1. Record Nr. UNISA990003693080203316

Titolo	Di linea e di colore : il Giappone, le sue arti e l'incontro con l'Occidente = Line and colour = a cura di = edited by Francesco Morena
Pubbl/distr/stampa	Livorno : Sillabe, 2012
ISBN	978-88-8347-635-8
Descrizione fisica	591 p. : ill. ; 28 cm
Disciplina	709.52
Soggetti	Opere d'arte giapponesi - Cataloghi di esposizioni
Collocazione	XII.2.D. 951
Lingua di pubblicazione	Italiano Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Catalogo della mostra tenuta a Firenze, Palazzo Pitti, 3 aprile-1 luglio 2012 In testa al frontespizio: Ministero per i Beni e le Attività Culturali; Direzione Regionale per i Beni Culturali e Paesaggistici della Toscana; Soprintendenza Speciale per il Patrimonio Storico, Artistico ed Etnoantropologico e per il Polo Museale della città di Firenze; Museo degli Argenti di Palazzo Pitti In copertina e nell'occhietto: Giappone terra di incanti

2. Record Nr. UNINA9910437854103321

Autore	Geigert J (John), <1948->
Titolo	The challenge of CMC regulatory compliance for biopharmaceuticals and other biologics / / John Geigert
Pubbl/distr/stampa	New York, : Springer, c2013
ISBN	1-4614-6916-3
Edizione	[2nd ed.]
Descrizione fisica	1 online resource (362 p.)
Disciplina	610 615.15 615.19 615.3
Soggetti	Pharmaceutical biotechnology Pharmaceutical biotechnology industry - Law and legislation Pharmaceutical biotechnology - Quality control
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	Complexity of Biologica CMC Regulation -- Biologics are Not Chemical Drugs -- An Effective CMC Strategy is Possible -- Challenge of Adventitious Agent Control -- Source Materials for Biologics -- Manufacture of the Biologic API -- The Biologic Final Product Process -- Complex Process-Related Impurities -- Molecular Structural Analysis -- Functional Activity (Potency) -- Setting Specifications and Expiry Dates -- Demonstrating Product Comparability -- CMC-Focused Regulatory Meetings -- References.
Sommario/riassunto	An effective CMC regulatory compliance strategy for biologics and biopharmaceuticals can seem like a mystery. Through means of this 2nd edition, this no longer needs to occur. A great deal of thanks goes to two regulatory authorities – the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA), who provide through their respective websites, an abundance of guidance, especially in the last several years. So much has changed since the 1st edition of this book was published in 2004. There are now additional manufacturing processes for producing commercial biopharmaceuticals – transgenic plant cell cultures and transgenic animals. In addition to

commercial recombinant proteins and monoclonal antibodies, there are now commercial cell-based medicines (cellular therapy) and DNA-based medicines (gene therapy). Biosimilars are now on the marketplace in Europe, and under review for commercial approval in the USA. Vaccine manufacturing has resurged due to the concerns of potentially pandemic mutated animal influenzas (e.g., swine flu, bird flu). Strategic international regulatory guidances have been adopted that are driving the entire pharmaceutical industry, including biopharmaceuticals, to a higher standard of performance, including Quality by Design (QbD), Quality Risk Management (QRM) and Pharmaceutical Quality Systems (PQS). The vast majority of the over 600 regulatory references listed in this book were either issued or updated since the release of the 1st edition. All of these changes are the reason this updated edition includes not only biopharmaceuticals but also other biologics (e.g., live virus vaccines, human plasma-derived proteins, cell-based medicines, natural-sourced proteins) that have CMC regulatory compliance concerns and challenges in common with the genetically-engineered biologics (i.e., the biopharmaceuticals). About The Author John Geigert is President of BioPharmaceutical Quality Solutions, which specializes in providing CMC regulatory strategy consulting for the biopharmaceutical and biologic industry. Dr. Geigert has over 35 years of CMC industrial experience and leadership in the biopharmaceutical industry. Dr. Geigert has served on the PDA Board of Directors, co-chaired the PDA Biotech Advisory Board and served as an expert member of the USP Biotechnology Committee. Dr. Geigert has written extensively for the Regulatory Affairs Professional Society (RAPS) Focus (What Senior Management Needs to Know About CMC Regulatory Compliance for Biotech Products (Aug-Nov 2009, 4-part series) and Demystifying CMC Regulatory Strategy (Sept 2011-Mar 2012, 4-part series)).