What Is Cell Therapy Manufacturing

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Cell Therapy GRIN Verlag
The next healthcare revolution will apply regenerative medicines using human cells and tissues. The aim of the regenerative medicine approach is to create biological therapies or substitutes in vitro for the replacement or restoration of tissue function in vivo lost through failure or disease. However, whilst science has revealed the potential, and early products have shown the power of such therapies, there is an immediate and long-term need for expertise with the necessary skills to face the engineering and life science challenges before the predicted benefits in human healthcare can be realized. Specifically, there is a need for the development of bioprocess technology for the successful transfer of laboratory-based practice of stem cell and tissue culture to the clinic as therapeutics through the application of engineering principles and practices. This Special Issue of Bioengineering on Stem Cell Bioprocessing and Manufacturing addresses the central role in defining the engineering sciences of cell-based therapies, by bringing together contributions from worldwide experts on stem cell biology and engineering, bioreactor design and bioprocess development, scale-up, and manufacturing of stem cell-based therapies.
Usp38-Nf33 Springer Nature
The emerging multidisciplinary field of regenerative engineering is devoted to the repair, regeneration, and replacement of damaged tissues or organs in the body. To accomplish this it uses a combination of principles and technologies from disciplines such as advanced materials science, developmental and stem cell biology, immunology, physics, and clinical translation. The term "regenerative engineering" reflects a new understanding of the use of tissue engineering for regeneration and also the growing number of research and product development efforts that incorporate elements from a variety of fields. Because regenerative engineered therapies rely on live cells and scaffolds, there are inherent challenges in quality control arising from variability in source and final products. Furthermore, each patient recipient, tissue donor, and product application is unique, meaning that the field faces complexities in the development of safe and effective new products and therapies which are not faced by developers of more conventional therapies. Understanding the many sources of variability can help reduce this variability and ensure consistent results. The Forum on Regenerative Medicine hosted a public workshop on October 18, 2018, in Washington, DC, to explore the various factors that must be taken into account in order to develop successful regenerative engineering products. Invited speakers and participants discussed factors and sources of variability in the development and clinical application of regenerative engineering products, characteristics of high-quality products, and how different clinical needs, models, and contexts can inform the development of a product to improve patient outcomes. This publication summarizes the presentation and discussion of the workshop.
Immobilised Growth Factors for Scalable Cell Therapy Manufacturing Platforms Springer
Guide to Cell Therapy GxP is a practical guide to the implementation of quality assurance systems for the successful performance of all cell-based clinical trials. The book covers all information that needs to be included in investigational medicinal product dossier (IMPD), the launching point for any clinical investigation, and beyond. Guide to Cell Therapy GxP bridges a knowledge gap with the inclusion of examples of design of GLP-compliant preclinical studies; design of bioprocesses for autologous/allogeneic therapies; and instruction on how to implement GLP/GMP standards in centers accredited with other quality assurance standards. Guide to Cell Therapy GxP is an

essential resource for scientists and researchers in hospitals, transfusion centers, tissue banks, and other research institutes who may not be familiar with the good scientific practice regulations that were originally designed for product development in corporate environments. This book is also a thorough resource for PhD students, Post-docs, Principal Investigators, Quality Assurance Units, and Government Inspectors who want to learn more about how quality standards are implemented in public institutions developing cell-based products. Easy access to important information on current regulations, state-of-the-art techniques, and recent advances otherwise scattered on various funding websites, within conference proceedings, or maintained in local knowledge Features protocols, techniques for trouble-shooting common problems, and an explanation of the advantages and limitations of a technique in generating conclusive data Includes practical examples of successful implementation of quality standards

Handbook of Cell and Gene Therapy CRC Press

This first open access European CAR-T Handbook, co-promoted by the European Society for Blood and Marrow Transplantation (EBMT) and the European Hematology Association (EHA), covers several aspects of CAR-T cell treatments, including the underlying biology, indications, management of side-effects, access and manufacturing issues. This book, written by leading experts in the field to enhance readers' knowledge and practice skills, provides an unparalleled overview of the CAR-T cell technology and its application in clinical care, to enhance readers' knowledge and practice skills.

Guide to Cell Therapy GxP National Academies Press

Stem Cells in Clinical Practice and Tissue Engineering is a concise book on applied methods of stem cell differentiation and optimization using tissue engineering methods. These methods offer immediate use in clinical regenerative medicine. The present volume will serve the purpose of applied stem cell differentiation optimization methods in clinical research projects, as well as be useful to relatively experienced stem cell scientists and clinicians who might wish to develop their stem cell clinical centers or research labs further. Chapters are arranged in the order of basic concepts of stem cell differentiation, clinical applications of pluripotent stem cells in skin, cardiac, bone, dental, obesity centers, followed by tissue engineering, new materials used, and overall evaluation with their permitted legal status.

Stem Cells in Clinical Practice and Tissue Engineering Academic Press

Essay from the year 2018 in the subject Medicine - Biomedical Engineering, grade: A, , course: Medical Biotechnology, language: English, abstract: This paper exclusively deals with medical biotechnology, which is the fusion of genetics, molecular biology and a number of other disciplines in biology to bring about advancements in medicine and health-science. There have been great advancements in the field of medical biotechnology due to the inculcation of new technique and practices such as PCR, cell cultures, recombinant DNA technology .etc. As the world is looking up to medical biotechnology to improve the lives and health of individuals in the coming years, we embark on a journey to explore some of the upcoming medical advancements offered by medical biotechnology. Some advancements being brought about in medical biotechnology have the ability to revolutionaries health-science in a manner we could have never imagined. Two such advancements in medical biotechnology that we will be exploring in this text include; the use of stem cells for regenerative medicine and the use of monoclonal anti-bodies for specific antibody-antigen response.

The EBMT/EHA CAR-T Cell Handbook Springer Nature

This handbook provides an in-depth review of information across the developmental spectrum of gene and cell therapy products. From introductory information to state-of-the-art technologies and concepts, the book provides insights into upstream processes such as vector design and construction, purification, formulation and fill/finish, as well as delivery options. Planning steps for compliance with current good manufacturing practice (cGMP) to readiness for chemistry, manufacturing and controls (CMC) are also discussed. This book wraps up with examples of successes and pitfalls addressed by experts who have navigated the multiple challenges that are part of any innovative endeavor. Features Provides the most up-to-date information on the development of gene therapy, from the technology involved to gene correction and genome editing Discusses siRNA, mRNA, and plasmid manufacturing Describes the importance of supplier-sponsor synergies on the path to commercialization Written for a diverse audience with a large number of individuals in the core technologies and supportive practices It is intended as a one-stop resource for the availability of state-of-the-art information related to cell and gene therapy products for researchers, scientists, management and other academic and research institutions.

Regulatory Aspects of Gene Therapy and Cell Therapy Products Cell Therapy

R.E. Nordon and K. Schindhelm, Introduction. -- L. Robb, A.G. Elefanty, and C.G. Begley, Transcriptional Control of Hematopoieses. -- R. Starr and N.A. Nicola, Cell Signaling by Hemopoietic Growth Factor Receptors. -- P.J. Simmons, D.N. Haylock, and J.-P. Lévesque, Influence of Cytokines and Adhesion Molecules on Hematopoietic Stem Cell Development. -- P.A. Rowlings, Allogeneic Hematopoietic Stem Cell Transplantation. -- U. Hahn and L.B. To, Autologous Stem Cell Transplantation. -- M.R. Vowels, Cord Blood Stem Cell Transplantation. -- S.R. Riddell, E.H. Warren, D. Lewinsohn, C. Yee, and P.D. Greenberg, Reconstitution of Immunity by Adoptive Immunotherapy with T Cells. -- L.Q. Sun, M. Miller, and G. Symonds, Exogenous Gene Transfer into Lymphoid and Hematopoietic Progenitor Cells. -- C. Dowding, T. Leemhuis, A. Jakubowski, and C. Reading, Process Development for Ex Vivo Cell Therapy. -- R.E. Nordon and K. Schindhelm, Cell Separation. -- P.W. Zandstra, C.J. Eaves, and J.M. Piret, Environ ...

Ex Vivo Cell Therapy National Academies Press

This book provides a comprehensive introduction to various types of perinatal stem cells. Given their unique regenerative abilities, stem cells offer a promising avenue in the treatment of degenerative diseases or injury. Currently, the limitations of postnatal cell sources and expanding efficiency may limit autologous stem cell therapies. Although embryonic stem cells (ESCs) and induced pluripotent stem cells (iPSCs) can be cultured indefinitely ex vivo, and can differentiate into three germ layers, ethical issues, the teratoma formation of ESCs and oncogenic risk of iPSCs are major obstacles to their clinical application. More recently, perinatal stem cells have been isolated from the umbilical cord, Wharton's Jelly, placenta, amniotic membrane and amniotic fluid, which are normally discarded as medical waste. This book, after describing perinatal stem cells in detail, introduces readers to the various types of perinatal stem cells, addressing their characterization, banking, quality control and stability. Importantly, it also reviews the clinical applications of perinatal stem cells to therapy of diseases. Accordingly, it offers a valuable resource for clinicians, researchers and graduate students alike.

Microfluidic and Computational Technologies to Improve Cell Therapy Manufacturing Springer Science & Business Media

In this volume, some of the leading authorities present their exploration of applications of stem cell therapy to the treatment of major causes of blindness, including degenerative diseases and glaucoma. The diagnostic approach to patients, general concepts of cell-based therapy, immunological considerations, approaches to cell delivery (including engineered scaffolds), combined cell and gene therapy, nanomedicine applications to cell therapy and regulatory issues pertaining to manufacture and production are all considered in detail. The book serves as an excellent introduction to a field that is now entering early-stage clinical trials and promises to operate at the leading edge of regenerative medicine. Retina specialists, general ophthalmologists as well as researchers will find here a wealth of information on the translational aspects of cell-based therapies. Further, business executives and students interested in understanding the potential applications of stem cell therapy to retinal degenerative disease and glaucoma will also find this book informative reading.

Cell Therapy Springer Nature

In the 1950s, Nobel Prize winner Dr. E. Donnall Thomas was the first to successfully transplant hematopoietic stem cells. Since then, studies on stem cells have evolved and expanded worldwide. There are more than 650,000 scientific publications on stem cells and more than 8000 stem cell clinical trials. This book summarizes types of stem cells, key studies, ongoing trials, and future perspectives. It also includes ethical, formal, and legal aspects to give the reader a comprehensive view of the field.

Gene Therapy and Cell Therapy Through the Liver MDPI

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.

Next generation MSC therapy manufacturing, potency and mechanism of action analysis BoD – Books on Demand

Underlying this work is the development of technologies to enable the large-scale manufacturing of cell therapies. Cell therapies are undergoing a transformation to a new class of therapeutic modality, and there are many emerging questions, especially related to the scale-up and scale-out of production processes. Together, this work aims to engineer technologies to improve cell therapy manufacturing processes, facilitate their clinical translation, and ensure their availability to all patients who would benefit from them.

Perinatal Tissue-Derived Stem Cells Academic Press

Stem Cell Manufacturing discusses the required technologies that enable the transfer of the current laboratory-based practice of stem cell tissue culture to the clinic environment as therapeutics, while concurrently achieving control, reproducibility, automation, validation, and safety of the process and the product. The advent of stem cell research unveiled the therapeutic potential of stem cells and their derivatives and increased the awareness of the public and scientific community for the topic. The successful manufacturing of stem cells and their derivatives is expected to have a positive impact in the society since it will contribute to widen the offer of therapeutic solutions to the patients. Fully defined cellular products can be used to restore the structure and function of damaged tissues and organs and to develop stem cell-based cellular therapies for the treatment of cancer and hematological disorders, autoimmune and other inflammatory diseases and genetic disorders. Presents the first 'Flowchart' of stem cell manufacturing enabling easy understanding of the various processes in a sequential and coherent manner Covers all bioprocess technologies required for the transfer of the bench findings to the clinic including the process components: cell signals, bioreactors, modeling, automation, safety, etc. Presents comprehensive coverage of a true multidisciplinary topic by bringing together specialists in their particular area Provides the basics of the processes and identifies the issues to be resolved for large scale cell culture by the bioengineer Addresses the critical need in bioprocessing for the successful delivery of stem cell technology to the market place by involving professional engineers in sections of the book

Cell-Based Therapy for Retinal Degenerative Disease Karger Medical and Scientific Publishers

Immune cell therapies have been studied in numerous clinical trials using Advanced Therapy Medicinal Products (ATMP) against a number of diseases having no or inadequate alternative therapies available, for example, various cancer types, cerebral stroke, cardiac infarction, severe autoimmune disorders, or chronic infections. Despite the enormous number of positive observation in ex vivo or animal studies, convincing results in clinical studies remain scanty. The chapter presents a survey and reveals that the manufacturing of immune cells especially for clinical trials is until today primarily performed using archaic, scarcely controlled, and incomparable processes and methods. A deeper characterization of ex vivo expanded immune cells is urgently needed not only on the level of a few receptors and ligands on the cell surface but also with respect to the ever-contained subtypes in an expanded immune cell population, the pattern of secreted effector molecules, and their amounts over time and influences from in vivo components on them.

Springer

On June 26, 2017, the Forum on Regenerative Medicine hosted a public workshop in Washington, DC, titled Navigating the Manufacturing Process and Ensuring the Quality of Regenerative Medicine Therapies in order to examine and discuss the challenges, opportunities, and best practices associated with defining and measuring the quality of cell and tissue products and raw materials in the research and manufacturing of regenerative medicine therapies. The goal of the workshop was to learn from existing examples of the manufacturing of early-generation regenerative medicine products and to address how progress could be made in identifying and measuring critical quality attributes. The workshop also addressed the challenges of designing and adhering to standards as a way of helping those who are working to scale up processes and techniques from a research laboratory to the manufacturing environment. This publication summarizes the presentations and discussions from the workshop.

Exploring Sources of Variability Related to the Clinical Translation of Regenerative Engineering Products BoD – Books on Demand

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.

Mesenchymal Stromal Cells World Scientific

This is a reference handbook for young researchers exploring gene and cell therapy. Gene therapy could be defined as a set of strategies modifying gene expression or correcting mutant/defective genes through the administration of DNA (or RNA) to cells, in order to treat disease. Important advances like the discovery of RNA interference, the completion of the Human Genome project or the development of induced pluripotent stem cells (iPSc) and the basics of gene therapy are covered. This is a great book for students, teachers, biomedical researchers delving into gene/cell therapy or researchers borrowing skills from this scientific field.

Stem Cells and Cell Therapy Springer

From patient referral to post-therapy management, Chimeric Antigen Receptor (CAR) T-Cell Therapies for Cancer: A Practical Guide presents a comprehensive view of CAR modified T-cells in a concise and practical format. Providing authoritative guidance on the implementation and management of CAR T-cell therapy from Drs. Daniel W. Lee and Nirali N. Shah, this clinical resource keeps you up to date on the latest developments in this rapidly evolving area. Covers all clinical aspects, including patient referral, toxicities management, comorbidities, bridging therapy, post-CAR monitoring, and multidisciplinary approaches to supportive care. Includes key topics on associated toxicities such as predictive biomarkers, infections, and multidisciplinary approaches to supportive care. Presents current knowledge on FDA approved CAR T-cell products as well as developments on the horizon. Editors and authors represent leading investigators in academia and worldwide pioneers of CAR therapy.

Manufacturing Clinical-Grade Cell and Gene Therapy Products Elsevier

An international team of investigators presents thought-provoking reviews of bioreactors for stem cell expansion and differentiation and provides cutting-edge information on different bioreactor systems. The authors offer novel insights into bioreactor-based culture systems specific for tissue engineering, including sophisticated and cost-effective manufacturing strategies geared to overcome technological shortcomings that currently preclude advances towards product commercialization. This book in the fields of stem cell expansion, bioreactors, bioprocessing, and bio and tissue engineering, gives the reader a full understanding of the state-of-art and the future of these fields. Key selling features: Describes various bioreactors or stem cell culturing systems Reviews methods for stem cell expansion and differentiation for neural, cardiac, hemopoietic, mesenchymal, hepatic and other tissues cell types Distinguishes different types of bioreactors intended for different operational scales of tissue engineering and cellular therapies Includes contributions from an international team of leaders in stem cell research