

Brian K. Nunnally · Vincent E. Turula  
Robert D. Sitrin *Editors*

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# Vaccine Analysis: Strategies, Principles, and Control

 Springer

# Vaccine Analysis Strategies Principles And Control

**Amine Kamen, Laura Cervera**



## **Vaccine Analysis Strategies Principles And Control:**

*Vaccine Analysis: Strategies, Principles, and Control* Brian K. Nunnally, Vincent E. Turula, Robert D. Sitrin, 2014-11-27

This book is an indispensable tool for anyone involved in the research development or manufacture of new or existing vaccines. It describes a wide array of analytical and quality control technologies for the diverse vaccine modalities. Topics covered include the application of both classical and modern bio-analytical tools, procedures to assure safety and control of cross-contamination, consistent biological transition of vaccines from the research laboratory to manufacturing scale, whole infectious attenuated organisms such as live attenuated and inactivated whole cell bacterial vaccines and antiviral vaccines using attenuated or inactivated viruses, principles of viral inactivation and the application of these principles to vaccine development, recombinant DNA approaches to produce modern prophylactic vaccines, bacterial subunit, polysaccharide and glycoconjugate vaccines, combination vaccines that contain multiple antigens as well as regulatory requirements and the hurdles of licensure.

### **Bioprocessing of Viral Vaccines**

Amine Kamen, Laura Cervera, 2022-09-06 This book focuses on cell culture produced viral vaccines to meet the needs of the rapidly expanding research and development in academia and industry in the field. This book introduces the basic principles of vaccination and the manufacturing of viral vaccines. Bioprocessing of Viral Vaccines will provide an overview of the advanced strategies needed to respond to the challenges of new and established viral infection diseases. The first few chapters cover the basics of virology and immunology as essential concepts to understand the function and design of viral vaccines. The core of the content is dedicated to process development including upstream processing and cell culture of viral vaccines, downstream processing and extensive analytical technologies specific to viral vaccines. Advanced process analytical technologies (PAT) and Quality by Design (QbD) concepts are also introduced in the context of vaccine manufacturing. The case studies included cover inactivated attenuated vaccines exemplified by influenza vaccines, subunit vaccines exemplified by Virus Like Particles (VLPs), HPV vaccines and subunit vaccines, Flublock vectored vaccines, adenoviruses and Vesicular stomatitis Virus (VSV) vectored vaccines, genomic vaccines, DNA and mRNA vaccines as developed for COVID-19 response in particular and a review of COVID-19 vaccines approved or in advanced clinical trials. This book is aimed at graduate engineers and professionals in the fields of vaccinology, bioprocessing and biomanufacturing of viral vaccines.

### *Recent Trends in Carbohydrate Chemistry* Amélia Pilar

Rauter, Bjørn E. Christensen, László Somsák, Paul Kosma, Roberto Adamo, 2020-04-29 *Recent Trends in Carbohydrate Chemistry: Synthesis and Biomedical Applications of Glycans and Glycoconjugates* covers biomedically relevant bacterial cell wall carbohydrates including recent findings on biosynthetic aspects, advances in the chemical assembly of bacterial lipopolysaccharide fragments and teichoic acids and modern NMR approaches to unravel structural details. The first part introduces and provides the relevant background for synthetic glycoconjugate vaccines. The second section focuses on synthetic carbohydrate-based vaccines of therapeutic potential that are licensed or under development. This second volume of

Recent Trends in Carbohydrate Chemistry is ideal for researchers working as synthetic organic chemists as well as those interested in glycoconjugation protein chemists immunologists and microbiologists in academia as well as in industry

**Lipids in Pulmonary Drug Delivery** Md Faiyazuddin, Hasan Ali, Md Akbar, Babar Iqbal, 2025-02-26 Lipid in Pulmonary Drug Delivery explores the most recent advancements strategies and state of the art technological progress in the development of lipid based nanocarriers for pulmonary administration The book presents wide coverage of various lipid based nano drug carriers such as liposomes solid lipid nanoparticles and nanoemulsions intended for the administration of drugs through the pulmonary route to treat different conditions It also includes a general description of the formulation aspects of various lipid based drug delivery vehicles post production processing and biofate aspects with special emphasis on the pulmonary microenvironment In addition the authors include an update on the clinical status of the potential lipid nanocarriers used for effective management of the pulmonary related diseases Written in a technical way covering the latest advancements in lipid based drug delivery for pulmonary administration this book is a useful reference for researchers scientists and graduate and postgraduate students working on or planning research in the field of lipid based nano drug pulmonary delivery platforms Presents unique and comprehensive information on lipid based nanomedicines for pulmonary drug delivery Provides insights into the biological fate and interplay of nanoparticles with the environment of the pulmonary system Acts as a guide for the future applications of lipid based nanomedicine in the clinical setting for the precise management of pulmonary diseases

**Role of Microbes in Industrial Products and Processes** Sanjay Kumar, Narendra Kumar, Shahid Ul Islam, 2022-10-10 ROLE OF MICROBES IN INDUSTRIAL PRODUCTS AND PROCESSES The book covers recent breakthroughs and highlights the major role microbes play in industrial products and processes With the advent of industrial biotechnology microbes became popular as cell factories and with the recent advancements in recombinant DNA technology the application of microorganisms in various sectors has increased enormously for the development of various processes and products Role of Microbes in Industrial Products and Processes covers recent breakthroughs and highlights the major role microbes play in industrial products and processes It mainly focuses on the bio refinery concept where bio energy production and wastewater treatment are done simultaneously using micro algae Additionally this book describes the role of microbes involved in the production of various enzymes organic acids and bio polymers It also provides detailed insight on modeling and simulation of bioprocess for the production of sugar alcohol recovery of value added products from organic waste using microbes is also reported Detailed insights into the treatment of wastewater released from various industries especially pharmaceutical wastewater are given Audience The book is intended for researchers scientists and postgraduates in chemical biochemical engineering and bioprocess engineering and others working in the domain of food microbiology bioenergy refinery waste valorization to value added products and microbial production of bioplastics sugar alcohols enzymes and organic acids

**Irradiation technologies for vaccine development** Viskam Wijewardana, Giovanni Cattoli, Sebastian

Ulbert,2023-02-27 *Green Techniques for Organic Synthesis and Medicinal Chemistry* Wei Zhang,Berkeley W.

Cue,2018-01-18 An updated overview of the rapidly developing field of green techniques for organic synthesis and medicinal chemistry Green chemistry remains a high priority in modern organic synthesis and pharmaceutical R D with important environmental and economic implications This book presents comprehensive coverage of green chemistry techniques for organic and medicinal chemistry applications summarizing the available new technologies analyzing each technique s features and green chemistry characteristics and providing examples to demonstrate applications for green organic synthesis and medicinal chemistry The extensively revised edition of Green Techniques for Organic Synthesis and Medicinal Chemistry includes 7 entirely new chapters on topics including green chemistry and innovation green chemistry metrics green chemistry and biological drugs and the business case for green chemistry in the generic pharmaceutical industry It is divided into 4 parts The first part introduces readers to the concepts of green chemistry and green engineering global environmental regulations green analytical chemistry green solvents and green chemistry metrics The other three sections cover green catalysis green synthetic techniques and green techniques and strategies in the pharmaceutical industry Includes more than 30% new and updated material plus seven brand new chapters Edited by highly regarded experts in the field Berkeley Cue is one of the fathers of Green Chemistry in Pharma with backgrounds in academia and industry Brings together a team of international authors from academia industry government agencies and consultancies including John Warner one of the founders of the field of Green Chemistry Green Techniques for Organic Synthesis and Medicinal Chemistry Second Edition is an essential resource on green chemistry technologies for academic researchers R D professionals and students working in organic chemistry and medicinal chemistry *COVID-19 vaccines* ,2021-08-04 Intellectual Property Rights Issues in Vaccine Development Sachin Kumar Jain, Ravikant Gupta, Sudha Vengurlekar, Nidhi Bais, Gajendra P.

Choudhary,2025-08-01 Intellectual Property Rights Issues in Vaccine Development offers a timely exploration of the evolving role of intellectual property IP in shaping global vaccine research innovation and accessibility As the world continues to grapple with public health challenges like the COVID 19 pandemic this book provides a critical lens on how patents trade secrets and international agreements influence vaccine development and distribution The contents of the book explore the historical evolution of IP in vaccinology the debate over patent protection the intersection of legal frameworks and ethical concerns and the tension between innovation and equitable access Special attention is given to global case studies the impact of international agreements and recommendations for stakeholders across policy industry and healthcare sectors Key features Traces the history and legal evolution of vaccine related IP Analyzes global access challenges and equity concerns Explores the role of IP during the COVID 19 pandemic Examines real world case studies of vaccine IP dynamics Offers actionable policy and industry recommendations *Global Virology V: 21st Century Vaccines and Viruses* Paul Shapshak,Seetharaman Balaji,Pandjassaram Kanguene,Jens H. Kuhn,Charurut Somboonwit,John T. Sinnott,2025-07-11 The

purpose of this fifth volume in the Global Virology series is to describe and propose vaccines focusing primarily on viral vaccines. In addition to human vaccines, animal viral vaccines are included since animals are used in vaccine research and the spread of diseases to and from animals, birds, and humans permeates the ecosystem. Due to climatic, geographical, and social factors, there is increased global spread of viruses and other infectious agents. Contributory factors include global warming, spread of vectors, increased human travel, encroachment into animal and avian environments, war, pestilence, malnutrition, and environmental, economic, and social collapse. GVV will address vaccines for many of the viruses addressed in previous series volumes as well as for viruses not previously covered and novel and future vaccine technologies. Advances in vaccine effectiveness and molecular engineering approaches are included such as gene therapy and CRISPR technologies.

*Bioreactor Design Concepts for Viral Vaccine Production* Surajbhan Sevda, Sachin Kumar, 2024-05-12. *Bioreactor Design Concepts for Viral Vaccine Production* covers a range of interdisciplinary chapters from the engineering perspective of bioreactor design to the biotechnological perspectives of vector design for vaccine development. The book covers bioreactor concepts such as static systems, single use systems, stirred tanks, perfusion, wave, and packed beds. It reviews options for efficient and economical production of human vaccines and discusses basic factors relevant for viral antigen production in mammalian cells, avian cells, and insect cells. This book will be a great resource for those interested in implementing novel bioreactor design or experimental schemes towards intensified or enhanced vaccine production. Covers the fundamentals of bioreactor designs. Provides strategies for designing a successful vector-based vaccine. Discusses the applications of biological kinetics, thermodynamics, and basic substrate requirements for viral vaccine production. Public Health Intervention For The Covid-19 Pandemic: From Virus To Vaccine David M Patrick, Ariana Saatchi, 2022-03-11. On March 11, 2020, the World Health Organization declared the COVID-19 pandemic, and life as we knew it paused indefinitely. Confusion, doubts, and uncertainty became daily companions as the world watched the pandemic consume country after country. At the University of British Columbia, Canada, a class of aspiring epidemiologists partnered with the professionals working at the frontline of COVID-19 healthcare and research to examine key questions which would capture a snapshot of the historical pandemic: What caused this outbreak? How does a virus spread? What are the best potential treatments? How did we achieve the development of vaccines and how do they work? What are the strategies to tackle a two-front war against the virus and the spread of dangerous misinformation and pseudoscience? These questions and more are examined throughout this volume.

**Fish Vaccines** Preetham Elumalai, Kim Thompson, Sreeja Lakshmi, 2023-06-30. This book is a timely reference text that highlights the role of vaccination in the fast-growing aquaculture industry. It discusses topics such as vaccine formulation, vaccine delivery, and enhancing the immune response of fish using nanoparticles. Information related to vaccine safety, ethical approval, and regulations is also discussed together with dissemination of vaccines to fish farms across the globe. This cutting-edge book presents novel strategies to meet the growing demand for vaccines in finfish aquaculture. This book is useful to

students academics clinicians and professionals in the field of fisheries sciences aquaculture and veterinary sciences

**Fundamentals of Biologicals Regulation** Rebecca Sheets, 2017-12-01 Fundamentals of Biologicals Regulation Vaccines and Biotechnology Medicines serves as an introduction to the international regulatory arena in which biologicals are developed and offers an overview of the processes and insight into the scientific concepts underpinning global regulations This book will provide multiple levels of readership with guidance on basic concepts a detailed look at regulatory challenges and practical insight into how regulators consider regulatory science and regulatory process issues across various regions With numerous case studies learning activities and real world examples across several classes of biotechnological products this book is a valuable and comprehensive resource for graduate students professors regulatory officials and industry scientists working with biologicals Provides a broad overview and introduction to the regulatory processes from product development pathways through clinical trials and product development stages and beyond Includes FDA EMA ICH and WHO recommendations and guidelines so readers can compare and contrast the different regulatory regions with their expectations and understand why they are different Contains chapters on some of the exceptions to the process including how biosimilars and in vitro diagnostics are regulated Includes numerous case studies learning activities and real world examples across several classes of biotechnological products

**The Complexities, Key Concepts and Mechanisms of Immunology** Seema Tripathy, Rashmi Rekha Sahu, 2024-07-23 This concise and comprehensive guide describes the complexities key concepts and mechanisms of the immune system in a simplified manner The book provides a clear and accessible overview of the body's defence mechanisms covering various aspects such as the structure and function of immune cells the mechanisms of antigen recognition and response the regulation of immune responses through the release of cytokines and dysfunctions of the immune system which lead to autoimmunity and hypersensitivity Additionally it covers different immunological techniques and the latest developments in immunotherapy including the use of monoclonal antibodies The multiple choice questions and answers provided at the end of each chapter will further enhance the understanding of the book's readership

**Drug Discovery and One Health Approach in Combating Infectious Diseases** Kanti Bhooshan Pandey, David J. Newman, Chukwuebuka Egbuna, 2025-08-01 Drug Discovery and One Health Approach in Combating Infectious Diseases A Multi sectoral Approach to address Infections explores the intersection of drug discovery and the One Health Approach along with the effectiveness of interdisciplinary approaches to combating infectious diseases The book covers both holistic and innovative drug discovery methodologies and technologies such as natural compounds harnessing genomics proteomics and nanotechnology Additionally the book reviews zoonotic diseases vaccine development ethical considerations and regulatory pathways Practice case studies demonstrate successful One Health and interdisciplinary initiatives to combating infectious disease This catalogue of knowledge provides a toolbox of innovative and interdisciplinary solutions of complex issues in drug discovery and infectious disease It will be a valuable resource to

professionals and researchers working in the fields of biomedical sciences pharmaceutical sciences infectious disease research and public health as well as those engaged in drug discovery development and the management of infectious diseases Presents practical case studies on successful One Health initiatives Covers the fundamentals of drug discovery and the One Health Approach through an interdisciplinary lens Explains innovative technologies and emerging trends in infectious disease management and drug discovery

*Engineering Health* Lara Marks, 2017-10-25 Biotechnology harnesses cellular and biochemical systems to advance knowledge of the molecular cause of disease and to provide new diagnostic tools and more precisely targeted drugs Within a decade global investment in medical biotechnology has increased more than ten fold resulting in therapies for previously untreatable conditions But what exactly is biotechnology and what are its origins What further benefits to human health could it offer in the future Written in an accessible style contributors to this book explore the history behind different biotechnology tools how they are used and how they are reshaping the future of diagnostics therapeutics and vaccines Among the technologies examined are genetic engineering DNA sequencing monoclonal antibodies stem cells gene therapy cancer immunotherapy and the most recent newcomer synthetic biology Applying new biotechnologies in medicine is not without great challenges As medicines shift from small organic molecules to large complex structures such as therapeutic proteins drugs become difficult to make administer and regulate This book will intrigue anyone interested in medicine and how we have been and may continue to engineer better health for ourselves Such changes have major implications for how and where drugs are manufactured the cost of medicine and the ethics of how far society is prepared to go to combat disease

Textbook of General Virology Sachin Kumar, 2025-03-31 This book is an introductory text that presents fundamental knowledge and recent advances in virology It provides comprehensive coverage of different aspects like classification structure emerging viruses cancer causing viruses and viral vaccines It covers the basic biology of virus existence evolution and reoccurrence It also incorporates the fundamentals of biophysical and biochemical aspects of viral replication The book discusses important topics such as immunity to viral infections bacteriophages and techniques used in virology The Textbook of General Virology is meant for undergraduate and postgraduate students of microbiology immunology genetics and medicine Key Features Discusses introductory and foundational knowledge of viruses for students of life sciences and medicine Covers the virus history diversity of its infection strategy and classification Summarizes the characteristics of different viruses on the basis of nucleic acid genome type Describes the biology of RNA and DNA viruses and their effect on cell growth control in animals and humans after infection Reviews topics like immunity to viruses and viral vaccines

**Marine Specialized (Secondary) Metabolites and their Diverse Applications** Thilina Jayawardena, Asanka Sanjeewa, 2025-06-13 Over the past 50 years more than 20 000 natural compounds have been identified in the marine environment with an increasing focus on marine metabolites as potential sources for developing effective therapeutic agents The field of marine drug discovery has seen remarkable growth in recent years with numerous marine



derived therapeutic candidates in various stages of clinical trials or awaiting approval The ocean is a potential source of natural products with diverse pharmacological properties including antimicrobial anticancer antiviral antioxidative and anti inflammatory activities However commercializing marine natural products has been challenging due to low yields and specificity of specialized secondary metabolites Marine specialized secondary metabolites and their diverse applications provides a broad overview of marine specialized metabolites and their potential in various industries With comprehensive coverage relevance to current trends interdisciplinary approach and practical applications this book includes specific compounds or organisms with a particular focus on addressing the challenges and limitations associated with them Includes chapters that follow a clear structure presenting a consistent and organized format that makes it easier for readers to navigate the content Takes an interdisciplinary approach providing readers with a broad perspective on natural compounds and secondary metabolites Covers critical and comprehensive literature reviews of the advancements and diverse applications of marine specialized metabolites

Role of Microorganisms in Pathogenesis and Management of Autoimmune Diseases Mitesh Kumar Dwivedi,A. Sankaranarayanan,E. Helen Kemp,Yehuda Shoenfeld,2023-01-01 This book which is the second volume of Role of Microorganisms in Pathogenesis and Management of Autoimmune Diseases provides comprehensive coverage on how microbial pathogens can subvert our immune system into responding against self and resulting in autoimmune diseases In particular the book covers the different aspects of linking gut microbiota dysbiosis with autoimmune mechanisms involved in disease development to identify future effective approaches based on the gut microbiota for preventing these autoimmune diseases Contributions in the book focus on the role of microbiota probiotics and their distinct mechanisms exerted in the management of autoimmune diseases of the kidney central nervous system eye blood vessel and bowel This could help in better understanding to design of therapeutic strategies that can be deployed to prevent these autoimmune diseases The book has an interdisciplinary appeal and scholars with an interest in immunology medical microbiology and nutritional sciences will value its contribution Overall the book gives new dimension and insight into the aspects of microbial role in autoimmune disease pathogenesis

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