

Adrian P. Gee *Editor*

Cell Therapy

cGMP Facilities and Manufacturing

Second Edition

 Springer

Cell Therapy Cgmp Facilities And Manufacturing

Anthony S. Fauci



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Cell Therapy Adrian Gee, 2009-09-18 *Cell Therapy cGMP Facilities and Manufacturing* is the source for a complete discussion of facility design and operation with practical approaches to a variety of day to day activities such as staff training and competency cleaning procedures and environmental monitoring This in depth book also includes detailed reviews of quality the framework of regulations and professional standards It meets a previously unmet need for a thorough facility focused resource *Cell Therapy cGMP Facilities and Manufacturing* will be an important addition to the cell therapy professional s library Additional topics in *Cell Therapy cGMP Facilities and Manufacturing* Standard operating procedures Supply management Facility equipment Product manufacturing review release and administration Facility master file

Cell Therapy Adrian P. Gee, 2021-11-10 This new edition presents a fully updated and expanded look at current Good Manufacturing Practice cGMP for cell therapy products It provides a complete discussion of facility design and operation including details specific to cord blood banking cell processing vector production and qualification of a new facility Several chapters cover facility infrastructure including cleaning and maintenance vendor qualification writing a Standard Operating Procedure staff training and process validation The detailed and invaluable product information covers topics like labelling release and administration transportation and shipment et al Further chapters cover relevant topics like writing and maintaining investigational new drug applications support opportunities in North America and the European Union commercial cell processing and quality testing services and financial considerations for academic GMP facilities A chapter on future directions rounds out *Cell Therapy cGMP Facilities and Manufacturing* making it essential reading for any cell therapy professional involved in the development use or management of this type of facility *Cell Therapy* Adrian P. Gee, 2022 This

new edition presents a fully updated and expanded look at current Good Manufacturing Practice cGMP for cell therapy products It provides a complete discussion of facility design and operation including details specific to cord blood banking cell processing vector production and qualification of a new facility Several chapters cover facility infrastructure including cleaning and maintenance vendor qualification writing a Standard Operating Procedure staff training and process validation The detailed and invaluable product information covers topics like labelling release and administration transportation and shipment et al Further chapters cover relevant topics like writing and maintaining investigational new drug applications support opportunities in North America and the European Union commercial cell processing and quality testing services and financial considerations for academic GMP facilities A chapter on future directions rounds out *Cell Therapy cGMP Facilities and Manufacturing* making it essential reading for any cell therapy professional involved in the development use or management of this type of facility Perinatal Tissue-Derived Stem Cells Babak Arjmand, 2016-12-01 This book covers several aspects of perinatal tissue derived stem cells from theoretical concepts to clinical applications Topics include functions and different sources immunomodulatory properties translational point of view GMP facility design and

manufacturing for clinical translation therapeutic potentials and finally ethical considerations The text provides a brief review of each type of perinatal stem cells and then focuses on their multi or pluripotent properties regenerative capacity and future therapeutic potential in regenerative medicine Additionally the book discusses GMP compliance in stem cell facilities and the manufacture of stem cells for clinical translation The chapters are authored by world renowned experts in the perinatal stem cell field Perinatal Tissue Derived Stem Cells Alternative Sources of Fetal Stem Cells part of Springer s Stem Cell Biology and Regenerative Medicine series is essential reading for basic and clinical scientists clinicians and pharmaceutical experts working or conducting research in the fields of stem cell biology molecular aspects of stem cell research tissue engineering regenerative medicine and cellular therapy

CAR-T Manufacturing Andy Kah Ping Tay, 2025-02-20 This edited volume describes innovations in all steps of the CAR T manufacturing chain These vital descriptions will help practitioners to overcome current challenges during the process and vastly reduce costs and enable timely and accessible administration of CAR T therapy to patients The book provides readers with information on key fundamental concepts of CAR T manufacturing in areas such as cell selection cell activation cell transfection cell expansion genetic engineering and quality control In each chapter a particular technological field in the CAR T manufacturing chain is discussed Each chapter will include an introduction to the importance of a particular technology for cell manufacturing comparisons of state of the art methods and discussions on respective emerging innovations This exposes readers to a high level view of the entire process while diving into details for each specific process step Readers will be able to apply their knowledge to make changes at each step of the CAR T manufacturing process to reduce the existing high costs and long production times so that cancer patients globally can benefit from CAR T therapy This book is an invaluable resource for practitioners in CAR T manufacturing who aim to improve their quality and efficiency while reducing time and costs It is also useful for advanced undergraduate and graduate students who wish to gain a strong foundation for continuing research in the field or interacting with practitioners

Cell Therapy Manufacturing Glyn N. Stacey, Tongbiao Zhao, 2025-10-24 This book focuses on the current developments and future perspectives on cell therapies It includes chapters on new scientific developments non scientific challenges standards development and brief summaries of the state of regulation in certain areas Taken with its companion volume *Advanced Cell Therapies Experiences on the pathway* these two volumes provide perspectives from other professionals focused on supporting successful delivery of safe and effective cell therapy products including regulators standards organisations and suppliers of raw materials and consulting services It will draw authors from both North America Europe and Asia and International organisations to provide a balance of approaches from different jurisdictions The financial and legal realities of delivering such products will also be addressed by expert authors in the field The ethical challenges in different parts of the world and for international translation of particular products will also be explored with specifics provided

Cell Therapy Current Developments and Future Directions and its companion volume are

essential reading for researchers moving into translational science industry and legal personnel wishing to understand cell therapies regulators and policy makers developing regulation and guidelines and advanced students researching this field

Biomedical Product Development: Bench to Bedside Babak Arjmand, Moloud Payab, Parisa Goodarzi, 2020-02-05 This textbook covers all the steps in manufacturing a biomedical product from bench to bedside It specifically focuses on quality assurance and management and explains the different good practice principles in the various phases of product development as well as how to fulfill them Good laboratory practice good manufacturing practice and good clinical practice It provides readers with the know how to design biomedical experiments to ensure quality and integrity to plan and conduct standard preclinical studies and to assure the quality of the final manufactured biomedical products Importantly it also addresses ethical concerns and considerations The book discusses the guidelines and ethical considerations for preclinical and clinical studies to allow readers to identify safety concerns regarding biomedical products and to improve pre clinical studies for the development of better products This textbook is a valuable guide for biomedical students B Sc M S and Ph D students in the field of molecular medicine medical biotechnology stem cell research and related areas as well as for professionals such as quality control staff tissue bankers policy makers and health professionals Mesenchymal Stromal Cells Hematti

Peiman, Sowmya Viswanathan, 2016-08-11 Mesenchymal Stromal Cells Translational Pathways to Clinical Adoption provides the latest information on the necessary steps for successful production of stem cells for a clinical trial Written by professionals with hands on experience in bringing MSC therapies to the clinic and building on the biology and mechanisms of action this unique book covers the development and production of clinical grade products that are suitable for use in humans From design of a cell production facility to obtaining regulatory approval and reimbursement issues it is a useful guide for researchers and administrators across biomedical research Provides methodologies for clinical MSC production from designing a facility to post market approval Includes real life examples of MSC production in academic centers and MSC production for biopharmaceutical clinical trials Offers a unique perspective on the clinical aspects of MSC studies Presents the principles of clinical trials that can be applied to the production of various cell therapies **Membrane**

Systems Loredana De Bartolo, Efrem Curcio, Enrico Drioli, 2017-06-12 Membrane processes today play a significant role in the replacement therapy for acute and chronic organ failure diseases Current extracorporeal blood purification and oxygenation devices employ membranes acting as selective barriers for the removal of endogenous and exogenous toxins and for gas exchange respectively Additionally membrane technology offers new interesting opportunities for the design of bioartificial livers pancreas kidneys lungs etc This book reviews the latest developments in membrane systems for bioartificial organs and regenerative medicine investigates how membrane technology can improve the quality and efficiency of biomedical devices and highlights the design procedures for membrane materials covering the preparation characterization and sterilization steps as well as transport phenomena The different strategies pursued for the development

of membrane bioartificial organs including crucial issues related to blood cell membrane interactions are described with the aim of opening new and exciting frontiers in the coming decades The book is a valuable tool for tissue engineers clinicians biomaterials scientists membranologists as well as biologists and biotechnologists It is also a source of reference for students academic and industrial researchers in the topic of biotechnology biomedical engineering materials science and medicine

Safety, Efficacy and Mechanisms of Action of Mesenchymal Stem Cell Therapies Guido Moll, Martin Johannes Hoogduijn, James A. Ankrum, 2020-07-24

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