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Autore	Geigert J (John), <1948->
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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)).