Manufacturing Clinical Grade Cell And Gene Therapy Products Economic Implications For Academic Gmp Facilities

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Usually, clinical-grade products are approved as drugs by regulators, and labeling or product documentation should state sterility and safety profile. On the other hand, GMP grade or cGMP grade refers to products manufactured under Current Good Manufacturing Practice s which require manufacturers ensure that their products are traceable, safe, pure and effective .

Clinical Grade vs GMP Grade Terminology for Ancillary ...

The feasibility of rapid clinical-grade manufacturing of virus-specific T cells from convalescent donors has not been demonstrated for this or prior pandemics. Methods One unit of whole blood was collected from each convalescent donor following standard blood bank practices.

SUCCESSFUL MANUFACTURING OF CLINICAL-GRADE SARS-CoV-2 ...

The therapeutic potential of mesenchymal stem/stromal cells (MSC) has triggered the need for high cell doses in a vast number of clinical applications. This demand requires the development of good manufacturing practices (GMP)-compliant ex vivo expansion protocols that should be effective to deliver a robust and reproducible supply of clinical-grade cells in a safe and cost-effective manner.

Clinical-Grade Manufacturing of Therapeutic Human ...

The edict for producing clinically compliant human embryonic stem cells (hESCs) necessitates adherence to global ethical standards for egg procurement and embryo donation, conformity to regulations controlling clinical-grade cell and tissue product development, and compliance with current good tissue and manufacturing practices (cGTPs and cGMPs, respectively).

The Generation of Six Clinical-Grade ... - Cell Stem Cell

Tune into this webinar as we provide you with comprehensive solutions for manufacturing clinical-grade Treg cells. Learn about how you can utilize our CliniMACS Platform and MACS GMP products for a range Treg applications. During the webinar, we share insights into: Clinical-scale Treg cell enrichment and isolation, cultivation, and analysis

Improve your clinical-grade regulatory T cell (Treg ...

Manufacturing Clinical Grade Recombinant Adeno-Associated Virus Using Invertebrate Cell Lines. Kotin RM (1), Snyder RO (2). Author information: (1)1 Gene Therapy Center, University of Massachusetts Medical School , Worcester, Massachusetts. (2)2 Brammer Bio, Alachua, Florida. Recombinant adeno-associated virus (rAAV) vectors are proving to be a reliable gene transfer system for several clinical applications, with an increasing body of evidence supporting safety and efficacy.

Manufacturing Clinical Grade Recombinant Adeno-Associated ...

Dublin, Nov. 12, 2020 (GLOBE NEWSWIRE) -- The "Global Contract Cell and Gene Therapy Manufacturing Market 2020-2026 - Supply Chain Optimization and Decentralized Manufacturing to Expand the Industry" report has been added to ResearchAndMarkets.com's offering. This research service focuses on the critical role being played by CDMOs in not only supporting new product research and development but ...

Global Contract Cell and Gene Therapy Manufacturing Market ...

Background: The NK-92/5.28.z cell line (also referred to as HER2.taNK) represents a stable, lentiviral-transduced clone of ErbB2 (HER2)-specific, second-generation CAR-expressing derivative of clinically applicable NK-92 cells. This study addresses manufacturing-related issues and aimed to develop a GMP-compliant protocol for the generation of NK-92/5.28.z therapeutic doses starting from a well-characterized GMP-compliant master cell bank.

Clinical grade manufacturing of genetically modified, CAR ...

Manufacturing Clinical-Grade Cell and Gene Therapy Products: Abou-El-Enein Mohamed: Amazon.com.au: Books

Manufacturing Clinical-Grade Cell and Gene Therapy ...

Clinical-grade human embryonic stem cells and human induced pluripotent stem cells have to be created according to current good manufacturing practices and regulations. Quality and safety must be of the highest importance when humans' lives are at stake.

Clinical-Grade Human Pluripotent Stem Cells for Cell ...

Manufacturing Clinical-Grade Cell and Gene Therapy Products: Economic Implications for Academic GMP Facilities [Abou-El-Enein, Mohamed] on Amazon.com. *FREE* shipping on qualifying offers. Manufacturing Clinical-Grade Cell and Gene Therapy Products: Economic Implications for Academic GMP Facilities

Manufacturing Clinical-Grade Cell and Gene Therapy ...

Adoptive cell therapy using CD19-targeted CAR-T cells has resulted in remarkable responses in patients

with acute lymphoblastic leukemia.3, 4, 5, 6 Promising clinical outcomes in phase 1/2 clinical trial studies have triggered active support and investment from pharmaceutical and biotechnology companies. 7, 8 The manufacturing of clinical-grade CAR-T cells under current good manufacturing procedure (cGMP) is a critical step and in its current state a bottleneck for the wide implementation of ...

Clinical manufacturing of CAR T cells: foundation of a ...

Creating a clinical grade iPS cell line to advance the cell and gene therapy industry. It is more than a decade since 2006, when scientists reprogrammed mouse skin cells into cells that behave like and share similar characteristics with embryonic stem cells. This process was repeated using human cells a year later.

Clinical grade iPS cell line - Catapult centres

Use of clinical-grade human induced pluripotent stem cell (iPSC) lines as a starting material for the generation of cellular therapeutics requires demonstration of comparability of lines derived from different individuals and in different facilities. This requires agreement on the critical quality a …

Quality Control Guidelines for Clinical-Grade Human ...

Clinical Grade (cGMP) Cell Bank Collection. Human embryonic stem (ES) cell lines banked under current Good Manufacturing Practices (cGMP) conditions with our collaborator, Waisman Biomanufacturing , ideal for use as starting material for clinical applications. Matched research bank material is available for assessment and use in preclinical applications.

Clinical Grade (cGMP) Cell Banks - WiCell

On March 11, 2020, the company received a license to manufacture clinical-grade cells from Japan's Ministry of Health, Labour and Welfare for its cell manufacturing facility located in Kyoto, Japan. The Pharmaceuticals and Medical Devices Agency (PMDA) audited I Peace's GMP facility Peace Engine-Kyoto and reviewed facility operation, sanitization, cell culturing, Quality Control, and maintenance standard operating procedures (SOPs) among others as part of the approval process to ...

Clinical-Grade iPSC Custom Manufacturing Service| I Peace ...

Treg were expanded with the CliniMACS Prodigy ® device using clinical-grade cell culture medium, rapamycin, IL-2, and ?CD3/?CD28 beads for 13–14 days. We successfully integrated expansion bead removal and final formulation into the automated procedure, finalizing the process with a ready to use product for bedside transfusion.

Automated Clinical Grade Expansion of Regulatory T Cells ...

Allogeneic natural killer (NK) cells are used for adoptive immunotherapy after stem cell transplantation. In order to overcome technical limitations in NK cell purification and activation, the following study investigates the impact of different variables on NK cell recovery, cytotoxicity, and T-cell depletion during good manufacturing practice (GMP)-grade NK cell selection.

Clinical grade purification and expansion of NK cell ...

The derivation of clinical-grade lines was carried out in our clinical-grade facility in the North West Embryonic Stem Cell Centre (NWESCC) under a GMP Quality Management System which is covered by the HFEA licence R0171, a licence for clinical application from the Human Tissue Authority (HTA; Licence 22627), a Certificate of GMP compliance and a Product Manufacturing Licence from the Medicines and Healthcare products Regulatory Agency (MHRA).

High quality clinical grade human embryonic stem cell ...

Long-term manufacturing of clinical-grade MSCs in vitro may incur chromosomal aberrations and

microorganism concerns [59, 60], indicating that the preliminary sorting of chromosomal stability and microorganism contamination in hDPSC products for the MCB and the WCB is essential and critical safety steps required for obtaining clinical applications the final hDPSC products. The present microorganism tests in hDPSC products are a reasonable verification of microorganism safety.

Advanced therapy medicinal products (ATMP) represents a new class of medicinal products, which include - amongst others - somatic cell and gene therapies. As the final product is intended for administration into humans, manufacturers of ATMPs are obligated to apply good manufacturing practice (GMP) standards within their processes. Reaching and maintaining such standards is cost intensive and requires sophisticated manufacturing facilities. As a result, academic researchers who are developing these novel therapeutic approaches are facing new technological and financial challenges. In order to bring more commercially accessible therapies to patients and demonstrate efficient manufacturing technologies, we established the clean-room technology assessment technique (CTAT). CTAT comprises several tools to identify and assign a reliable monetary value to the different operational processes. The model also serves as a guideline for optimizing the operation of an academic GMP facility.

With the discovery of stem cells capable of multiplying indefinitely in culture and differentiating into many other cell types in appropriate conditions, new hopes were born in repair and replacement of damaged cells and tissues. The features of stem cells may provide treatment for some incurable diseases with some therapies are already in clinics, particularly those from adult stem cells. Some treatments will require large number of cells and may also require multiple doses, generating a growing demand for generating and processing large numbers of cells to meet the need of clinical applications. With this in mind, our aim is to provide a book on the subject of stem cells and cell therapy for researchers and students of cell biotechnology, bioengineering and bioproduction. This book is exceptional as it teaches researchers stem cells and cell therapy in that it covers the concepts and backgrounds necessary so that readers get a good understanding of the production of stem cells. The book covers three topics: The basics of stem cells and cell therapy, the use of stem cells for the treatment of human diseases, and stem cell processing. It includes chapters on neural and vascular stem vascular stem cell therapy, expansion engineering of embryonic stem cells, stem cell based production of blood cells and separation technologies for stem cells and cell therapy products. It is an informed and informative presentation of what modern research, science and engineering have learned about stem cells and their production and therapies. Addressing both the medical and production issues, this book is an invaluable contribution to having an academic and industrial understanding with respect to R&D and manufacturing of clinical grade stem cells.

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engineering of embryonic stem cells, stem cell based production of blood cells and separation technologies for stem cells and cell therapy products. It is an informed and informative presentation of what modern research, science and engineering have learned about stem cells and their production and therapies. Addressing both the medical and production issues, this book is an invaluable contribution to having an academic and industrial understanding with respect to R&D and manufacturing of clinical grade stem cells.

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

Human pluripotent stem cells, including human embryonic stem cells and induced pluripotent stem cells, are a key focus of current biomedical research. The emergence of state of the art culturing techniques is promoting the realization of the full potential of pluripotent stem cells in basic and translational research and in cell-based therapies. This comprehensive and authoritative atlas summarizes more than a decade of experience accumulated by a leading research team in this field. Hands-on step-by-step guidance for the derivation and culturing of human pluripotent stem cells in defined conditions (animal product-free, serum-free, feeder-free) and in non-adhesion suspension culture are provided, as well as methods for examining pluripotency (embryoid body and teratoma formation) and karyotype stability. The Atlas of Human Pluripotent Stem Cells - Derivation and Culturing will serve as a reference and guide to established researchers and those wishing to enter the promising field of pluripotent stem cells.

This book discusses why specific diseases are being targeted for cell-based retinal therapy, what evidence exists that justifies optimism for this approach, and what challenges must be managed in order to bring this technology from the laboratory into routine clinical practice. There are a number of unanswered questions (e.g., surgical approach to cell delivery, management of immune response, optimum cell type to transplant) that very likely are not going to be answered until human trials are undertaken, but there is a certain amount of “de-risking” that can be done with preclinical experimentation. This book is essential reading for scientists, clinicians, and advanced students in stem cell research, cell biology, and ophthalmology.

This textbook is a comprehensive overview of the development of cell-based biopharmaceuticals. Beginning with the underlying biology of stem cell and cell-based products, it traces the long and complex journey from preclinical concept to initiation of a pivotal clinical trial and the potential business model behind it.The book also takes into consideration the different regulatory landscapes and

their continuous evolution in Europe, North America and other parts of the world. The authors describe a path to manufacture a clinical grade therapeutic that passes all necessary quality measures as a robust and marketable product including an outlook on next generation products and innovative strategies.This reference book is a must-have guide for any professional already active in biopharmaceuticals and anyone interested in getting involved in a scientific, medical or business capacity.

This Brief describes the concept and realization of gene therapy for HIV from the unique historic perspective and insight of two pioneers of the clinical applications of stem cell gene therapy for HIV. Gerhard Bauer applied ribozyme-anti-HIV and other vectors to manufacture clinical grade, HIV-resistant hematopoietic stem cells for the first patients that received stem cell gene therapy for HIV, including the first child in the world and the first fully marrow-ablated HIV infected patient. Joseph Anderson developed the most recent and most potent combination anti-HIV lentiviral vectors and pluripotent stem cell applications for HIV gene therapy and tested these in the appropriate in vitro and vivo models, paving the way for novel HIV gene therapy approaches to possibly cure patients. In Gene Therapy for HIV, Bauer and Anderson discuss the unique aspects of this therapy, including its limitations and proper safety precautions and outline a path for a possible functional cure for HIV using stem cell gene therapy based on a cure already achieved with a bone marrow stem cell transplantation performed in Germany using donor stem cells with a naturally arising CCR5 mutation. In addition, the Brief provides a thorough and methodical explanation of the basics of gene therapy, gene therapy vector development, in vitro and in vivo models for HIV gene therapy and clinical applications of HIV gene therapy, including Good Manufacturing Practices.

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

The limit capacity of heart muscle and brain cells for self-repair constitutes a significant challenge to traditional medicine for tissue and function restoration in seeking cures for a wide range of heart diseases and neurological disorders. Given their limited capacity for self-repair, cell-based therapy represents a promising therapeutic approach closest to provide a cure to restore normal tissue and function. However, the existing markets lack a scalable clinically-suitable human neuronal or heart cell source with adequate regenerative potential, which has been the major setback in developing safe and effective cell-based therapies. To date, the need to restore vital tissue and function for a wide range of neurological and heart diseases remains a daunting challenge to the conventional mode of drugs and treatments. The pluripotent human embryonic stem cells (hESC), the nature source of human pluripotent stem cells (hPSC), have unlimited expansion and differentiation capabilities, offering a practically inexhaustible source of replacement cells for tissue and function restoration. Therefore, they have been regarded as an ideal source to provide an unlimited supply of clinically-relevant functional human cells to heal the damaged or lost tissues that have naturally limited capacity for self-repair, such as the human brain and heart. As neurological and heart diseases incur exorbitant costs on the healthcare system worldwide, there is a strong focus on translating hPSC research to provide newer, more efficient solutions for these unmet therapeutic needs. However, a persistent challenge for clinical translation is to

enable a well-controlled and efficient induction of non-functional hPSC exclusively and uniformly to a specific clinically relevant functional lineage. PluriXcel is a pioneer in stem cell therapeutics and remarkable advancement in stem cell research related to the differentiation of non-functional hPSC into specific functional lineages by small molecule induction. The PluriXcel technology platforms offer currently the only available human cell products with the pharmacological capacity to regenerate neurons and contractile heart muscles that allow restitution of function in the clinic. PluriXcel technological breakthroughs allow the achievement of a highly efficient direct conversion of clinical-grade hPSC into a large supply of high-purity human neuronal cells or heart muscle cells with adequate capacity to regenerate neurons or contractile heart muscles for cell regeneration or replacement therapies, as well as for tissue or organ biofabrication. The PluriXcel platforms not only constitute clinically representative progresses in both human neuronal and cardiac therapeutic products for treating a wide range of incurable or hitherto untreatable neurological and heart diseases, but also offer manufacturing innovations for production scale-up and creation of replacement human tissue and organ products. Medical innovations of PluriXcel technology provide scalable platforms to ensure a high degree of efficacy and safety of hPSC-derived cellular products, thus robust clinical benefits leading to therapies, for treating major human diseases challenging traditional medicine. Manufacturing innovations of PluriXcel technology provide scale-up cGMP manufacturing capability for production of large quantities of high quality clinical-grade hPSC-based cell therapy products to support clinical trials and tissue or organ engineering/biofabrication, improving the availability, reproducibility, accessibility, and standardization of manufacturing materials, technologies, and processes to create human repairing or replacing cell, tissue, and organ products. Medical and manufacturing innovations of PluriXcel technology provide life scientists and clinicians with novel, efficient, and powerful resources and tools to address major health concerns, which will shape the future of medicine and bring new therapeutics into the market.