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Nota di contenuto	Biopharmaceutical Landscape -- Regulatory Pathways Impacting Biopharmaceuticals -- Differences in CMC Regulatory Compliance: Biopharmaceuticals Versus Chemical Drugs -- Risk Management of the Minimum CMC Regulatory Compliance Continuum -- Ever-Present Threat of Adventitious Agent Contamination -- Starting Materials for Manufacturing the Biopharmaceutical Drug Substance -- Upstream Production of the Biopharmaceutical Drug Substance -- Downstream Purification of the Biopharmaceutical Drug Substance -- Manufacturing the Biopharmaceutical Drug Product -- Complex Process-Related Impurity Profiles -- Seemingly Endless Biomolecular Structural Variants

-- Indispensable Potency (Biological Activity) -- Biopharmaceutical Critical Quality Attributes -- The Art of Setting Biopharmaceutical Specifications – Release and Shelf-Life -- The Challenge of Demonstrating Biopharmaceutical Product Comparability -- Strategic CMC-Focused Interactions with Regulatory Authorities.

Sommario/riassunto

Each year for the past three years, there have been about 50 new molecular medicines approved by the United States Food & Drug Administration (FDA), of which approximately 25% were new biopharmaceuticals. Over 200 recombinant proteins, monoclonal antibodies, antibody drug conjugates, fusion proteins, and Fab fragments are now in the marketplace in both the United States of America (USA) and European Union (EU). There are also now over 60 biosimilars available for all major classes of recombinant proteins and monoclonal antibodies. In addition, gene therapies using genetically engineered viruses and genetically engineered cells are now in the marketplace, and continually growing. This degree of change is reflected in the over 400 CMC regulatory compliance references listed in this book that were either issued or updated since the release of the third edition. Deficiencies in biopharmaceutical CMC regulatory compliance rarely result in termination of a product, but incan readily cause months if not years of delay in initiating clinical trials, or advancing clinical development stages, or even market approval. In summary, this book: Updates real-world CMC deficiency examples with current examples; Addresses current FDA and EMA requirements and expectations for CMC regulatory compliance; Now includes CMC regulatory compliance for the new gene-based biopharmaceuticals.