Guide to Cell Therapy GxP: Quality Standards in the Development of Cell-Based Medicines in Non-Pharmaceutical Environments provides a practical guide to the implementation of quality assurance systems for successful performance of all cell-based clinical trials. The book includes all information that should be used in investigational medicinal product dossier (IMPD), the launching point for any clinical investigation, and beyond, bridging the gap in knowledge with the inclusion of examples of design of GLP-compliant preclinical studies, design of bioprocesses for autologous/allogeneic therapy

2. Record Nr.	UNINA9910164971903321
Titolo	Summary : Merchants of Doubt // BusinessNews Publishing
Pubbl/distr/stampa	[Place of publication not identified] : , : CapitolReader, , [2012] ©2012
ISBN	2-511-00125-X
Edizione	[First edition.]
Descrizione fisica	1 online resource (25 p.)
Disciplina	634.9
Soggetti	Scientists - Professional ethics
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di contenuto	Intro -- Title page -- Book Presentation -- Book Abstract -- About the Author -- Important Note About This Ebook -- Summary of Merchants of Doubt (Naomi Oreskes and Erik Conway) -- The Big Six -- Tobacco Causes Cancer -- Star Wars - Applying the Tobacco Strategy to the Strategic Defense Initiative -- Acid Rain and the Ozone Hole - Applying the Tobacco Strategy in New Contexts -- Secondhand Smoke - Bad Science or Even Worse Politics? -- Global Warming - Scientific Fact or Scientific Trojan Horse? -- Conclusion -- Buy the Book -- About the Summary Publisher -- Copyright.
Sommario/riassunto	This ebook consists of a summary of the ideas, viewpoints and facts presented by Naomi Oreskes and Erik Conway in their book "Merchant of Doubt, How a Handful of scientists Obscured the Truth on Issues from Tobacco Smoke to Global Warming". This summary offers a concise overview of the entire book in less than 30 minutes reading time. However this work does not replace in any case Naomi Oreskes and Erik Conway book. Oreskes and Conway argue that science must wait until empirical proof emerges to draw conclusions. Hence they say that the best way to discredit science regarding the climate chang