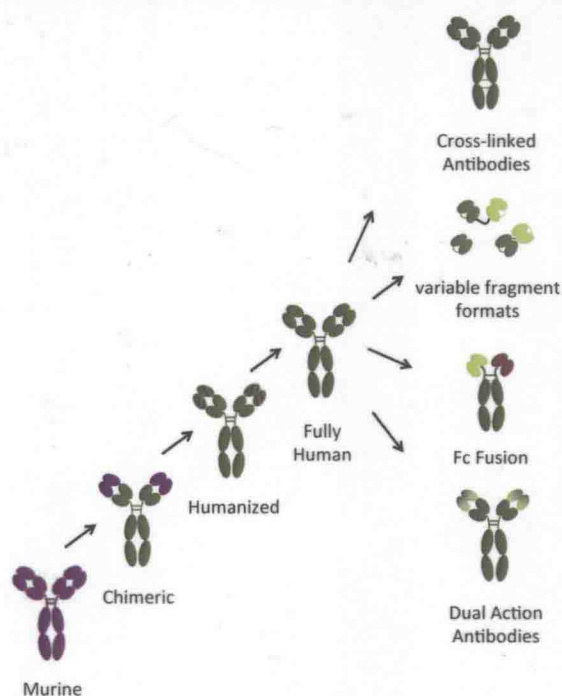
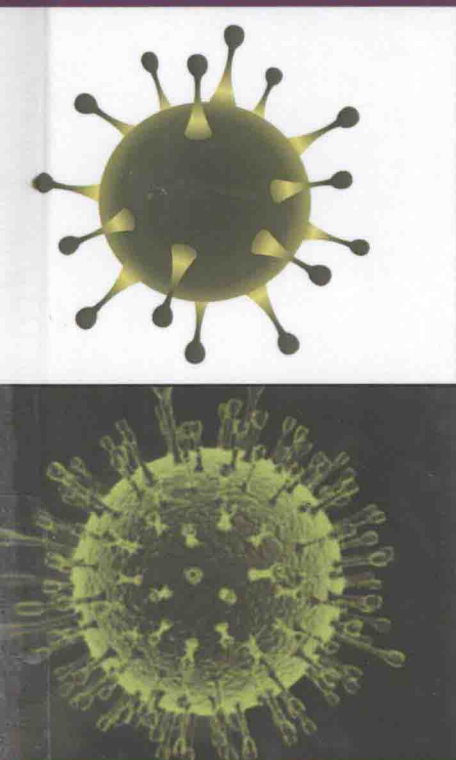


Nonclinical Development of Novel Biologics, Biosimilars, Vaccines and Specialty Biologics



Edited by
Lisa M. Plitnick
Danuta J. Herzyk



NONCLINICAL DEVELOPMENT OF NOVEL BIOLOGICS, BIOSIMILARS, VACCINES AND SPECIALTY BIOLOGICS

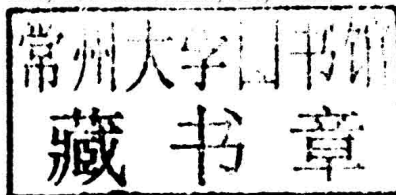
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NONCLINICAL DEVELOPMENT OF NOVEL
BIOLOGICS, BIOSIMILARS, VACCINES
AND SPECIALTY BIOLOGICS

Dedication

The Editors would like to dedicate this book to Peter J. Bugelski who passed away in 2011. Peter was not only a leader in the field of immunotoxicology and biologics but a friend, a mentor, and an invaluable collaborator to many authors of this book.

Peter's contributions to the field, especially in the form of his numerous important publications, will be recognized and remembered long after his passing and he will remain in our hearts and memories for many years to come.

Preface

Biological medicines have been proven to be very effective both as prophylactic treatment in the form of vaccines and as a desirable solution for complex unmet medical needs in the form of biopharmaceuticals. Development of these medicines has been highly successful. Nevertheless, it remains very expensive, time-consuming, and requires many special considerations in comparison with small-molecule drugs. Although the nonclinical development of biological and small molecule drugs differ in many ways, the approaches for nonclinical evaluation have begun to converge. Development programs between biologics and small molecules are sometimes quite similar as the specificity of the latter increases and therapeutic targets for all types of novel drugs begin to involve similar molecular signaling pathways.

Since the discovery of early biologics such as vaccines and blood products, the field of biologics has evolved to include more advanced, target-specific modalities. *Nonclinical Development of Novel Biologics, Biosimilars, Vaccines and Specialty Biologics* is a testament to this evolution. The goal of this book and of all the many world-renowned

experts who contributed to this effort is to educate and inform those interested in biopharmaceutical development, from students and academicians to those currently working in the biopharmaceutical industry. This book complements and builds upon the solid foundation provided in the first comprehensive book dedicated to nonclinical development of biopharmaceuticals edited by Joy Cavagnaro. In only a few short years the science has advanced sufficiently to warrant a second book on nonclinical development of biologics, which includes topics such as biosimilars and multispecific antibodies and fragments that were only an idea a few years ago, but have since become a reality. As those fields have progressed, so too have the regulatory guidelines such as the ICH S6 addendum, and specific documents for biosimilars, vaccines, gene therapy, and stem cells which aid researchers in the design of consistent and comprehensive nonclinical programs. The editors sincerely hope readers find the subject matter interesting and educational, and that the knowledge and enthusiasm of the authors will be appreciated.

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