

FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY

FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY REPRESENTS A CRITICAL FRAMEWORK DESIGNED TO ENSURE THE HIGHEST STANDARDS IN CELLULAR THERAPY PRACTICES. THIS FOUNDATION SUPPORTS INSTITUTIONS AND LABORATORIES IN MEETING RIGOROUS QUALITY AND SAFETY BENCHMARKS ESSENTIAL FOR PATIENT CARE AND THERAPEUTIC EFFICACY. ACCREDITATION IN CELLULAR THERAPY IS VITAL DUE TO THE COMPLEX NATURE OF CELL PROCESSING, TRANSPLANTATION, AND TREATMENT PROTOCOLS INVOLVED. THIS ARTICLE EXPLORES THE ESSENTIAL COMPONENTS AND PROCESSES OF THE FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY, HIGHLIGHTING ITS SIGNIFICANCE IN REGULATORY COMPLIANCE, QUALITY ASSURANCE, AND CLINICAL OUTCOMES. BY UNDERSTANDING THE FOUNDATION, STAKEHOLDERS CAN BETTER NAVIGATE THE ACCREDITATION JOURNEY, ENHANCING OPERATIONAL STANDARDS AND FOSTERING TRUST IN CELLULAR THERAPIES. THE FOLLOWING SECTIONS PROVIDE A DETAILED OVERVIEW OF THE ACCREDITATION FRAMEWORK, REQUIREMENTS, AND BEST PRACTICES IN CELLULAR THERAPY.

- UNDERSTANDING THE FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY
- KEY STANDARDS AND REQUIREMENTS
- ACCREDITATION PROCESS AND EVALUATION
- QUALITY MANAGEMENT SYSTEMS IN CELLULAR THERAPY
- IMPACT OF ACCREDITATION ON CLINICAL PRACTICE

UNDERSTANDING THE FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY

THE FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY ESTABLISHES A COMPREHENSIVE SET OF CRITERIA AND GUIDELINES THAT CELLULAR THERAPY FACILITIES MUST FOLLOW TO ENSURE SAFETY, QUALITY, AND EFFECTIVENESS OF THEIR SERVICES. CELLULAR THERAPY INVOLVES THE MANIPULATION AND ADMINISTRATION OF LIVING CELLS FOR THERAPEUTIC PURPOSES, WHICH NECESSITATES STRINGENT CONTROLS TO PREVENT CONTAMINATION, ENSURE CELL VIABILITY, AND MAINTAIN TRACEABILITY. ACCREDITATION FOUNDATIONS TYPICALLY ENCOMPASS REGULATORY COMPLIANCE, TECHNICAL COMPETENCY, AND CONTINUOUS QUALITY IMPROVEMENT TAILORED SPECIFICALLY TO CELLULAR PRODUCTS AND PROCEDURES.

CELLULAR THERAPY ACCREDITATION IS USUALLY PROVIDED BY RECOGNIZED ORGANIZATIONS THAT SPECIALIZE IN HEALTHCARE QUALITY STANDARDS, OFFERING A STRUCTURED APPROACH FOR LABORATORIES AND CLINICAL CENTERS TO VALIDATE THEIR PROTOCOLS AND OPERATIONS. THIS FOUNDATION ACTS AS A BENCHMARK, PROMOTING CONSISTENCY ACROSS DIFFERENT INSTITUTIONS AND ENHANCING OVERALL PATIENT SAFETY IN CELLULAR TREATMENTS.

KEY STANDARDS AND REQUIREMENTS

THE FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY IS BUILT UPON A DETAILED FRAMEWORK OF STANDARDS THAT COVER ALL ASPECTS OF CELLULAR THERAPY PRACTICE. THESE STANDARDS ARE DEVELOPED BY EXPERT COMMITTEES AND REGULATORY BODIES TO ADDRESS THE UNIQUE CHALLENGES IN THIS SPECIALIZED FIELD.

FACILITY AND PERSONNEL QUALIFICATIONS

ACCREDITATION STANDARDS REQUIRE THAT FACILITIES MAINTAIN APPROPRIATE INFRASTRUCTURE, INCLUDING CLEANROOM ENVIRONMENTS AND VALIDATED EQUIPMENT TAILORED TO CELLULAR PROCESSING. PERSONNEL INVOLVED MUST HAVE DOCUMENTED QUALIFICATIONS, TRAINING, AND COMPETENCY ASSESSMENTS TO PERFORM THEIR DUTIES EFFECTIVELY AND SAFELY.

CELL PROCESSING AND HANDLING

STRICT PROTOCOLS FOR CELL COLLECTION, PROCESSING, STORAGE, AND TRANSPORTATION ARE MANDATED. THESE PROTOCOLS ENSURE CELL INTEGRITY AND MINIMIZE RISKS OF CONTAMINATION OR DEGRADATION. PROPER DOCUMENTATION AND CHAIN-OF-CUSTODY PROCEDURES ARE CRUCIAL COMPONENTS.

DOCUMENTATION AND RECORD KEEPING

ACCREDITATION FOUNDATIONS EMPHASIZE COMPREHENSIVE DOCUMENTATION, INCLUDING STANDARD OPERATING PROCEDURES (SOPs), BATCH RECORDS, AND QUALITY CONTROL LOGS. ACCURATE RECORD-KEEPING SUPPORTS TRACEABILITY AND ACCOUNTABILITY THROUGHOUT THE CELLULAR THERAPY PROCESS.

QUALITY CONTROL AND VALIDATION

FACILITIES MUST IMPLEMENT RIGOROUS QUALITY CONTROL MEASURES, INCLUDING VALIDATION OF EQUIPMENT, PROCESSES, AND ASSAYS USED IN CELLULAR THERAPY. REGULAR MONITORING AND CORRECTIVE ACTIONS ARE ESSENTIAL TO MAINTAIN COMPLIANCE WITH ESTABLISHED STANDARDS.

- CLEANROOM AND ENVIRONMENTAL CONTROLS
- PERSONNEL TRAINING AND COMPETENCY EVALUATIONS
- STANDARD OPERATING PROCEDURES (SOPs)
- PROCESS VALIDATION AND QUALITY ASSURANCE
- TRACEABILITY AND DOCUMENTATION PROTOCOLS

ACCREDITATION PROCESS AND EVALUATION

THE FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY INVOLVES A STRUCTURED EVALUATION PROCESS DESIGNED TO VERIFY COMPLIANCE WITH ESTABLISHED STANDARDS. THIS PROCESS INCLUDES APPLICATION, SELF-ASSESSMENT, ON-SITE INSPECTION, AND ONGOING SURVEILLANCE.

APPLICATION AND SELF-ASSESSMENT

FACILITIES SEEKING ACCREDITATION MUST SUBMIT DETAILED APPLICATIONS DESCRIBING THEIR OPERATIONS, PERSONNEL, AND QUALITY MANAGEMENT SYSTEMS. A SELF-ASSESSMENT AGAINST THE ACCREDITATION STANDARDS HELPS IDENTIFY GAPS AND AREAS REQUIRING IMPROVEMENT PRIOR TO FORMAL EVALUATION.

ON-SITE INSPECTION AND AUDITS

AN INDEPENDENT TEAM OF EXPERTS CONDUCTS THOROUGH ON-SITE INSPECTIONS TO OBSERVE FACILITY CONDITIONS, REVIEW DOCUMENTATION, AND INTERVIEW STAFF. AUDITS FOCUS ON CRITICAL CONTROL POINTS IN THE CELLULAR THERAPY PROCESS TO ENSURE COMPLIANCE AND OPERATIONAL EXCELLENCE.

CORRECTIVE ACTIONS AND CONTINUOUS IMPROVEMENT

IF DEFICIENCIES ARE IDENTIFIED, FACILITIES ARE REQUIRED TO IMPLEMENT CORRECTIVE ACTIONS WITHIN SPECIFIED TIMEFRAMES. THE FOUNDATION FOR ACCREDITATION ENCOURAGES CONTINUOUS QUALITY IMPROVEMENT, WITH PERIODIC RE-EVALUATIONS TO MAINTAIN CERTIFICATION STATUS.

QUALITY MANAGEMENT SYSTEMS IN CELLULAR THERAPY

INTEGRAL TO THE FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY IS THE IMPLEMENTATION OF A ROBUST QUALITY MANAGEMENT SYSTEM (QMS). A WELL-DESIGNED QMS ENSURES CONSISTENT DELIVERY OF SAFE AND EFFECTIVE CELLULAR PRODUCTS.

COMPONENTS OF QUALITY MANAGEMENT

THE QMS ENCOMPASSES POLICIES, PROCEDURES, AND RESPONSIBILITIES THAT COLLECTIVELY SUPPORT QUALITY ASSURANCE AND CONTROL. KEY ELEMENTS INCLUDE DOCUMENT CONTROL, RISK MANAGEMENT, INTERNAL AUDITS, AND PERFORMANCE MONITORING.

RISK ASSESSMENT AND MITIGATION

RISK ASSESSMENT IS FUNDAMENTAL, IDENTIFYING POTENTIAL HAZARDS IN CELL PROCESSING AND HANDLING. MITIGATION STRATEGIES ARE DEVELOPED TO ADDRESS RISKS RELATED TO CONTAMINATION, MISIDENTIFICATION, AND PROCEDURAL ERRORS.

TRAINING AND COMPETENCY PROGRAMS

CONTINUOUS EDUCATION AND COMPETENCY ASSESSMENT ENSURE PERSONNEL REMAIN PROFICIENT IN EVOLVING CELLULAR THERAPY TECHNIQUES AND REGULATORY REQUIREMENTS. THIS FOCUS ON WORKFORCE DEVELOPMENT STRENGTHENS OVERALL QUALITY AND COMPLIANCE.

IMPACT OF ACCREDITATION ON CLINICAL PRACTICE

THE FOUNDATION FOR ACCREDITATION OF CELLULAR THERAPY SIGNIFICANTLY INFLUENCES CLINICAL PRACTICE BY ENHANCING THE RELIABILITY AND SAFETY OF CELLULAR TREATMENTS. ACCREDITED FACILITIES DEMONSTRATE COMMITMENT TO EXCELLENCE, WHICH TRANSLATES INTO IMPROVED PATIENT OUTCOMES.

ENHANCED PATIENT SAFETY AND TREATMENT EFFICACY

ACCREDITATION ENSURES THAT CELLULAR THERAPY PRODUCTS MEET STRINGENT QUALITY STANDARDS, REDUCING RISKS OF ADVERSE EVENTS AND IMPROVING THERAPEUTIC EFFECTIVENESS. THIS FOSTERS GREATER CONFIDENCE AMONG HEALTHCARE PROVIDERS AND PATIENTS ALIKE.

REGULATORY COMPLIANCE AND MARKET ACCESS

MEETING ACCREDITATION REQUIREMENTS HELPS FACILITIES COMPLY WITH NATIONAL AND INTERNATIONAL REGULATIONS, FACILITATING SMOOTHER REGULATORY APPROVALS AND ACCESS TO BROADER MARKETS FOR CELLULAR THERAPY PRODUCTS.

PROMOTION OF RESEARCH AND INNOVATION

ACCREDITED ENVIRONMENTS SUPPORT RIGOROUS SCIENTIFIC RESEARCH AND INNOVATION BY MAINTAINING HIGH-QUALITY STANDARDS AND REPRODUCIBILITY. THIS FOUNDATION PROMOTES THE ADVANCEMENT OF CUTTING-EDGE CELLULAR THERAPIES AND NOVEL TREATMENT APPROACHES.

FREQUENTLY ASKED QUESTIONS

WHAT IS THE FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

(FACT)?

THE FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) IS AN INTERNATIONAL NONPROFIT ORGANIZATION THAT ESTABLISHES STANDARDS FOR QUALITY AND SAFETY IN CELLULAR THERAPY, INCLUDING HEMATOPOIETIC STEM CELL TRANSPLANTATION AND CELLULAR IMMUNOTHERAPY.

WHY IS FACT ACCREDITATION IMPORTANT FOR CELLULAR THERAPY PROGRAMS?

FACT ACCREDITATION ENSURES THAT CELLULAR THERAPY PROGRAMS MEET RIGOROUS STANDARDS FOR PATIENT CARE, LABORATORY PRACTICES, AND CLINICAL OUTCOMES, THEREBY PROMOTING SAFETY, QUALITY, AND CONSISTENCY IN CELLULAR THERAPY TREATMENTS.

WHAT TYPES OF CELLULAR THERAPY PROGRAMS CAN SEEK FACT ACCREDITATION?

PROGRAMS INVOLVED IN HEMATOPOIETIC PROGENITOR CELL COLLECTION, PROCESSING, TRANSPLANTATION, AND CELLULAR IMMUNOTHERAPY CAN SEEK FACT ACCREDITATION, INCLUDING ADULT AND PEDIATRIC TRANSPLANT CENTERS, CORD BLOOD BANKS, AND CELL PROCESSING LABORATORIES.

HOW DOES FACT ACCREDITATION BENEFIT PATIENTS RECEIVING CELLULAR THERAPIES?

FACT ACCREDITATION HELPS ENSURE THAT PATIENTS RECEIVE CARE FROM PROGRAMS THAT ADHERE TO HIGH QUALITY AND SAFETY STANDARDS, REDUCING RISKS ASSOCIATED WITH CELLULAR THERAPIES AND IMPROVING OVERALL TREATMENT SUCCESS AND PATIENT OUTCOMES.

WHAT ARE THE MAIN STANDARDS FACT USES TO EVALUATE CELLULAR THERAPY PROGRAMS?

FACT STANDARDS COVER AREAS SUCH AS PROGRAM ORGANIZATION, CLINICAL AND LABORATORY PRACTICES, DONOR AND RECIPIENT MANAGEMENT, PATIENT CARE, QUALITY MANAGEMENT, AND DATA COLLECTION TO ENSURE COMPREHENSIVE QUALITY ASSURANCE IN CELLULAR THERAPY.

HOW OFTEN MUST A CELLULAR THERAPY PROGRAM RENEW ITS FACT ACCREDITATION?

FACT ACCREDITATION TYPICALLY REQUIRES RENEWAL EVERY THREE YEARS, DURING WHICH THE PROGRAM UNDERGOES A THOROUGH ON-SITE INSPECTION AND REVIEW TO CONFIRM CONTINUED COMPLIANCE WITH FACT STANDARDS.

HOW CAN A CELLULAR THERAPY PROGRAM PREPARE FOR A FACT ACCREDITATION INSPECTION?

PROGRAMS SHOULD CONDUCT INTERNAL AUDITS, ENSURE STAFF ARE TRAINED ON FACT STANDARDS, MAINTAIN THOROUGH DOCUMENTATION OF PROCEDURES AND OUTCOMES, AND ADDRESS ANY IDENTIFIED DEFICIENCIES PRIOR TO THE ON-SITE INSPECTION TO SUCCESSFULLY ACHIEVE ACCREDITATION.

ADDITIONAL RESOURCES

1. *FOUNDATIONS OF CELLULAR THERAPY ACCREDITATION: PRINCIPLES AND PRACTICES*

THIS BOOK OFFERS A COMPREHENSIVE OVERVIEW OF THE FUNDAMENTAL PRINCIPLES BEHIND THE ACCREDITATION OF CELLULAR THERAPY FACILITIES. IT COVERS REGULATORY REQUIREMENTS, QUALITY MANAGEMENT SYSTEMS, AND BEST PRACTICES FOR COMPLIANCE WITH INTERNATIONAL STANDARDS. ESSENTIAL FOR PROFESSIONALS PREPARING FOR ACCREDITATION OR SEEKING TO UNDERSTAND ITS FRAMEWORK.

2. *QUALITY MANAGEMENT IN CELLULAR THERAPY: A GUIDE TO ACCREDITATION*

FOCUSING ON QUALITY MANAGEMENT SYSTEMS, THIS GUIDE DETAILS THE PROCESSES NECESSARY TO MEET ACCREDITATION

STANDARDS IN CELLULAR THERAPY. IT INCLUDES CASE STUDIES, CHECKLISTS, AND PRACTICAL ADVICE ON DOCUMENTATION, PROCESS CONTROL, AND CONTINUOUS IMPROVEMENT. A VALUABLE RESOURCE FOR LAB MANAGERS AND QUALITY OFFICERS.

3. *REGULATORY FRAMEWORKS FOR CELLULAR THERAPY ACCREDITATION*

THIS BOOK EXPLORES THE GLOBAL REGULATORY LANDSCAPE AFFECTING CELLULAR THERAPY ACCREDITATION. IT COMPARES GUIDELINES FROM MAJOR ACCREDITING BODIES SUCH AS FACT, AABB, AND JACIE, AND EXPLAINS HOW TO NAVIGATE COMPLEX COMPLIANCE REQUIREMENTS. USEFUL FOR REGULATORY AFFAIRS SPECIALISTS AND HEALTHCARE ADMINISTRATORS.

4. *CLINICAL AND LABORATORY STANDARDS IN CELLULAR THERAPY ACCREDITATION*

PROVIDING IN-DEPTH COVERAGE OF CLINICAL AND LABORATORY STANDARDS, THIS TEXT OUTLINES THE TECHNICAL REQUIREMENTS FOR ACCREDITATION. IT ADDRESSES CELL COLLECTION, PROCESSING, STORAGE, AND INFUSION PROTOCOLS CRUCIAL TO MAINTAINING QUALITY AND PATIENT SAFETY. IDEAL FOR CLINICIANS, TECHNOLOGISTS, AND QUALITY ASSURANCE PERSONNEL.

5. *IMPLEMENTING ACCREDITATION PROGRAMS IN CELLULAR THERAPY CENTERS*

THIS PRACTICAL MANUAL GUIDES HEALTHCARE FACILITIES THROUGH THE STEP-BY-STEP PROCESS OF ACHIEVING ACCREDITATION. TOPICS INCLUDE SELF-ASSESSMENT, GAP ANALYSIS, STAFF TRAINING, AND AUDIT PREPARATION. A MUST-HAVE FOR CELLULAR THERAPY PROGRAM DIRECTORS AND PROJECT MANAGERS.

6. *RISK MANAGEMENT AND COMPLIANCE IN CELLULAR THERAPY ACCREDITATION*

THIS BOOK DELVES INTO RISK ASSESSMENT AND MITIGATION STRATEGIES ESSENTIAL FOR ACCREDITATION SUCCESS. IT DISCUSSES IDENTIFYING POTENTIAL HAZARDS, MANAGING ADVERSE EVENTS, AND MAINTAINING COMPLIANCE UNDER EVOLVING REGULATORY CONDITIONS. BENEFICIAL FOR RISK MANAGERS AND CLINICAL GOVERNANCE TEAMS.

7. *DOCUMENTATION AND RECORD-KEEPING FOR CELLULAR THERAPY ACCREDITATION*

HIGHLIGHTING THE CRITICAL ROLE OF DOCUMENTATION, THIS VOLUME PROVIDES TEMPLATES AND GUIDELINES FOR MAINTAINING ACCURATE RECORDS. IT COVERS EVERYTHING FROM PATIENT CONSENT TO BATCH RECORDS AND EQUIPMENT LOGS, ENSURING TRACEABILITY AND ACCOUNTABILITY. USEFUL FOR LABORATORY STAFF AND QUALITY CONTROL PERSONNEL.

8. *TRAINING AND COMPETENCY ASSESSMENT FOR CELLULAR THERAPY ACCREDITATION*

THIS RESOURCE EMPHASIZES THE IMPORTANCE OF WORKFORCE COMPETENCY IN MEETING ACCREDITATION STANDARDS. IT OFFERS STRATEGIES FOR TRAINING PROGRAMS, COMPETENCY EVALUATIONS, AND ONGOING PROFESSIONAL DEVELOPMENT TAILORED TO CELLULAR THERAPY STAFF. IDEAL FOR EDUCATORS AND HUMAN RESOURCES PROFESSIONALS.

9. *EMERGING TRENDS AND FUTURE DIRECTIONS IN CELLULAR THERAPY ACCREDITATION*

LOOKING AHEAD, THIS BOOK DISCUSSES ADVANCEMENTS IN CELLULAR THERAPY TECHNOLOGIES AND THEIR IMPACT ON ACCREDITATION PROCESSES. IT ADDRESSES CHALLENGES SUCH AS NOVEL CELL TYPES, AUTOMATION, AND DIGITAL RECORD-KEEPING. PERFECT FOR RESEARCHERS, POLICY MAKERS, AND ACCREDITATION BODIES AIMING TO STAY CURRENT.

Foundation For Accreditation Of Cellular Therapy

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foundation for accreditation of cellular therapy: *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.

foundation for accreditation of cellular therapy: *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.

foundation for accreditation of cellular therapy: *Guide to Cell Therapy GxP* Joaquim Vives, Gloria Carmona, 2015-07-24 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

foundation for accreditation of cellular therapy: *Thomas' Hematopoietic Cell Transplantation* Stephen J. Forman, Robert S. Negrin, Joseph H. Antin, Frederick R. Appelbaum, 2015-12-23 Fully revised for the fifth edition, this outstanding reference on bone marrow transplantation is an essential, field-leading resource. Extensive coverage of the field, from the scientific basis for stem-cell transplantation to the future direction of research Combines the knowledge and expertise of over 170 international specialists across 106 chapters Includes new chapters addressing basic science experiments in stem-cell biology, immunology, and tolerance Contains expanded content on the benefits and challenges of transplantation, and analysis of the impact of new therapies to help clinical decision-making Includes a fully searchable Wiley Digital Edition with downloadable figures, linked references, and more References for this new edition are online only, accessible via the Wiley Digital Edition code printed inside the front cover or at www.wiley.com/go/forman/hematopoietic.

foundation for accreditation of cellular therapy: *Thomas' Hematopoietic Cell Transplantation* Frederick R. Appelbaum, Stephen J. Forman, Robert S. Negrin, Karl G. Blume, 2011-09-26 This outstanding reference source on bone marrow transplantation has become

recognised as the bible in the field. This fourth edition has been fully revised to reflect latest developments, and now features over 500 illustrations, including a colour plate section. The need for this new edition cannot be overstated - more than 13,000 new cases per year of haematopoietic stem cell transplantation have been reported to the International Bone Marrow Transplant Registry. The original editor, Donnal Thomas, was a pioneer in stem cell research and won the 1990 Nobel Prize for his discoveries concerning organ and cell transplantation in the treatment of human diseases. The book also now includes a fully searchable CD with PDFs of the entire content.

foundation for accreditation of cellular therapy: Bone Marrow Transplantation, An Issue of Hematology/Oncology Clinics of North America Bipin Savani, 2016-03-25 This issue of Hematology/Oncology Clinics of North America, guest edited by Drs. Bipin Savani and Mohamad Mohty, is devoted to Bone Marrow Transplantation. Articles in this issue include: Acute Myeloid Leukemia (AML); Acute Lymphoid Leukemia (ALL); Myelodysplastic Syndrome (MDS); Myeloproliferative disorders (MPD); Chronic Lymphoid Leukemia; Chronic Myeloid Leukemia (CML); Multiple Myeloma and Amyloidosis; Non-Hodgkin Lymphoma (NHL); Hodgkin Lymphoma (HL); Severe Aplastic Anemia (SAA) and Paroxysmal Nocturnal Hemoglobinuria (PNH); Sickle Cell Anemia; Thalassemia; Benign immunodeficiency diseases; and Referral to transplant centers.

foundation for accreditation of cellular therapy: Best Practices in Processing and Storage for Hematopoietic Cell Transplantation Joseph Schwartz, Beth H. Shaz, 2017-12-05 This concise book examines clinically relevant issues relating to the ways in which bone marrow, cord blood and apheresis products, are processed and stored for the purpose of Hematopoietic Cell Transplantation and Cell Therapy. The twin aims are to offer up-to-date content covering a wide spectrum of topics and controversies and to provide practitioners in the field of transplant and cell therapy with practical, immediately applicable information from the internationally experts in the field. Each chapter focuses on a particular subject, and numerous working tables, algorithms, and figures are included. Whenever appropriate, the reader's attention is drawn to the availability of potentially high-impact clinical trials and expert practices. The authors are all experts who have been carefully selected for their knowledge of the topics that they address. The book will appeal to clinical and laboratory personnels, residents, fellows, and faculty members responsible for the care of hematopoietic cell transplant products and patients. Its format ensures that it will also serve as a robust, engaging tool to aid vital activities in every hematology and oncology trainee's daily work.

foundation for accreditation of cellular therapy: Hematopoietic Stem Cell Transplantation and Cellular Therapies for Autoimmune Diseases Richard K. Burt, Dominique Farge, Milton A. Ruiz, Riccardo Saccardi, John A. Snowden, 2021-11-17 This book summarizes the global progress in medical and scientific research toward converting traditionally chronic autoimmune diseases into a drug-free reversible illness using hematopoietic stem cell transplantation (HSCT) and other cellular therapies such as T regulatory cells (Treg), mesenchymal stromal/stem cells, and chimeric antigen receptor T (CAR T) cells in order to reintroduce sustained immune tolerance. This title provides information on different types of stem cells and immune cells; post-transplant immune regeneration; cellular regulatory requirements; ethical and economic considerations; and the advantages and disadvantages of HSCT in the treatment of a variety of autoimmune diseases versus current conventional treatments. Arranged by disease, the text provides a comprehensive guide to HSCT for all types of autoimmune/immune disorders including monogenetic autoimmune diseases; autoimmune aplastic anemia; neurologic immune diseases including multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, neuromyelitis optica, and stiff person syndrome; rheumatologic diseases such as systemic sclerosis and systemic lupus erythematosus; dermatologic diseases such as pemphigus; gastrointestinal disorders such as Crohn's disease and celiac disease; and immune-mediated endocrinologic disease type I diabetes mellitus. Guidance is provided on the transplantation technique, cell collection and processing, conditioning regimens, infections, and early and late complications. Key Features Outlines therapies and techniques for HSCT for autoimmune diseases Discusses the advantages of HSCT over conventional therapies Reviews the entire process of stem cell therapy from harvest and ethics to

indications, efficacy, and regulatory oversight

foundation for accreditation of cellular therapy: Thomas' Hematopoietic Cell

Transplantation, 2 Volume Set Stephen J. Forman, Robert S. Negrin, Joseph H. Antin, Frederick R. Appelbaum, 2016-12-27 Fully revised for the fifth edition, this outstanding reference on bone marrow transplantation is an essential, field-leading resource. Extensive coverage of the field, from the scientific basis for stem-cell transplantation to the future direction of research Combines the knowledge and expertise of over 170 international specialists across 106 chapters Includes new chapters addressing basic science experiments in stem-cell biology, immunology, and tolerance Contains expanded content on the benefits and challenges of transplantation, and analysis of the impact of new therapies to help clinical decision-making Includes a fully searchable Wiley Digital Edition with downloadable figures, linked references, and more References for this new edition are online only, accessible via the Wiley Digital Edition code printed inside the front cover or at www.wiley.com/go/forman/hematopoietic.

foundation for accreditation of cellular therapy: Manual of Stem Cell and Bone Marrow

Transplantation Joseph H. Antin, Deborah Yolin Raley, 2013-10-17 Fully revised throughout, the second edition of Manual of Stem Cell and Bone Marrow Transplantation is based on the in-house handbook used at the world-renowned Dana-Farber Cancer Institute. It is a practical pocket manual for all members of the stem cell and bone marrow transplant team. Written by experts at Dana-Farber, the contents are handily arranged in outline format for maximum usefulness and convenience. This essential and user-friendly manual covers all aspects of the transplantation process, from stem cell processing through management of transplant-related complications. Topics discussed thoroughly include evaluation and counselling of patients and donors, preventative care, graft-versus-host disease and conditioning regimens. A new extensive chapter on oral health in stem cell transplantation has been added. These features make the Manual of Stem Cell and Bone Marrow Transplantation an ideal resource for the entire transplant team.

foundation for accreditation of cellular therapy: Fast Facts: CAR T-Cell Therapy Richard

J. Buka, Ankit J. Kansagra, 2021-02-28 Chimeric antigen receptor (CAR) T cells are genetically engineered immune cells that can seek out and destroy cancer cells. The results from their use in cancer immunotherapy have been very promising, but treatment is often associated with frequent, serious short-term toxicities. 'Fast Facts: CAR-T Therapy' explains what CAR T cells are and how they were developed, discusses the results of clinical trials and the management of toxicities, and outlines future improvements and applications. It is ideal reading for any healthcare professional wanting to know more about this exciting therapeutic field. Table of Contents: • CAR T cells • Clinical application • Practical aspects • Future directions

foundation for accreditation of cellular therapy: Blood and Marrow Transplant Handbook

Richard T. Maziarz, Susan Schubach Slater, 2015-04-20 This updated and expanded edition developed by the Blood and Marrow Stem Cell Transplant team at Oregon Health & Science University Knight Cancer Institute features the latest medical management guidelines and standards of care for hematopoietic stem cell transplant patients. Spanning the timeline from the initial consultation throughout the transplant process, this handbook includes indications for transplantation and donor selection, treatment guidelines for addressing complications during and after transplant, and recommendations for long-term follow up care. Concise, comprehensive, and easy-to-use, Blood and Marrow Transplant Handbook, 2nd Edition presents a multidisciplinary approach to information for physicians and advanced practice medical providers who care for transplant patients, and also residents, fellows, and other trainees.

foundation for accreditation of cellular therapy: Federal Register , 2005-02

foundation for accreditation of cellular therapy: Regulatory Aspects of Gene Therapy and Cell Therapy Products Maria Cristina Galli, 2023-08-01 This book discusses the different regulatory pathways for Advanced Therapy Medicinal Products implemented by national agencies in North and South America, Europe and Asia and by international bodies in the effort of international harmonization. This book represents an update of the first edition, as it covers regulatory novelties

and accumulated experience in the regions already addressed. In addition, this new edition offers a wider international perspective: new chapters are included covering Advanced Therapy Medicinal Products regulations in India, Malaysia, Spain and Thailand, the European Pharmacopoeia texts for gene therapy medicinal products as well as international harmonization programs. Each chapter, authored by experts from various regulatory bodies throughout the international community, walks the reader through the applications of nonclinical research to translational clinical research to licensure and therapeutic use of these innovative products. More specifically, each chapter offers insights into fundamental considerations that are essential for developers of Advanced Therapy Medicinal Products in the areas of product quality, pharmacology and toxicology, clinical trial design and HTA pathways, as well as pertinent 'must-know' guidelines and regulations. Regulatory Aspects of Gene Therapy and Cell Therapy Products: a Global Perspective is part of the American Society of Gene & Cell Therapy sub-series of the highly successful Advances in Experimental Medicine and Biology series. It is essential reading for graduate students, clinicians, and researchers interested in gene and cell therapy and the regulation of pharmaceuticals.

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