Lyophilized Biologics and Vaccines: Modality-Based Approaches

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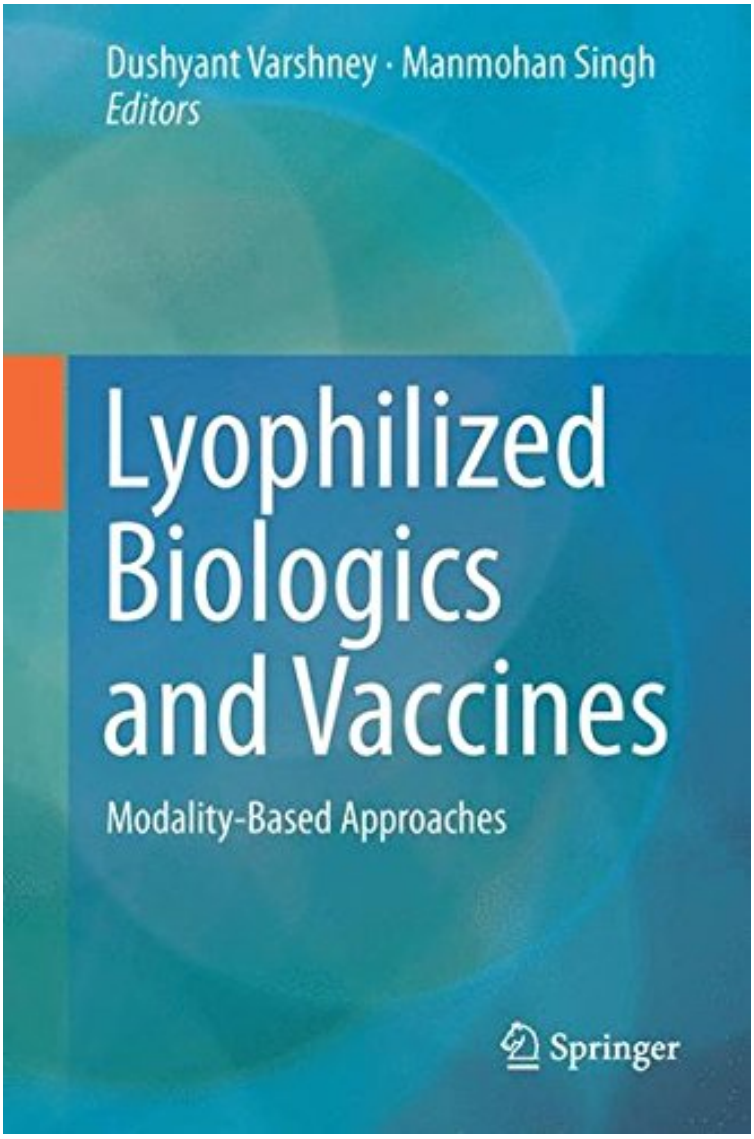

#4326023 in Books 2015-05-21Original language:EnglishPDF # 1 9.21 x .94 x 6.14l, .0 #File Name: 149392382X401 pages | File size: 53.Mb

From Springer : Lyophilized Biologics and Vaccines: Modality-Based Approaches before purchasing it in order to gage whether or not it would be worth my time, and all praised Lyophilized Biologics and Vaccines: Modality-Based Approaches:

This book provides a detailed account of the most recent developments, challenges and solutions to seamlessly

advance and launch a lyophilized biologics or vaccine product, based on diverse modalities, ranging from antibodies (e.g., monoclonal, fused), complex biologics (e.g., antibody drug conjugate, PEGylated proteins), and vaccines (e.g., recombinant-protein based). The authors adeptly guide the reader through all crucial aspects, from biophysical and chemical stability considerations of proteins, analytical methods, advances in controlled ice nucleation and quality-by-design approaches, alternate drying technology, to latest regulatory, packaging and technology transfer considerations to develop a stable, safe and effective therapeutic protein, vaccine and biotechnology products.Lyophilized Biologics and Vaccines: Modality-Based Approaches is composed of four sections with a total of 17 chapters. It 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 and selection of appropriate buffer for stabilization of lyophilized formulationsDetails the latest developments in instrumental analysis and controlled ice nucleation technology Explains in-depth lyophilized (or dehydrated) formulation strategies considering diverse modalities of biologics and vaccines, including plasmid DNA and lipid-based therapeuticsDetails an exhaustive update on quality-by-design and process analytical technology approaches, illustrated superbly by case studies and FDA perspectiveProvides the latest detailed account of alternate drying technologies including spray drying, bulk freeze-drying and crystallization, supported exceptionally by case studiesProvides a step-by-step guide through critical considerations during process scale-up, technology transfer, packaging and drug delivery device selection, for a successful lyophilization process validation, regulatory submission and product launchChapters 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.

From the Back CoverThis 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 therapeuticsRecent updates on quality-by-design and process analytical technology approaches, illustrated by case studies and FDA perspectiveProvides thelatest 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, vaccinesand small molecules. He is currently a Director of Manufacturing Assessment, MST 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 RD for the last 20 years. He is currently the Head of Global Drug Product Development at Novartis Vaccines and Diagnostics in Holly Springs, NC. About the AuthorDushyant B. Varshney, Ph. D., has made significant contributions in manufacturing science and technology, tech transfer, product and process development (including lyophilization), quality-by-design and process analytical technologies for biologics, vaccines and small molecules. Having earned his Ph.D. from the University of Iowa, Dr. Varshney has authored several peer-reviewed scientific publications, review articles, and book chapters, and has presented at several international conferences and chaired scientific workshops. He is currently a Director of Manufacturing Assessment, MST at Hospira, Inc. He has previously worked at Novartis, Bristol-Myers Squibb, Sanofi and Eli Lilly Company.Manmohan Singh, Ph.D., is a well-known expert in the area of vaccine formulations and adjuvant research, and has been working in vaccine RD for the last 20 years. He has authored over 130 peer reviewed manuscripts, review articles, and book chapters, and has edited five books in this area. Dr. Singh is on the editorial board of 11 International Journals and has collaborated in organizing several international vaccine conferences. Currently, he is the Head of Global Drug Product Development at Novartis Vaccines and Diagnostics in Holly Springs, NC 27540.