

## AABB Cellular Therapies Certificate Program SYLLABUS

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## Program Description

Welcome to the AABB Cellular Therapies Certificate Program – a partnership between AABB and The George Washington University.

The field of Cellular Therapies – utilizing cells found naturally as part of the immune system – is exciting and evolving. Manipulated cells can be used to treat cancer and other illnesses and conditions. Cells combined with other modalities (e.g., scaffolds, matrixes) also offer potential to (re)generate, repair and improve function of damaged organs including heart, eye, liver, and knee.

The Cellular Therapy industry continues to expand – attracting individuals from different disciplines needed for therapeutic collections, cell processing and production, development of new applications, product manufacturing, and oversight of quality through standards and regulation to name a few. Specific basic knowledge and training are critical to ensuring quality contributions that ultimately impact clinical safety and effectiveness.

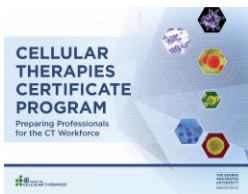
Whether you are just entering the workforce or already have experience, the AABB Cellular Therapies Certificate Program, is designed to provide a solid foundation to understanding cellular therapies via a comprehensive overview of topics critical to the field.

The program is divided into 3 major areas, each consisting of different topic modules:

- 1) **Scientific** -provides background information on the science behind the applications to understand how different cells are delineated and the underlying immunological principles
- 2) **Operational** -includes information on how and where cells are handled, manufactured, cryopreserved and the precautions necessary to ensure safe products and
- 3) **Regulatory**–describes information critical to ensure patient safety

The program is presented in a series of 12 instructional modules produced by expert faculty with years of relevant experience from academic, clinical and commercial domains. The faculty that have contributed to a particular module are listed within the module description. An 80% or higher is required for passing on each module assessment.

**Click on the image to view a short animation** about the program.



## Program Goals

Upon successful completion of the program, students will be able to:

1. Develop a working knowledge of terms and acronyms used in the Cellular Therapy field.
2. Describe hematopoiesis – lineage from stem/progenitor cells to differentiated cells.
3. Discuss basic immunological principles, the innate and adaptive immune systems, cell-antigen interactions, and the HLA system and its role in transplantation.
4. Identify therapeutic cells and their clinical potential.
5. Identify assays commonly used to characterize cells of the immune system, assess cell viability and determine cell potency.
6. Describe aseptic processing and requirements for meeting standards.
7. Discuss environmental monitoring and requirements.
8. Evaluate regulations relevant to product quality, consistency and safety.
9. Define the essential components of quality systems.
10. Apply knowledge learned from the CT Certificate Program to scenarios.

## Module Learning Objectives

Each module will cover elements relevant to developing an overall understanding of the concepts and practices in Cellular Therapies. It is important to read the material carefully. As you follow the presentations think about how you might apply or relate the principles and concepts to actual situations.

The Program modules:

### 1. *Scientific Modules*

#### Module 1: Hematopoiesis and Basic Immunology

*Serves as the foundation of the scientific knowledge and background important to understanding how cellular therapies are conceived, designed and developed.*

**Objectives:** Upon completion of this module, students will be able to:

1. Define hematopoiesis and the hematopoietic cell lineages.
2. Describe the innate and adaptive systems--- how they are defined, their components and their mechanism of action to understand how cells interact in the body and help protect against disease and infection.
3. Describe the HLA system and the role of the Major Histocompatibility Complex to illustrate the specificity of the immune system and how the body regulates its reactivity.

*(faculty: Magali Fontaine, MD, PhD; Achsah Keegan, PhD; Kamal Moudgil, MD, PhD; Susan Saidman, PhD, and Christina M. Celluzzi, PhD, MS)*

## Module 2: Stem Cell Sources and Applications

*Presents information on the different sources of stem cells, preparation, processing, collection methods, and specific applications including their roles in cellular therapies.*

**Objectives:** Upon completion of this module, students will be able to:

1. Describe the different sources of stem cells and their characteristics.
2. Define key/commonly used terms and acronyms such as hematopoietic cell therapy products (HCT/P).
3. Describe the most commonly used stem cell sources.
4. Describe how stem cells are obtained or collected.
5. Describe how stem cells are processed, stored and prepared for infusion.
6. Describe the different direct applications of stem cells in myeloablative and non-myeloablative therapies and regenerative medicine.
7. Outline the course of the transplant process.
8. Distinguish between acute and chronic graft versus host disease.
9. Identify resources to coordinate the search for a donor, procure and ship the stem cells needed for transplant.

*(faculty: Aleksandar Babic, MD, PhD and Tami Yonke, MT(ASCP)SBB, M.Ed.)*

## Module 3: Therapeutic Cells and Potential Applications

*Describes the range of different cell types beyond the 'basic stem cell' (at different stages of the hematopoietic pathway) including mesenchymal stromal cells (MSCs), dendritic cells (DCs), lymphocytes, and macrophages used in cellular therapies. The therapeutic potential of these cells including the basic science of cell function, characteristics and methods of cell preparation will be discussed.*

**Objectives:** Upon completion of this module, students will be able to:

1. Identify immune cells and describe their therapeutic biology.
2. Describe how immune cells are procured.
3. Describe how immune cells are manufactured.
4. Recognize the challenges of clinical adoptive transfer of immune cells.
5. Evaluate the future of immunocellular medicine.

*(faculty: Andrew Fesnak, MD, Alexey Bersenev, MD, PhD and Jo-Anna Reems, PhD, MT(ASCP)SBB)*

## Module 4: Assays and Assay Validation

*Assays that determine the identity, viability, sterility and potency are essential to delivering high quality, consistent cellular therapy products as well as satisfying requirements for their release for use. A variety of assay methods employed in cellular therapies include laboratory procedures such as flow cytometry, cytokine testing, and cell culture. This module will cover different assays and determination of statistical significance.*

**Objectives:** Upon completion of this module, students will be able to:

1. Identify different assay methods used to characterize cells.
2. Evaluate the assay methods used for representative cell types and cellular products.
3. Evaluate the principles behind the sterility assays.
4. Interpret the principles of flow cytometry.
5. Describe preparation of cells and cell products for particular assays.
6. Identify a commonly used statistical test and its application.
7. Apply a statistical test based on an example.

*(faculty: Stephen Spellman, MBS, Gayl Chrysler, MBA, RN, BAN, and Ping Law, PhD)*

## 2. Operational Modules

### Module 5: Aseptic Processing

*Proper precautions are necessary to ensure safe products. This serves as an introduction into the concepts and principles of aseptic processing of cell-based products intended for human administration. Facility design considerations as well as cleanroom activities including gowning requirements with training, equipment use, and cleaning procedures will be covered.*

**Objectives:** Upon completion of this module, students will be able to:

1. Define aseptic processing.
2. Interpret current guidances and regulations.
3. Identify major validation plan activities.
4. Describe gowning requirements.
5. Describe procedures for using biological safety cabinet-equipment.

*(faculty: Timothy D. Wood, BA)*

## Module 6: Product Sterility and Environmental Monitoring

*The classification and control of the environment is critical to developing quality cellular products. This module addresses the methods to control and monitor the environment with validation.*

**Objectives:** Upon completion of this module, students will be able to:

1. Define a clean room and classifications.
2. Recognize alternate and rapid sterility methods for HCT/Ps and why they are needed.
3. Identify best practices in the industry with current guidances and regulatory requirements.
4. Identify and describe sterility tests used in the industry- selecting type and number of organisms as well as approaches to limited sample volumes.
5. Describe environmental factors that influence sterility and efficacy.
6. List features of environmental monitoring programs.

*(faculty: Timothy D. Wood, BA)*

## Module 7: Product Potency and Efficacy

*To ensure efficacy, testing is necessary to measure product attributes associated with product quality and manufacturing controls. Testing is performed to assure identity, purity, stability and strength or potency of products used during all phases of clinical study. This module will address the features of potency assays and regulations that guide their development and use.*

**Objectives:** Upon completion of this module, students will be able to:

1. Identify tests to measure product potency.
2. Interpret regulatory requirements associated with potency.
3. Recognize approaches that assess product efficacy.

*(faculty: Peiman Hematti, MD, Gayl Chrysler, MBA, RN, BAN, and Christina M. Celluzzi, PhD, MS)*

## Module 8: Manufacturing Technologies

*Scaling up production of cell therapy products is important to producing high yields and ensuring sufficient amount of product available to recipients. This module will address the latest in manufacturing equipment and processing technologies to address process scale-up: From T-flasks to bioreactors-- From manual to automated filling. Cryopreservation-cold chain management will also be discussed.*

**Objectives:** Upon completion of this module, students will be able to:

1. Describe scale up equipment and technologies.
2. Describe and discuss manual to automated processing.
3. Describe cryopreservation technologies.
4. Describe supply chain and distribution.

*(faculty: Aby J. Mathew, PhD)*

## Module 9: Technology Transfer

*Technology transfer is a systematic procedure that is followed in order to pass knowledge and experience gained during product development and/or commercialization to an appropriate, responsible and authorized party. Issues centered on these procedures are addressed.*

**Objectives:** Upon completion of this module, students will be able to:

1. Describe the definitions and basics of technology transfer from academia to industry.
2. Identify the different perspectives of academia and industry with respect to transfer technology.
3. Identify challenges in technology transfer.
4. Identify the steps in the technology transfer process for successful execution.

*(faculty: Alexey Bersenev, MD, PhD and Aby J. Mathew, PhD)*

### 3. Regulatory Modules

#### Module 10: Regulations

*Cellular therapy products are processed and delivered globally. Regulations are critical for standardization to ensure quality, consistency and safety. This module will discuss regulatory issues, highlighting important terms and providing information on U.S. regulations, international regulations, guidances and resources.*

**Objectives:** Upon completion of this module, students will be able to:

1. Describe the agencies that regulate cell therapy products (U.S. FDA, foreign agencies).
2. Describe key resources/FDA cellular and gene therapy guidances to finding regulations that apply to cell therapy products.
3. Define key terms important to regulations (human cells, tissues and cellular and tissue-based products, HCT/Ps, safety, purity and potency).
4. Identify the U.S. Code of Federal Regulations applicable to cellular therapy products.
5. Understand the distinction between different regulations and to which cellular therapy product they apply.
6. Identify types and uses of products regulated under 21CFR1271 and section 361 or 351 U.S. Public Health Service (PHS) Act.
7. Describe reporting of adverse events and product deviations.

*(faculty: Hanh Khuu, MD)*

#### Module 11: Donor Screening- Eligibility

*Donor screening is important to the acquisition and safe handling of biologic products. This module will address the steps involved in the determination of donor eligibility, the screening process and the related issues.*

**Objectives:** Upon completion of this module, students will be able to:

1. Define donor testing in general.
2. Discuss how donor-eligibility is determined.
3. Identify diseases or conditions that require screening.
4. Identify specific testing requirements for HCT/P donors.
5. Identify relevant communicable disease agents or diseases.
6. Describe the donor history questionnaire.
7. Recognize methods and procedures used for testing donors for relevant communicable disease agents and diseases.
8. Assess the content of Title 21CFR, part 1271 regarding screening.
9. Identify risk factors or conditions to look out for when screening a donor.

*(faculty: Hanh Khuu, MD)*



## Module 12: Considerations for Product Development

*Quality systems are essential to product commercialization for patient safety and product reproducibility. This module will discuss the important issues for quality and commercialization of cellular therapy products.*

**Objectives:** Upon completion of this module, students will be able to:

1. Define common acronyms (IND, BLA, CLIA, CMS).
2. Discuss a quality system and list the essential elements.
3. Compare and contrast differences between investigative new drug (IND) and biologic license application (BLA) and procedures involved in obtaining each.
4. Identify biological products that have been licensed.

*(faculty: Hanh Khuu, MD)*

## Module Content Accessibility

The module content is narrated. The volume level can be adjusted by moving the volume icon (visible on the screen), in the preferred direction and/or adjusting your own computer volume controls.

When you ‘click’ on the module link, the first slide, which will automatically present the name of the module and the faculty responsible for creating the content.

Each module is divided into different topic headings representing a slide set. You will be able to advance the slide set or return to those slides you wish to review by selecting the “next” or “previous” command button. You can also select the slide from the list in the side panel. We recommend that you first view the material in its intended order for best understanding. You will always be able to return to slides for review as many times as you wish.

Key ideas, bulleted lists, images, illustrations and videos support the narrative. In a few of the modules, interactive exercises provide feedback to see how well you have captured information as you work through.

Written transcripts and glossaries that explain the terms are located via tabs found above the topic headings.

Additional references, journal articles, and web sources are included for further information. To view these, “click” on the highlighted links and pointers appearing on module screens.

## Activities for Successful Completion of the AABB Cellular Therapies Certificate Program

Read and study all of the materials for each module including additional readings that support and reinforce basic information presented. Follow the modules sequentially as information is

built upon preceding learnings. Module 1, “Hematopoiesis and Basic Immunology,” is the foundation of the program and its elements will touch on all of the modules. It is estimated that each module will take about 4 hours or less to complete. Since this is a self-paced program, you may decide how much time is needed to review and study the materials. A suggested strategy is to create a study plan or timeline for completing each module. Follow that plan to ensure timely completion within the year that you will have access to the Program.

## Assessment and Grading for Conferral of Certificate

For successful completion of the program resulting in conferral of the CT Certificate:

1. Read and carefully study each slide in all modules. This is required for passing the Certificate Program.
2. Answer all of the assessment materials; scoring 80% or higher.
  - You will receive test questions (i.e., multiple choice, true-false questions) based on scenarios and asked to select the correct answer.
  - You will receive feedback as to whether an answer choice is correct or incorrect. Each correct answer choice will have an explanation as to why that answer is correct.
  - For each module, you will have 2 opportunities to achieve 80% or higher on the assessment. If after your first attempt at answering the assessment questions you do not achieve the minimum score, you will be provided another attempt to complete the assessment for that module.
3. Complete the AABB Cellular Therapies Certificate Program Post-Program Evaluation

You will receive a message in Blackboard with information on how to retrieve your Certificate of Completion from AABB when you have completed (1) all 12 modules, (2) all assessments scoring 80% or higher, (3) the Post-Program Evaluation and, (4) designate your continuing education credit type.

## Additional Program Information

- Within 7 days following confirmation of completion of the Program, you will receive via email from AABB your “Cellular Therapies Certificate of Completion.”
- Continuing Education and Medical credits (CE/CME) are awarded for this program. You will receive your CE/CME certificate via email with your certificate of completion.
- Blackboard access to the program materials will be available to you for 1 year from the date of your enrollment in the program. This program is self-paced; however, you must complete all of the modules, all assessments, and a program evaluation within the year following enrollment date to receive the Certificate. If you are unable to complete the program within the one year period and still wish to complete the program to receive a Certificate, then you must re-purchase the program and re-register (if your access has expired and you have been removed from Blackboard) or complete a retake registration form to extend your access. Questions related to registration should be directed to [eLearning@aabb.org](mailto:eLearning@aabb.org).

## Technical Requirements and Contact Information for Assistance

This program is offered entirely online as independent, self-paced study through [Blackboard](#), a learning management system (LMS).

**Technical Requirements-** In order to succeed in this program, learners must:

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

We strongly recommend that students use either the Google Chrome or Safari browsers to access the course. Anyone using MAC or PC can [download Google Chrome](#).

For **technical questions** related to program access and difficulty in opening any content, submit an inquiry to [hsptech@gwu.edu](mailto:hsptech@gwu.edu). A response should be expected during business hours (US Eastern Standard Time or EST) within 48 hours of request. Answers to basic Blackboard frequently asked questions can be found on The George Washington University (GW) [Blackboard FAQ webpage](#).

For **billing, enrollment issues, and issues related to documentation** following completion of all modules and testing requirements, email AABB Education and Professional Development Department at [eLearning@aabb.org](mailto:eLearning@aabb.org).