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Altri autori (Persone)	WangWei <1957 March 10-> Manmohan Singh <1964 November 8->
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Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	An overview of discovery and development process for biologics / Heather H. Shih, Paula Miller, Douglas C. Harnish -- Nonclinical safety assessment of biologics, including vaccines / Liangbiao George Hu, David W. Clarke -- Clinical assessment of biologics agents / Lesley Ann Saketkoo, Shikha Mittoo, Luis R. Espinoza -- Key regulatory guidelines for development of biologics in the U.S. and Europe / Richard Kingham, Gabriela Klasa, Krista Hessler Carver -- Landscape and consideration of intellectual property for development of biosimilars / Srikumaran Melethil -- Scientific aspects of sterility assurance, sterility, asepsis, and sterilization / James E. Akers and James P. Agalloco -- Cell cell culture processes in monoclonal antibody production / Feng Li, Amy (Yijuan) Shen, Ashraf Amanullah -- Protein/peptide purification and virus reduction / Beckley K. Nfor, Esteban Freydell, and Marcel Ottens -- Chemical and genetic modification / M Farys ... [et al.] -- Analytical characterization of proteins/peptides / Yajun Jennifer Wang and Brian Hosken -- Protein/peptide formulation development / Satoshi Ohtake and Wei Wang -- Regulatory strategies and lessons in the development of biosimilars / Umang S. Shah -- Vaccine development : history, current status, and future trends / Leo Van Der Pol, Jean-Pierre Amorij -- Role and application of adjuvants and delivery systems in vaccines / Rajesh K. Gupta -- Methods for characterizing proteins in aluminum

adjuvant formulations / Martinus A.H. Capelle, Emilie Poirier, Tudor Arvinte -- The state of the art and future of gene medicines / Frank Jacobs, Stephanie C. Gordts, Bart De Geest -- Nucleic acid vaccines / Rachel Buglione-Corbett ... [et al.] -- Multifunctional polymeric nano-systems for RNA interference therapy / Arun Iyer ... [et al.] -- Advent and maturation of regenerative medicine / Abner M. Mhashilkar, Anthony Atala -- Conventional and novel container closure/delivery systems / Joseph Wong, Mahesh V. Chaubal -- Controlled-release systems for biologics / Mayura Oak ... [et al.] -- Routes of delivery for biological drug products / Darrell J. Irvine, Xingfang Su, Brandon Kwong.

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#### Sommario/riassunto

Tested and proven solutions to the challenges of biological drug product development. Biological drug products play a central role in combating human diseases; however, developing new successful biological drugs presents many challenges, including labor intensive production processes, tighter regulatory controls, and increased market competition. This book reviews the current state of the science, offering readers a single resource that sets forth the fundamentals as well as tested and proven development strategies for biological drugs. Moreover, the book prepares readers for th

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