Preface

Lyophilization has become a popular approach for stabilization of the biologics. In the recent years, advances in biotechnology have resulted in various modalities of antibodies, antigens, and cancer drugs being explored in the development of therapeutic proteins, effective drugs, and vaccines. Diverse forms of antibodies (e.g., monoclonal, domain, fused), complex biologics (e.g., antibody drug conjugate, PEGylated proteins), peptides (e.g., cyclic peptides), and vaccines (e.g., combination type, inactivated virus, recombinant protein based) are being stabilized in the lyophilized form. Recent advances in lyophilization equipment, formulation, analytical instrumentation, delivery devices (e.g., cartridges), and manufacturing processes are being explored to overcome challenges posed by differences in the biophysical and chemical stability of each modality. The book "*Lyophilized Biologics and Vaccines—Modality-Based Approaches*" covers advances in lyophilization theories, product and process development approaches, and delivery approaches based on new modalities of biologics and vaccines. Recent advances in alternate drying methods and bulk lyophilization are also discussed in depth. The book is composed of four major sections having a total of 17 chapters, presented by expert and world renowned authors from academia, industry, and regulatory agencies.

Part I—Lyophilization History and Fundamentals is covered in five chapters. First a detail account of the historical development of lyophilization is discussed followed by recent advances in the understanding of heterogeneity of protein environment in the frozen or dried state, new developments in understanding buffer behavior and instrumental analysis of lyophilized biologics or vaccines is described. Special focus is given on recent advances in controlled ice nucleation with a specific discussion on VERISEQ® nucleation technology.

Part II—Lyophilized Biologics and Vaccines—Modality Considerations are discussed in five chapters. First an overview of the challenges and developments in lyophilized formulations for different modalities of biologics or vaccines is presented. Next, recent advances in quality by design (QbD) and process analytical technology (PAT) approaches for process scale-up of therapeutic protein are discussed in depth. The chapter on lyophilized vaccine provides a complete and detailed overview of a typical vaccine product and process development, from scale-up to optimization.

A special highlight on advances in stabilization of plasmid DNA and lipid-based therapeutics as dehydrated formulations is covered.

Part III—Advances in Alternate Drying methods is covered in four chapters. A detailed account of alternate drying methods compared to traditional vial lyophilization is discussed. Some of these include sterile spray drying, sterile powder filling, vacuum drying and drying on a fiber matrix. Chapters on recent advances in the spray drying, bulk freeze drying and crystallization provide an in-depth understanding of technology, challenges, and advantages, with nicely illustrated case studies.

Part IV—Regulatory, Packaging, and Technology Transfer Considerations is discussed in three important chapters, providing the latest regulatory perspective on lyophilized biologics, recent trends in lyophilized delivery devices, and packaging. The chapter on lyophilization technology transfer process provides critical considerations with case studies in detail for successful process scale-up to process validation and launch of lyophilized biologics and vaccines.

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