FOUNDATIONS OF CELL THERAPY COURSE SYLLABUS

AABB

Foundations of Cell Therapy

Syllabus

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Technical Requirements and Contact Information for Assistance

This course is offered online as independent, self-paced study through the AABB Education Platform located at http://education.aabb.org.

Technical Requirements - learners must:

- Have an internet connection to access the course
- Navigate and be able to use the features of the course content and Education Platform

The course can be viewed on a mobile device; however, a desktop or laptop computer is recommended. AABB recommends learners use either the Google Chrome, Safari, Microsoft Edge or Firefox browsers to access the course. Anyone using MAC or PC can download Google Chrome. Internet Explorer is not supported.

For questions related to the program submit an enquiry via email to the AABB eLearning team at eLearning@aabb.org. A response should be expected Monday – Friday during business hours (US Eastern Standard Time or EST) within 48 hours of request.

Course Description

Individuals new to a career in cellular therapies (CT) may benefit from access to basic information, training, or experience to help them quickly adapt to a CT work environment. Recognizing the need for basic knowledge to prepare early-career professionals, the *Foundations of Cell Therapy* course was developed to provide a concise overview of the essential elements to help one navigate the field.

The course is divided into individual modules covering 8 key topic areas:

1. The Quality Mindset
2. Cell Therapy Regulations
3. Laboratory Maintenance
4. Aseptic Technique
5. Cell Processing/Handling Techniques
6. Cell Analytics
7. Cell Therapy Infusion Reactions
8. Mechanics of Apheresis

Course Goals

Upon completion of this course, learners should be able to:

- Identify the core elements of quality and compliance with real-world examples.
- Evaluate regulations relevant to CT products.
- Describe best practices in laboratory maintenance.
- Describe technical aspects of common procedures for cell processing.
- Identify common techniques used to characterize cells.
- Discuss CT infusion reactions.
- Discuss basic mechanism of apheresis cell collection and impact of variability.

The course is expected to take approximately 4-4.5 hours to complete. The course can be taken asynchronously at the convenience of the learner; however, access to the course is available for one year from the date of registration.

Module Overview & Learning Objectives

Each module will cover elements relevant to developing an overall understanding of basic concepts and practices in Cell Therapy. It is important to read through the material and think about how the topics apply - relating the principles to actual situations.

Learning objectives are listed for each module. Additional resources are provided at the end of each presentation. At the conclusion of each module, learners are provided knowledge check questions designed to reinforce learning (two attempts on each knowledge check are provided). Although there is no required passing score, learners are encouraged to review the appropriate sections of the course modules when questions are missed to ensure a better understanding of the content.

Module 1: The Quality Mindset

Awareness and understanding of quality practices are critical to ensuring product and patient safety. This module introduces core elements of quality and compliance with real-world examples of how to implement these processes.

Upon completion of this module, a learner should be able to:

- Discuss the purpose of a Quality Assessment Program (Quality System) in cell therapy manufacturing.
- Identify the core quality system manufacturing components and their potential impact on cell therapy products safety and quality during the manufacturing life cycle.

Presented by: Ronit Slotky, PhD, MSc

Module 2: Cell Therapy Regulations

Regulations are key to ensuring consistency and safety of cell products. This module provides an overview of characteristics of compliant products, regulatory pathways, requirements and where they can be found. This module also compares GMPs/GTPs with respect to cell-based biological drug products. In addition, investigational New Drugs (INDs) and achieving compliance are discussed.

Upon completion of this module, a learner should be able to:

- Define 361 (GTP) and 351 (GMP) regulated products.
- Contrast HCT/P products regulated solely under 361 vs IND and licensed biological products: CGTPs vs CGMPs.
- Discuss specific applicable regulations for each to illustrate differences.
- Highlight specific operational considerations with each of these types of products.

Presented by: J. Wade Atkins, MS, MT(ASCP)SBB, CQA

Module 3: Laboratory Maintenance

Laboratory maintenance is important to ensure processing of safe and effective cell products. This module introduces the core elements of laboratory procedures and processes to maintain control and regulatory and safety compliance.

Upon completion of this module, a learner should be able to:

- Review best practices in facilities design, cleaning, environmental monitoring (EM) and alarms.
- Review approaches to equipment maintenance.
- Discuss an example on how to validate one of the above systems.

Presented by: Federico Rodriguez Quezada, SBB, MLS^{i}(ASCP)^{CM}

Module 4: Aseptic Technique

Aseptic technique is a set of principles and practices used by laboratory workers to reduce the potential of unwanted microorganisms or other infectious material from being introduced into a variety of items including biologics, solutions and humans. This module introduces common techniques used to minimize contamination in the laboratory.

Upon completion of this module, a learner should be able to:

- Define aseptic technique and demonstrate why it is important.
- Review basic principles and best practices of aseptic technique.

Presented by: Matthew J. Wilgo

Module 5: Cell Processing/Handling Techniques

To optimize quality and efficacy, it is important to understand how to collect, handle and know when to use cell products in applications. This module introduces the technical aspects of common procedures for cell processing and handling.

Upon completion of this module, a learner should be able to:

- Discuss the importance of cryopreservation in transplants.
- Discuss the use of dimethyl sulfoxide (DMSO) in cryopreservation.
- Describe potential manipulations of products.

Presented by: Eapen Jacob, MD

Module 6: Cell Analytics

It is critical to know what is in cell products to ensure their quality and consistency for safe administration to patients. 'Analytics' is a term used to determine the composition of cells and includes how cells are characterized. This module describes various techniques used to characterize cells and the criteria to be met prior to release and infusion to patients.

Upon completion of this module, a learner should be able to:

- Describe the significance and basic techniques used for the characterization of cells used in cellular therapy products (CTPs).
- Recognize the scope, advantages and limitations of the techniques.
- Discuss the requirements that must be met before a CTP is released for infusion.
- Discuss new methodologies and platforms on the horizon in the CT cell analytics field.

Presented by: Indira Guleria, PhD, D(ABHI)

Module 7: Cell Therapy Infusion Reactions

Knowledge of potential risks to any treatment or therapy is essential to increase awareness to ensure patient safety. This module introduces the broad categories of reactions to CT infusions, including hematopoietic stem cell transplantation (HSCT) products and commonly engineered cell therapies.

Upon completion of this module, a learner should be able to:

- Review the diagnosis and grading of common cell therapy infusion reactions.
- Discuss the causes and clinical spectrum of infusion reactions.
- Describe the options for prevention and management of infusion reactions.

Presented by: Thomas R. Spitzer, MD

Module 8: Mechanics of Apheresis

Understanding the composition of cell starting material and how it is collected is important to maintaining its quality and ultimately, efficacy. This module introduces the concepts of real- time, continuous and semi-continuous flow blood separation concepts.

Upon completion of this module, a learner should be able to:

- Describe the basic mechanism of apheresis separation.
- Describe typical content of mononuclear cell products.
- Discuss the impact of donor-to-donor variability.

Presented by: Andrew Fesnak, MD

Activities for Successful Completion of the Course

This introductory course provides material important in understanding the core elements involved in CT to help in the initial adjustment to CT work environments. Watch the video for each module and complete the knowledge checks provided. Learners can view the modules multiple times during the access period. After completing all the modules, a course evaluation is required before the course is marked as complete and continuing education credits are awarded. This is your opportunity to share with AABB your experiences and recommendations to further enhance the program. Since this is a self-paced program, learners may decide how much time is needed to review and study the materials. It is estimated the course will take approximately 4-6 hours to complete.

Continuing Education Credits/Certificate of Completion

This course is eligible for four (4) continuing education credits/contact hours for General Participation, California Nurse, California Lab Personnel or Florida Lab Personnel. The number and type of credits awarded for this course was determined by the estimated program completion time. This course is not eligible for continuing medical education credit for physicians. For more information on each credit type please visit AABB's Continuing Education Credits webpage. A continuing education certificate of completion will be immediately provided upon reviewing all modules and completion of the course evaluation. Learners will also be able to access the continuing education certificate in the My Transcripts section of the AABB Education Platform.

Course Faculty & Contributors

While there are numerous participants that have brought this program to fruition, key faculty and contributors include (titles and affiliations at the time of program development):

Contributing Faculty

J. Wade Atkins, MS, MT(ASCP) SBB, CQA
Supervisor, DTM QA/RA, National Institutes of Health, Bethesda, MD

J. Wade Atkins, MS, MT(ASCP) SBB, CQA, has worked for 20 years as a quality assurance and regulatory specialist for the Department of Transfusion Medicine (DTM) at the National Institutes of Health in Bethesda Maryland. He is the current supervisor of a team of five quality specialists. The DTM is a full- service blood bank with a licensed collection facility and a full transfusion service. Atkins earned a Bachelor of Science in Biology from Pfeiffer College in 1987 and was awarded a second degree in Medical Technology in 1988 after completing the rigorous program at Charlotte Memorial Hospital in North Carolina. He successfully challenged the American Society of

Clinical Pathologist Specialist in Blood Banking exam in 1995. He earned a Master of Science degree from the University of Maryland University College in 1998.

Andrew Fesnak, MD
Assistant Professor of Clinical Pathology, Deputy Director, Clinical Cell and Vaccine Production Facility at the University of Pennsylvania, Director, Hematopoietic Stem Cell and Cell Processing Laboratory, Hospital of the University of Pennsylvania, Philadelphia, PA

Andrew Fesnak, MD, is a transfusion medicine physician with clinical and technical expertise in the area of cellular immunotherapy, biomanufacturing and medical education. He earned his Bachelor of Arts in Molecular Biology from Princeton University and MD from UMDNJ-Robert Wood Johnson Medical School. Fesnak completed Clinical Pathology residency and Transfusion Medicine fellowship at the University of Pennsylvania. Fesnak is currently the Deputy Director of the Clinical Cell and Vaccine Production Facility and the Director of the Hematopoietic Stem Cell and Cell Processing Laboratory at the University of Pennsylvania. In these roles he oversees cell processing and manufacturing for clinical-scale cell therapy research and FDA approved applications. He served on the AABB committee that established the Cellular Therapy Certificate Program and is a previous chair of the Education Committee.

Indira Guleria, PhD, D(ABHI)
Assistant Professor of Medicine, Harvard Medical School, Associate Director, HLA Tissue Typing Laboratory, Associate Immunobiologist, Renal Transplant Program, Division of Renal Medicine, Brigham and Women's Hospital, Boston, MA

Indira Guleria, PhD, D(ABHI), earned her PhD in Immunology from the National Institute of Immunology and completed a postdoctoral fellowship at Albert Einstein College of Medicine. Guleria's primary research involves studying the mechanisms of transplant tolerance with a focus on the role of various costimulatory molecules in allograft tolerance. She has also made significant contributions to the field of immunobiology of solid and stem cell transplantation and has been part of the multi-disciplinary team facilitating stem cell transplants at the Dana Farber Cancer Institute. In addition to her research, Guleria has been a leader in providing education to fellows, residents and faculty through developing professional educational programs and learning tools. She currently serves on AABB's Cellular Therapies Section Coordinating Committee and is a co-lead on the Current and Emerging Technology Committee. Her work focuses on exploring the role of myeloid derived suppressor cells and T regulatory cells in graft survival and Graft Versus Host Disease in stem cell transplant patients.

Eapen Jacob, MD
Consultant, Division of Transfusion Medicine, Associate Professor of Laboratory Medicine and Pathology, Fellowship Director, Human Cellular Therapy Fellowship, Medical Director, Human Cellular Therapy Lab, Associate Director, IMPACT Lab, Associate Medical Director, Immunohematology Reference Lab, Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN

Eapen Jacob, MD, is the Medical Director of multiple cellular therapy laboratories at Mayo that support hematopoietic progenitor cell transplants as well as novel cellular products, which are manufactured both internal and external to Mayo. He co-founded one of the first dedicated cellular therapy fellowships focusing on manufacturing of GMP products.

Federico Rodriguez Quezada, SBB, MLS^{i}(ASCP)^{CM}
Collections and Processing Lab Facility Manager, UF Health Shands BMT Program, Gainesville, FL

Federico Rodriguez Quezada, SBB, MLS^{i}(ASCP)^{CM}, has more than 30 years of experience in cellular therapy and immunohematology. He earned his Bachelor of Science in Medical Technology from the Autonomous University of Nuevo Leon in Monterrey, Mexico, and attended the Specialist in Blood Banking School at the University of Texas Medical Branch in Galveston, TX. He later became certified as an SBB by the American Society for Clinical Pathology (ASCP). He has held different positions during his professional career: Medical Technologist, Sales Specialist, Laboratory Supervisor, Education Coordinator, Laboratory Manager, Technical Director, Adjunct Faculty, Coordinator and, recently, consultant. His experience includes all aspects of manufacturing, regulatory requirements and compliance, process design, process improvement and quality management systems in the Cellular Therapy field, including bone marrow, cord blood and peripheral blood, as well as other novel therapies.

Ronit Slotky, PhD, MSc
Director, Cell Therapies Manufacturing Facility, Hackensack University Medical Center, Hackensack, NJ. Associate Professor of Oncology, Hackensack Meridian School of Medicine, Nutley, NJ

Ronit Slotky, PhD, MSc, earned her PhD in Biology at the Technion, Israel Institute of Technology in Haifa, Israel, and her MSc in Biostatistics at Columbia University Mailman School of Public Health in New York. She completed her post doctorate at Columbia University Medical Center studying proteins' structure and function. Slotky has been working in the cellular therapy field for more than 15 years and is currently the Director of the Cell Therapies Manufacturing Facility at the Hackensack University Medical Center and Associate Professor of oncology at the Hackensack Median Health School of Medicine. Her current work and research efforts focus on improving cell processing methods and patient outcomes and providing education opportunities for clinicians and researchers.

Thomas R. Spitzer, MD
Medical and Laboratory Director, Cellular Therapy and Transplantation Laboratory, Emeritus Director of the Bone Marrow Transplant Program, Massachusetts General Hospital, Professor of Medicine, Harvard Medical School, Boston, MA

Thomas Spitzer, MD, is Director Emeritus of the Bone Marrow Transplant Program and Medical and Laboratory Director of the Cellular Therapy and Transplantation Laboratory at the Massachusetts General Hospital (MGH) and is Professor of Medicine at Harvard Medical School. He is also Walter Bauer Firm Chief in the Department of Medicine. Spitzer received his Bachelor of Science degree in Biology from Bucknell University and his MD from the University of Rochester School of Medicine. He completed his internship and residency in Internal Medicine at New York Hospital-Cornell Medical Center and Memorial-Sloan Kettering Cancer Center, and his Hematology-Oncology fellowship at Case Western Reserve University. His primary research interests have included the development of novel strategies for performing hematopoietic cell transplants across HLA barriers for hematologic malignancies and for inducing specific tolerance for organ transplantation by performing combined bone marrow and kidney transplants. The cellular therapy lab that he directs has provided all the products for hematopoietic cell transplantation at MGH and is currently involved with many novel immune effector cellular therapy trials. He has assumed leadership roles in AABB, including serving as Chair of the Cellular Therapy Section Coordinating Committee and as a member of the Board of Directors. He is a devoted teacher of medical students and residents in his Firm Chief role, and he has been the recipient of teaching awards for his contributions to medical education.

Matthew J. Wilgo
Cell Biology Scientist, General Supervisor, New England Cord Blood Bank/New England Cryogenic Center, Marlborough, MA

Matthew Wilgo is the resident Cell Biology Scientist at New England Cord Blood Bank and New England Cryogenic Center, with over two decades of experience in research and development in the fields of cellular and stem cell biology. He graduated from the University of New Hampshire with a Bachelor of Science in Microbiology, and has a passion for the biological fields of science. He obtained a deep understanding of stem cells after working for nearly a decade in Millipore's stem cell R&D division. Wilgo has presented numerous educational sessions and abstracts at scientific societies such as AABB and the American Society for Cell Biology and has co-authored a chapter in Methods for Cell Biology. He currently serves on AABB's Cellular Therapies Section Coordinating Committee as well as a co-lead on the Cord Blood subsection. His current work focuses on hematopoietic stem cells from cord blood and mesenchymal stem cells from umbilical cord tissue and dental pulp.

Reviewers:

- Wanxing Cui, MD, PhD, Director, Cell Therapy Manufacturing Facility, MedStar Georgetown University Hospital, Washington, DC
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- Kevin J. Land, MD, Medical Director Cell Therapy, Vice President Clinical Services, Vitalant, San Antonio, TX, Adjunct Professor, Department of Pathology, UT
- Christina M. Celluzzi, PhD, MS, Director Biotherapies, AABB, Bethesda, MD

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