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Nota di bibliografia	Includes bibliographical references and index at the end of each chapters.
Nota di contenuto	Preface -- Part I – Lyophilization History and Fundamentals -- History of Lyophilization -- Heterogeneity of protein environments in frozen solutions and in the dried state -- Advance understanding of buffer behavior during lyophilization -- Advances in Instrumental Analysis Applied to the Development of Lyophilization Cycles -- New Developments in Controlled Nucleation: Commercializing VERISEQ® Nucleation technology -- Part II – Lyophilized Biologics and Vaccines – Modality Considerations -- Lyophilized Biologics -- Lyophilization of Therapeutic Proteins in Vials - Process Scale-up and Advances in Quality by Design -- Advances in Process Analytical Technology in Freeze Drying -- Process Scale-up and Optimization of Lyophilized Vaccine Products -- Stabilization of Plasmid DNA and Lipid-based Therapeutics as Dehydrated Formulations -- Part III – Advances in Alternate Drying -- Alternatives to Vial Lyophilization -- Spray Drying

of Biopharmaceuticals -- Current Trends and Advances in Bulk Crystallization and Freeze Drying of Biopharmaceuticals -- Case Studies and Examples of Biopharmaceutical Modalities -- Processed by Bulk Crystallization or Bulk Freeze Drying -- Part IV– Regulatory, Packaging and Technology Transfer Considerations -- Lyophilization of Biologics - An FDA Perspective -- Recent Trends in Lyophilized Delivery Devices and Packaging -- Lyophilization Technology Transfer towards Product Launch.

Sommario/riassunto

This book provides a detailed account of the most recent developments, challenges and solutions to seamlessly advance and launch lyophilized biologics or vaccine products, based on diverse modalities, ranging from antibodies (e.g., monoclonal, fusion), complex biologics (e.g., antibody drug conjugates, PEGylated proteins) and vaccines (e.g., recombinant protein based). The authors adeptly guide you through everything you need to know, from biophysical and chemical stability considerations of proteins, to critical assessment during process scale-up, technology transfer, packaging, alternate drying and device selection for a successful process validation, regulatory submission and launch of a stable, safe and effective product. Lyophilized Biologics and Vaccines: Modality-Based Approaches serves as a reference to all critical assessments and steps from early pre-formulation stages to product launch: Provides recent understanding of heterogeneity of protein environment in frozen systems, buffer stabilization, instrumental analysis and controlled ice nucleation technology Details product development strategies based on diverse modalities of biologics and vaccines, including plasmid DNA and lipid-based therapeutics Recent updates on quality-by-design and process analytical technology approaches, illustrated by case studies and FDA perspective Provides the latest account of alternate drying technologies including spray drying and bulk freeze-drying Chapters are written by one or more world-renowned leading authorities from academia, industry or regulatory agencies, whose expertise cover lyophilization of the diverse modalities of biopharmaceuticals. Their contributions are based on the exhaustive review of literature coupled with excellent hands-on experiences in laboratory or GMP setup, making this an exceptional guide to all stages of lyophilized or dehydrated product development and commercial manufacturing. Dushyant B. Varshney, Ph.D., has made significant contributions in manufacturing science and technology, due diligence, tech transfer, product and process development (including lyophilization), quality-by-design and process analytical technologies for biologics, vaccines and small molecules. He is currently a Director of Manufacturing Assessment, MS&T at Hospira Inc. Manmohan Singh, Ph.D., is a well-known expert in the area of vaccine formulations and adjuvant research and has been working in vaccine R&D for the last 20 years. He is currently the Head of Global Drug Product Development at Novartis Vaccines and Diagnostics in Holly Springs, NC.