1. Record Nr. UNINA9910337940703321

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Titolo	The Challenge of CMC Regulatory Compliance for Biopharmaceuticals / / by John Geigert
Pubbl/distr/stampa	Cham : , : Springer International Publishing : , : Imprint : Springer, , 2019
ISBN	3-030-13754-6
Edizione	[3rd ed. 2019.]
Descrizione fisica	1 online resource (338 pages)
Disciplina	615.7 615.19
Soggetti	Pharmacology Pharmacy Pharmacology/Toxicology Drug Safety and Pharmacovigilance
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di contenuto	Complexity of Biologics CMC Regulation -- Biopharmaceutics are Not Chemical Drugs -- An Effective CMC Strategy is Possible -- Challenge of Adventitious Agent Control -- Biopharmaceutical Source Materials -- Manufacturing of Biopharmaceutical APIs -- Manufacturing of the Drug Product -- Complex Process-Related Impurity Profiles -- Product Characterization is a Journey -- Priceless Potency (Therapeutic Activity) -- Quality Attributes of a Biopharmaceutical -- Designing the Stability Program -- The Art of Setting Specifications -- Demonstrating Product Comparability After Process Changes -- Invaluable CMC-Focused Meetings with Regulatory Authorities.
Sommario/riassunto	This book since first published in 2004 has been a major resource providing insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and genetically engineered human cells) from early clinical stage development through market approval. The third edition of this book provides added coverage for the biosimilars, antibody drug conjugates (ADCs), bispecific antibodies,

genetically engineered viruses, and genetically engineered cells. This third edition of the book also addresses the heightened pressure on CMC regulatory compliance timelines due to the introduction of expedited clinical pathways moving the clinical development closer to a seamless phase process (e.g., FDA Breakthrough Therapy designation, CBER Regenerative Medicine Advanced Therapy (RMAT) designation, EMA Priority Medicines (PRIME) designation). The Challenge of CMC Regulatory Compliance for Biopharmaceuticals is essential, practical information for all pharmaceutical development scientists, Manufacturing and Quality Unit staff, Regulatory Affairs personnel, and senior management involved in the manufacture of biopharmaceuticals.