Covering all aspects of vaccine research and development in one volume, this authoritative resource takes a comprehensive and systematic approach to the science of vaccinology focusing not only on basic science, but also on the many stages required to commercialize and navigate the regulatory requirements for human application, both in the United States and Europe:

- Reviews in detail the process of designing a vaccine, from the initial stages of antigen discovery to human application
- Includes evaluation of vaccine efficacy and safety
- Details clinical trial design, including regulatory requirements
- Discusses the emerging field of active cellular immunotherapy

Vaccinology: Principles and Practice provides an invaluable resource for clinicians, scientific and medical researchers, lecturers and postdoctoral fellows working in the field of vaccines.

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2012
9781444335675

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Principles and Practice
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Preface

“Vaccinology” is a term that encompasses the whole process of producing vaccines – from basic research and preclinical demonstration of efficacy, to approval and clinical trial in humans. While there are many excellent books that detail the various steps, such as antigen discovery or delivery systems, there are fewer that also cover so called “downstream development,” such as the design of clinical trials, or their regulation in the United States and the European Union. In this book we have aimed to fill this gap by providing the reader with a comprehensive and authoritative reference that describes the design and construction of vaccines from first principles to implementation. We hope it will appeal both to scientists engaged in vaccine research and development, and to clinicians, or indeed anyone, with an interest in the opportunities and challenges facing the development of new vaccines.

To tackle this vast subject we have organized the chapters into sections. We start with an examination of the concept and scope of modern vaccines. We follow this with the basic tenets of the immune system that govern our thinking about vaccines, with chapters on innate immunity, antigen processing and presentation, mucosal immunity, immunological memory in T and B cells, and the utility of mouse and nonhuman primate models for testing vaccine efficacy. In the following section we explore antigen discovery in the postgenomic era, during which there has been remarkable progress in proteomic mining for potential vaccine antigens, and powerful predictive algorithms and high-throughput assay and display technologies. Together these offer unprecedented opportunities for the rapid development of new vaccines. This is then followed by a selection of chapters on antigen engineering and delivery: attenuated microbe vaccines, virus-like particles, recombinant viruses (orthopox, avipox, lentivirus, and adenovirus) and bacteria, DNA vaccines, and artificial cells. In parallel we explore methods for antigen delivery, with chapters on transcutaneous vaccination, needle-free jet delivery, and oral vaccines. The need to potentiate otherwise inert proteins is the subject of the next section, with chapters on designing adjuvants, particulate delivery systems such as PLGs and microspheres, co-administration of co-stimulatory moieties, and the role of TLR signaling in adjuvanticity. We then transition from basic research to vaccine implementation. The first of these sections discusses regulatory considerations, with chapters on working with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), developmental pipelines, the design of clinical trials, immune monitoring and biomarkers, and vaccine safety. This is followed by chapters on mass immunization strategies, and mathematical models and epidemiological monitoring.

This book would not be possible without the impressive array of experts who have contributed chapters. We wish to thank every one of you for making this possible and bearing with us on this ambitious project. Finally we wish to thank the production team at John Wiley, especially Julie Elliott, Maria Khan, and Michael Bevan. This has been a team effort, but ultimately any omissions or errors are the responsibility of the editors. We welcome comments and feedback for future editions of this book.

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PART 1

Introduction