

Preface

The objective of this book is to compile the concepts essential for the understanding of the pharmaceutical science and technology associated with the delivery of subunit vaccines. The book's goal is to provide a comprehensive overview of the scientific and regulatory challenges facing scientists who research and develop subunit vaccines. The scope of the book is wide. It is written in a manner that will enlighten newcomers to the field (e.g., Ph.D. students or experienced scientist switching fields) yet provides an in-depth knowledge that would benefit a skilled worker in the field.

A significant improvement in the safety of modern vaccines has been the development of subunit vaccines, as these are composed of very well-defined and highly pure components, often recombinant proteins. However, since protein-based antigens in general are weakly immunogenic by themselves, co-administration of adjuvants is required to induce potent and persistent specific immune responses. In recent years, there has been substantial progress in the discovery of new efficient adjuvants for subunit vaccines that are often classified into delivery systems (e.g., liposomes, emulsions, and polymeric nanoparticles) and immunopotentiating compounds that constitute pathogen-associated molecular patterns, such as the toll-like receptor ligands. The combination of delivery systems and immunopotentiators has created highly efficacious adjuvants due to concomitant enhanced antigen delivery and potent stimulation of immunity. Many of these adjuvants are of a particulate nature and mimic the structure and/or composition of microbes in a reductionist fashion. Examples are liposomes, polymeric nanoparticles, emulsions, and virus-like particles. However, there are a substantial number of pharmaceutical challenges associated with the subunit vaccine development process due to the complex nature of the antigen–adjuvant combinations. These challenges will be presented and discussed in this book.

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