



AABB | Certified Advanced Biotherapies Professional

Examination Syllabus





**Association for the
Advancement of
Blood & Biotherapies**

About AABB

The Association for the Advancement of Blood & Biotherapies (AABB) is an international, not-for-profit Association representing individuals and institutions involved in the fields of transfusion medicine and biotherapies. The Association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers. AABB members and accredited institutions are located in more than 80 countries.

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Introduction

The AABB Certified Advanced Biotherapies Professional (CABP) credentialing program is the first and only certification for biotherapies professionals. Becoming a CABP is a mark of distinction, establishing that qualified professionals have demonstrated necessary knowledge to credibly practice in the field of biotherapies.

This credentialing program benefits the entire biotherapies field by establishing minimum standards of competence, identifying qualified and proficient professionals, and advancing safety and quality. CABP certification provides an opportunity for recognition of high-performing professionals among peers, patients, health care organizations and more.

The AABB CABP credential is designed to:

- Advance safety and quality practice
- Establish minimum standards of competence
- Identify qualified and competent professionals for employers
- Provide a recognition opportunity for professionals

The following pages include a detailed outline of the content areas and tasks and skills evaluated in the examination, with an indication of the approximate percentage of examination questions devoted to each of the seven major content areas. Please note that questions from the various domains will be mixed throughout the examination. The questions will NOT be presented in domain order on the examination.

Please refer to the AABB Certified Advanced Biotherapies Professional (CABP) Certification Handbook for policies and procedures that govern the preparation for and maintenance of the (CABP) credential. For more information on the CABP certification, please visit aabb.org/cabp.

Intended Audiences for the Certification

CABP is open to all advanced biotherapies professionals, including those working in the following positions:

- Laboratorians
- Researchers
- Medical directors
- Fellows
- Quality specialists
- Regulatory specialists
- Nurses
- Pharmacists

Domains Covered by the Exam

1. Biotherapies in the Patient Care Ecosystem (11%)
2. Biotherapies Science and Ethics (9%)
3. Operations and Equipment (19%)
4. Biotherapies Development Lifecycle (15%)
5. Manufacturing (15%)
6. Quality Systems (21%)
7. The Regulatory Environment (10%)

Suggested Reading

The following references can be used when preparing for the exam. It is not an exhaustive list but can serve as a guide for preparation. Inclusion on the list does not indicate endorsement by the AABB, nor does the AABB wish to imply that the content of the examination will be drawn solely from these resources and publications:

Books

- Areman EM, Loper K, eds. [Cellular Therapy: Principles, Methods, and Regulations. 2nd ed.](#) Bethesda, MD: AABB, 2016. [Print](#) | [Digital](#)
- Atala A, Lanza R, Mikos T, Nerem R, eds. [Principles of Regenerative Medicine. 3rd ed.](#) Cambridge, MA: Academic Press, 2018.
- Creer MH, Lemas MV, Mathew AJ. [Practical Handbook of Cellular Therapy Cryopreservation.](#) Bethesda, MD: AABB Press, 2015.
- Domen RE, ed. [Ethical Issues in Transfusion Medicine and Cellular Therapies.](#) Bethesda, MD: AABB Press, 2015.
- Kalodimou VE. [Basic Principles in Flow Cytometry.](#) Bethesda, MD: AABB Press, 2013.

Other

- Standards (e.g., AABB, FACT, ISO, ANSI, ICCBBA)
- Competent Authorities (e.g., FDA Guidances, EMEA Directives)
- Standards Coordinating Body Portal
- Clinical Trial Registries (e.g., ClinicalTrials.gov, WHO Registry Network, etc.)
- Association Resources (e.g., AABB, WMDA, CBA, ASCGT, ISCT, AATM, ARM, etc.)

Peer-reviewed Journals

Examples of peer-reviewed journals include:

- [Biopreservation and Biobanking.](#) Published by Mary Ann Liebert, Inc.
- [blood.](#) Published by American Society of Hematology.
- [Cell and Tissue Banking.](#) Published by Springer Nature.
- [Cytotherapy.](#) Published by International Society of Cell and Gene Therapy (ISCT).
- [Immunology.](#) Published by Wiley.
- [Journal of Clinical Oncology.](#) Published by the American Society of Clinical Oncology.
- [Nature.](#) Published by Springer Nature.
- [The New England Journal of Medicine.](#) Published by the Massachusetts Medical Society.
- [STEM CELLS Translational Medicine.](#) Published by Oxford University Press.
- [Tissue Engineering and Regenerative Medicine.](#) Published by Springer.
- [TRANSFUSION.](#) Published by Wiley.

Examination Blueprint



Domain 1: Biotherapies in the Patient Care Ecosystem

DOMAIN WEIGHTING: THIS DOMAIN COVERS 11% OF THE EXAM

- 1.1 Educates patients, caregivers, colleagues, and others regarding the unique mechanisms of action in biotherapies, including distributive processes, product characteristics, risk and efficacy and the entire process of collection/acquisition, research, manufacture, delivery, and administration.**
 - Given a scenario about educating a patient regarding unique mechanisms of action in biotherapies, identify how the risk and efficacy should be explained to the patient.
 - Given a scenario about educating a patient regarding unique mechanisms of action in biotherapies, identify how the delivery and administration should be explained to the patient.
 - Given a scenario about educating a patient regarding unique mechanisms of action in biotherapies, identify how the human subject research (clinical trial) should be explained to the patient.
 - Given a scenario about educating a caregiver regarding unique mechanisms of action in biotherapies, identify how the side effects (risk/adverse events) should be explained to the caregiver.
 - Given a scenario about educating a caregiver regarding unique mechanisms of action in biotherapies, identify how the distributive process or product characteristics should be explained to the caregiver.
 - Given a scenario about educating a colleague regarding unique mechanisms of action in biotherapies, identify how the delivery process should be explained to the colleague.
 - Given a scenario about educating a colleague regarding unique mechanisms of action in biotherapies, identify how the administration process should be explained to the colleague.
- 1.2 Connects biotherapy medicine and techniques to individual patient needs through coordination and bi-directional communication with multidisciplinary peers.**
 - Given a scenario where a patient is prescribed a biotherapy, identify steps that must be coordinated with other healthcare providers.
 - Given a scenario where a patient is prescribed a biotherapy, identify the information that should be communicated to the prescriber.
- 1.3 Translates standards of quality and regulation into individualized care, including route of administration, administration rates, premedication, and Risk Evaluation and Mitigation Strategies (REMS).**
 - Given a scenario about a patient including a biotherapy, identify the routes of administration that could impact standards of quality and regulation.
 - Given a scenario about a patient including a biotherapy, identify the premedication that could impact standards of quality and regulation.
 - Given a scenario about a patient including a biotherapy, identify the symptoms that may present in the REM strategy.
- 1.4 Facilitates patient navigation to reduce barriers to care and support adherence to treatment protocols.**
 - Given a scenario when a patient must have a caregiver to complete treatment procedures, identify the various forms of care resources that can reduce barriers.
- 1.5 Verifies suitability of biotherapy product and the patient condition prior to infusion.**

- 1.6 Supports and performs product administration (including actual infusion when appropriate) and provides monitoring care/oversight for adverse events.**
- Given a scenario where the product is administered intravenously, identify possible adverse reactions related to the route of administration.
- 1.7 Monitors post-administration effects and makes adaptations as needed recognizing potential reactions (immunological and non-immunological).**
- Given a patient who has received a biotherapy, identify some of the immunological side effects that may be experienced and how to recognize them.
 - Given a patient who has received a biotherapy, identify some of the non-immunological side effects that may be experienced and how to recognize them.
- 1.8 Engages patients and their families in long-term follow-up to inform longitudinal experiences with biotherapies.**
- Given a patient who has received a biotherapy, identify the activities that may be involved in long-term follow-up.



Domain 2: Biotherapies Science and Ethics

EXAM WEIGHTING: THIS DOMAIN COVERS 9% OF THE EXAM

- 2.1 Applies the emerging science to applications in biotechnology and innovative biotherapy products, such as immunotherapy, gene therapy, convalescent plasma, CAR T cell therapy, etc.**
- Given a scenario about an immunotherapy, identify how the emerging science is applied to show whether the immunotherapy can be effective in treatment.
 - Given a scenario about a gene therapy, identify how the emerging science is applied to characterize the gene therapy product or Given a scenario about CAR T cell therapy, a type of immunotherapy, identify how the emerging science is applied to characterize CAR T cell products for patient use.
- 2.2 Exercises ethical conduct in Human Subject Research e.g., Revised Common Rule, Geneva Convention, Universal Declaration on Bioethics and Human Rights, Integrated Addendum to ICH E6.**
- Given a scenario about Human Subject Research, identify how research information is communicated to research participants.
 - Given a scenario about Human Subject Research, identify how the different rules are applied to protect research subjects globally.
- 2.3 Articulates the mechanisms of action for novel therapies including cell selection, cell expansion, genetic transduction or modification (e.g., CRISPR, viral vectors), and immunomodulation.**
- Given a scenario for cell selection, identify the mechanism of action for a novel therapy.
 - Given a scenario for cell expansion, identify the mechanism of action for a novel therapy or Given a scenario for genetic transduction using CRISPR, identify the mechanism of action for a novel therapy or Given a scenario for immunomodulation, identify the mechanism of action for a novel therapy.

2.4 Applies the science of genetic modification and related technology to current therapeutic applications.

- Given a scenario for therapeutic applications, identify how genetically modified cells are used in treatment or Given a scenario for therapeutic applications, identify how technologies related to genetic modification of cells are used in treatments.
- Given a scenario for therapeutic applications, identify the Risk Mitigation strategies (REMS) for genetically modified cells which are used in treatment.

2.5 Employs viral vector science and technology and transgene sequencing to current therapy products.

- Given a scenario, identify how vector science and technology are applied in current therapy protocols.
- Given a scenario, identify how transgene sequencing is applied in current therapy protocols.

2.6 Researches and maintains an awareness of current developments in biotherapy science and technology and pharmaceutical therapies and evaluates the applications of such to translate it into potential therapy products.

- Given a scenario of current biotherapy developments, identify the ways to show awareness of biotherapy science and technology.
- Given a scenario of current biotherapy developments, identify the types of resources to show awareness of pharmaceutical therapies.
- Given a scenario of current biotherapy developments, identify how to evaluate applications to translate them into potential therapy products.

2.7 Researches and maintains an awareness of biological product development, through new assay developments, new testing techniques and the applications of such to biologic products.

- Given a scenario of biological product development, identify how to apply new assay developments and new testing techniques.



Domain 3: Operations and Equipment

EXAM WEIGHTING: THIS DOMAIN COVERS 19% OF THE EXAM

3.1 Practices aseptic or sterile techniques, using appropriate levels of clean room procedures, environmental monitoring, and laboratory testing, per international and domestic standards.

- Given a scenario about aseptic or sterile techniques, identify the appropriate levels of clean room procedures or environmental monitoring procedures per international and domestic standards.
- Given a scenario about aseptic or sterile techniques, identify the appropriate laboratory testing procedures applying international and domestic standards.

3.2 Collects cells and other biological material by appropriate methods.

- Given a scenario about collection of cells, identify the appropriate collection methods.
- Given a scenario about collection of biological materials, identify the appropriate collection methods.

3.3 Isolates cultures and processes cellular material, using appropriate equipment as required.

- Given a scenario about isolating cell cultures, identify the appropriate equipment required or Given a scenario about processing cells, identify the appropriate equipment required.

- 3.4 Preserves, stores and transports cellular material using sterile media, cryopreservation, lyophilization or other appropriate techniques.**
- Given a scenario about cell preservation, identify the appropriate sterile media to use.
 - Given a scenario about cell preservation, identify the appropriate cryopreservation technique to use.
 - Given a scenario about cell preservation, identify the appropriate lyophilization technique to use.
 - Given a scenario about cell storage, identify the appropriate sterile media to use.
 - Given a scenario about cell storage, identify the appropriate cryopreservation technique to use.
 - Given a scenario about transporting cells, identify the appropriate strategies to maintain the viability and characteristics of the cell.
 - Given a scenario about transporting cells, identify the appropriate cryopreservation technique to use.
- 3.5 Utilizes and maintains standard laboratory equipment.**
- Given a scenario about standard laboratory equipment, identify how equipment is utilized.
 - Given a scenario about standard laboratory equipment, identify how equipment is maintained.
- 3.6 Maintains necessary records to satisfy compliance requirements.**
- Given a scenario about record keeping, identify how compliance requirements for operations or equipment are met/satisfied.
- 3.7 Documents critical steps and decisions concurrently.**
- Given a scenario about critical steps in operations, identify how the critical steps are documented.
 - Given a scenario about decision making in operations, identify how the decisions are documented.
- 3.8 Demonstrates competence in the qualification, operation, and maintenance of equipment.**
- Given a scenario in equipment qualification, identify how competency is evaluated.
 - Given a scenario in equipment operation, identify how competency is evaluated.
 - Given a scenario in equipment maintenance, identify how competency is evaluated.
- 3.9 Ensures chain of custody documentation is completed for all cellular products.**
- Given a scenario about custody, identify how the chain of custody documentation is completed for all cellular products.
- 3.10 Utilizes standard safe lab practices, including the use of all appropriate PPE.**
- Given a scenario about safe laboratory practices, identify the standards used or Given a scenario about safe laboratory practices, identify the appropriate PPE to use.
- 3.11 Assesses the availability and accessibility of cellular starting material used in biotherapies, including the potential sources, acquisition methods, collection efficiency, storage techniques, and testing approaches and methods.**
- Given a scenario about the availability and accessibility of cellular starting material used in biotherapies, identify how to assess the potential sources.
 - Given a scenario about the availability and accessibility of cellular starting material used in biotherapies, identify how to assess the acquisition methods.
 - Given a scenario about the availability and accessibility of cellular starting material used in biotherapies, identify how to assess the collection efficiency.
 - Given a scenario about the availability and accessibility of cellular starting material used in biotherapies, identify how to assess the storage techniques.

- Given a scenario about the availability and accessibility of cellular starting material used in biotherapies, identify how to assess the testing approaches.
- Given a scenario about the availability and accessibility of cellular starting material used in biotherapies, identify how to assess the testing methods.

3.12 Maintains and monitors inventory of critical products in manufacturing of biotherapies.

- Given the scenario about critical products used in manufacturing biotherapies, identify how the inventory is maintained or monitored.



Domain 4: Biotherapies Development Lifecycle

EXAM WEIGHTING: THIS DOMAIN COVERS 15% OF THE EXAM

4.1 Conducts critical phases of product development according to established guidelines.

- Given a scenario about the biotherapies development lifecycle, identify the critical phases of product development according to established guidelines.

4.2 Ensures adequate documentation and controls are achieved for each trial phase.

- Given a scenario about the biotherapies development lifecycle, identify how adequate documentation is ensured for each trial phase.
- Given a scenario about the biotherapies development lifecycle, identify how adequate controls are ensured for each trial phase.

4.3 Researches, interprets and applies scientific literature and results to product development.

- Given a scenario about product development, identify how research is interpreted in the product development process.
- Given a scenario about product development, identify how research is incorporated in the product development process.
- Given a scenario about product development, identify how scientific literature is utilized in the product development process.

4.4 Identifies the essential elements of a robust R&D effort to support cell therapy products.

- Given a scenario about cell therapy products, identify the essential elements of a robust research and development (R&D) effort to support development of cell therapy products.
- Given a scenario about cell therapy products, identify the essential steps of a robust research and development (R&D) effort to support development of cell therapy products.

4.5 Applies accepted best practices and methodologies in the developing new cellular therapies.

- Given a scenario about developing new cellular therapies, identify how accepted best practices are applied.
- Given a scenario about developing new cellular therapies, identify how accepted best methodologies are applied.

4.6 Applies research and product development experience to the design of clinical manufacturing processing of developed products.

- Given a scenario about the design of clinical manufacturing processing of developed products, identify how to apply research experience to designing clinical manufacturing processing.
- Given a scenario about the design of clinical manufacturing processing of developed products, identify how to apply product development experience to designing clinical manufacturing processing.

4.7 Utilizes appropriate statistical analysis tools in the development of new or improved products and patient care delivery improvements.

- Given a scenario about the development of new or improved products, identify how appropriate statistical analysis tools are utilized.
- Given a scenario about the development of patient care delivery improvements, identify how appropriate statistical analysis tools are utilized.

4.8 Applies scientific knowledge for translating biotherapies to development of products for therapeutic potential.

- Given a scenario for translating biotherapies to development of products for therapeutic potential, identify how scientific knowledge is applied to development.
- Given a scenario for translating biotherapies to development of clinical protocols for therapeutic potential, identify how scientific knowledge is applied to develop treatment protocols or administration of product.

4.9 Identifies viable commercial opportunities in the biotherapies field supported by the application of adaptive business models.

- Given a scenario about the application of adaptive business models, identify viable commercial opportunities in the biotherapies field supported by such models.

4.10 Investigates barriers to developmental and/or commercialization challenges in order to facilitate improvements.

- Given a scenario about product development challenges in order to facilitate improvements in cell products, identify the barriers and how to investigate the barriers.
- Given a scenario about product commercialization challenges in order to facilitate improvements in cell products, identify the barriers and how to investigate the barriers.

4.11 Contributes to the evidence base of biotherapies through peer-collaboration, publication, and/or practice-based literature to advance knowledge and innovation.

- Given a scenario about peer collaboration, identify how to contribute to the evidence base of biotherapies to advance knowledge and innovation.
- Given a scenario about publication, identify how to contribute to the evidence base of biotherapies to advance knowledge and innovation.
- Given a scenario about practice-based literature, identify how to contribute to the evidence base of biotherapies to advance knowledge and innovation.



Domain 5: Manufacturing

EXAM WEIGHTING: THIS DOMAIN COVERS 15% OF THE EXAM

5.1 Employs manufacturing processes and techniques using cell and gene therapy processes such as viral vectors, CRISPR, isolation, expansion, purification, cryopreservation, and lyophilization.

- Given a scenario about viral vectors, identify a manufacturing process using cell and gene therapy and viral vectors.
- Given a scenario about CRISPR technology, identify a manufacturing process using cell and gene therapy and CRISPR technology.
- Given a scenario about cell isolation, identify a manufacturing process using cell and gene therapy and cell isolation techniques.
- Given a scenario about cell expansion, identify a manufacturing process using cell and gene therapy and cell expansion techniques.
- Given a scenario about cell purification, identify a manufacturing process using cell and gene therapy and cell purification techniques.
- Given a scenario about cryopreservation, identify a manufacturing process using cell and gene therapy and cell cryopreservation techniques.

5.2 Identifies, collects/extracts and supplies necessary materials for intended biotherapy products (upstream processing).

- Given a scenario about upstream processing of biotherapy products, identify how to identify or supply the materials necessary for processing intended products.

5.3 Produces finished cellular products according to specifications, and the safe, timely delivery of products to end users (downstream processing).

- Given a scenario about production of finished cellular products to end users (downstream processing), identify the specifications to ensure safe, timely delivery of products.

5.4 Identifies challenges and solutions in the scale-up of manufacturing processes.

- Given a scenario about scale up of a manufacturing process, identify the challenges faced in producing consistent quality products.
- Given a scenario about scale up of a manufacturing process, identify the solutions to producing consistent quality products.

5.5 Troubleshoots manufacturing system and equipment issues, providing recommendations for quality and safety.

- Given a scenario on cell manufacturing, identify how to troubleshoot manufacturing system issues providing recommendations for product quality.
- Given a scenario on cell manufacturing, identify how to troubleshoot manufacturing system issues providing recommendations for product safety.
- Given a scenario on equipment issues, identify how to troubleshoot equipment issues providing recommendations for product quality.
- Given a scenario on equipment issues, identify how to troubleshoot equipment issues providing recommendations for product safety.

5.6 Develops and maintains specifications, assays, methodologies, and analytical tools to generate evidence about bio-therapeutic product safety, purity, potency, viability, identity, and quality.

- Given a scenario about manufacturing specifications, identify the ways/specifications to generate evidence about biotherapeutic product safety, purity, potency, viability, identity, or quality.

- Given a scenario about assays, identify how to generate evidence about biotherapeutic product safety, purity, potency, viability, identity, and quality.
- Given a scenario about methodologies, identify how to generate evidence about biotherapeutic product safety, purity, potency, viability, identity, and quality.
- Given a scenario about analytical tools, identify how to generate evidence about biotherapeutic product safety, purity, potency, viability, identity, and quality.

5.7 Translates business goals into process changes/improvements in the manufacturing setting.

- Given a scenario about business goals, identify how process changes or improvements in the manufacturing setting translate to the business goals.

5.8 Applies and appropriately adapts standard manufacturing/process control techniques to production of cell-based products.

- Given a scenario about production of cell-based products, identify how standard manufacturing techniques appropriately adapt to production of cell-based products.
- Given a scenario about production of cell-based products, identify how process control techniques apply to production of cell-based products.

5.9 Investigates deviations, out-of-specification findings, or unexpected results to prevent untoward outcomes.

- Given a scenario about manufacturing, identify how to investigate deviations, out-of-specifications, or unexpected findings to prevent untoward outcomes.

5.10 Generates concurrent documentation of processes applied and supporting evidence.

- Given a scenario about manufacturing process, identify how concurrent documentation is applied.



Domain 6: Quality Systems

EXAM WEIGHTING: THIS DOMAIN COVERS 21% OF THE EXAM

6.1 Applies best practice quality management system guidelines and principles in GMP/GCP/GTP/GCLP settings.

- Given a scenario about researching quality management system principles, identify various resources that represent applicable guidelines.

6.2 Follows GMP regulations, standards, and guidelines during the collection, processing, testing, storage and release of cellular products.

- Given an international scenario about GMP regulations, identify the types of regulatory agencies overseeing collection, processing, testing, storage and release of cellular products.

6.3 Ensures that established policies and procedures are followed during critical activities.

- Given a scenario of a critical activity, identify the role of policies.
- Given a scenario of a critical activity, identify the role of procedures.

6.4 Identifies or develops optimal assays to support the manufacturing process.

- Given a scenario about assay development, identify the appropriate approach to optimize manufacturing.

- Given a scenario about assay development, identify how to develop the appropriate approach to optimize manufacturing.
- 6.5 Conducts equipment qualification and validation activities to assure intended outcomes.**
- Given a scenario for new equipment, identify installation qualification to assure intended outcomes.
 - Given a scenario for new equipment, identify operational qualification to assure intended outcomes.
 - Given a scenario for new equipment, identify performance qualification to assure intended outcomes.
- 6.6 Reads, applies, and adapts SOPs, sampling plans, protocols, and specifications using appropriate change control to ensure quality.**
- Given a scenario for reading an SOP, identify how the appropriate sampling plans is established to ensure quality.
 - Given a scenario for applying an SOP, identify how the appropriate protocol is established to ensure quality.
 - Given a scenario for adapting an SOP, identify how the appropriate specifications are established to ensure quality.
- 6.7 Measures effectiveness, efficiency, and quality of team performance and workforce engagement.**
- Given a scenario about the workforce, identify how to establish effectiveness, efficiency, and quality of team performance and workforce engagement.
- 6.8 Utilizes statistical analysis tools to interpret QC results and make improvements.**
- Given a scenario about QC results, identify the appropriate statistical tools to interpret performance.
 - Given a scenario about QC results, identify the appropriate statistical tools to make improvements.
- 6.9 Applies effective quality management systems, techniques and tools such as Six-Sigma to manufacture of cellular products.**
- Considering a scenario, identify appropriate techniques to statistically measure quality.
 - Considering a scenario, identify appropriate tools to statistically measure quality.
- 6.10 Performs risk assessment for steps in the manufacturing process of biotherapies to identify critical risks to ensure safety and efficacy of the product.**
- Given a scenario for risk assessment of the manufacturing process, identify critical risks to ensure safety of the product.
 - Given a scenario for risk assessment of the manufacturing process, identify critical risks to ensure efficacy of the product.
 - Given a scenario for identification and documentation of CAPA, identify the effectiveness.
- 6.11 Articulates measures necessary to assure viability, stability, potency, and prevent contamination of biotherapies.**
- Given a scenario, identify the measures necessary to assure viability.
 - Given a scenario, identify the measures necessary to assure stability.
 - Given a scenario, identify the measures necessary to assure potency.
 - Given a scenario, identify the measures necessary to prevent contamination.
- 6.12 Engages multiple disciplines in problem-solving across a distributive ecosystem.**
- Given a scenario, identify the various disciplines involved in problem-solving across the distributive ecosystem.

6.13 Contributes to standard-setting and best practices through participation in accreditation organizations.

- Given a scenario, identify how accredited organizations can elevate standard-setting.
- Given a scenario, identify how accredited organizations can elevate best practices.

6.14 Establishes terms of reference and agreements (service level agreements, backup agreements, quality agreements, etc.).

- Given a scenario, identify the terms of reference contained in service level agreements.
- Given a scenario, identify the terms of reference contained in back-up agreements.
- Given a scenario, identify the terms of reference contained in quality agreements.



Domain 7: The Regulatory Environment

EXAM WEIGHTING: THIS DOMAIN COVERS 10% OF THE EXAM

7.1 Identifies relevant regulatory bodies and standards affecting biotherapy products, processes, distribution, and maintains current understanding of such.

- Given a scenario, identify the standards to ensure compliance appropriate to biotherapies product development, processing, or distribution.

7.2 Ensures compliance to SOPs and cGMP regulations as promulgated by the FDA (21CFR) and other approving organizations (e.g., ISO, EU, ministries of health) ranging from to minimally manipulated processes for homologous use to bespoke gene and cell therapies.

- Given a scenario, identify how to maintain compliance with minimally manipulated homologous biotherapies products.
- Given a scenario, identify how to maintain compliance with more than minimally manipulated combination biotherapies products.

7.3 Applies regulatory guidance to submittals of new product applications including the testing and documentation of such products at appropriate points in the development process.

- Given a scenario, identify application of regulatory guidance to new product applications.
- Given a scenario, identify application of regulatory guidance to the developmental process of product applications.

7.4 Identifies and communicates events that may impact product safety and efficacy, and/or regulatory success.

- Given a scenario, identify events that may impact product safety.
- Given a scenario, identify events that may impact product efficacy.
- Given a scenario, identify events that may impact product regulatory success.
- Given a scenario, identify how to communicate events that may impact product safety.
- Given a scenario, identify how to communicate events that may impact product efficacy.
- Given a scenario, identify how to communicate events that may impact product regulatory success.

- 7.5 Applies evolving regulatory requirements pertaining to biotherapy processes and products and educates others accordingly.**
- Given a scenario, identify how to educate others in the regulatory requirements for biotherapies processes and products.
- 7.6 Contributes to the regulatory environment by participating on multi-institutional committees working to improve good governance processes.**
- Given a scenario, identify the role of multidisciplinary committees to improve governance.
- 7.7 Identifies reportable events and conveys reports them to the appropriate authorities.**
- Given a scenario, identify how events are reported to the appropriate authorities.
 - Given a scenario, identify if an event needs to be reported to the appropriate authorities.

Sample Questions

- 1. A patient had an allogeneic bone marrow transplant two months earlier and has now developed a rash on the ears, neck, chest, and hands. The patient's caregiver is concerned that this rash may be a sign of acute Graft-versus-Host Disease (GVHD).**

What is the cause of this problem?

 - Allergy to the donor marrow
 - T-cells from the donor marrow
 - Infection due to immune suppression
 - Delayed reaction to the pre-transplant chemotherapy
- 2. A team is working on a clinical trial for a novel gene therapy for Hemophilia B and is debating which vector to use to deliver the therapy. The team is considering the use of adenovirus.**

What is one advantage of this choice?

 - Overcomes pre-existing viral immunity
 - Specific tropism for different tissue targets
 - Epichromosomal persistence in the host cell
 - Low transduction efficiency, both in quiescent and dividing cells
- 3. A child with relapsed ALL is a candidate for autologous CAR T-cell therapy.**

Which collection method is most suitable for this donor?

 - Non-mobilized MNC (A) collection
 - Non-mobilized bone marrow harvest
 - G-CSF mobilized HPC (A) collection
 - G-CSF mobilized bone marrow harvest
- 4. A facility is developing a cell therapy product that is capable of engraftment after cryopreservation and needs to determine which post-thaw research data point should be used to set its expiration date.**

Which post-thaw research data point should be used?

 - Use the post-thaw data obtained within a week after initial cryopreservation to define the expiration date.
 - Compare post-thaw data soon after initial cryopreservation with the post-thaw data sampled at multiple time points.
 - Compare pre-cryopreservation data to post-thaw cryopreservation data gathered within three months after cryopreservation.
 - Determine the expiration date based on post thaw data of any products cryopreserved in liquid nitrogen within 48 hours.
- 5. A laboratory supervisor of a cell processing facility is tasked with determining the sterility method to use for a new dendritic cell process that would have a final volume of 10mL per container. The supervisor carefully reviews the contributing factors which will impact the sterility method.**

Which two factors have this impact? (Choose two.)

 - The type of cell
 - The volume of the inoculum
 - The container of the cell therapy product
 - Whether the excipient contains antibiotics
 - The storage temperature of the cell therapy product
- 6. A product arrived in the cell therapy laboratory, and a review was performed. The unique identifier, however, did not match the collection paperwork. The staff would like to begin processing the product due to its short expiration time and just notify the collection facility later, even though procedures state that the collection facility must be notified immediately.**

Why is it critical to follow the laboratory's policy for this event?

 - The facility will have to be called for collection details.
 - The donor will have to be called for recollection if the identifier is incorrect.
 - The product identifier provides the traceability for the product from one step to another.
 - The correct identification of the product ensures that the right product, processing, and patient usage is occurring.
- 7. A clinical program infuses a red-cell reduced HPC(M) collection from a first-degree related individual to a patient with acute myelogenous leukemia. Seven days after the infusion, the clinical team receives notification that the pre- and post-processing microbial samples tested positive for Cutibacterium acnes.**

Which entity, if any, must report this deviation to the FDA?

 - Clinical facility
 - Collection facility
 - Processing facility
 - Reporting is not required.

Answer Key & References Used:

Quick Answer Key: 1-B; 2-C; 3-A; 4-B; 5-B,D; 6-D; 7-D

References Used:

1. Correct Answer: B
 - <https://bethematch.org/patients-and-families/life-after-transplant/physical-health-and-recovery/graft-versus-host-disease-basics/>
 - Zeiser R and Blazar BR. Acute Graft-versus-Host Disease — Biologic Process, Prevention, and Therapy. N Engl J Med 2017;377:2167-79. DOI:10.1056/NEJMra1609337
2. Correct Answer: C
 - <https://www.nature.com/articles/s41392-021-00487-6>
3. Correct Answer: A
 - <https://pubmed.ncbi.nlm.nih.gov/32750197/>
4. Correct Answer: B
 - Practical Handbook of Cellular Therapy Cryopreservation -- pages 129-130
5. Correct Answer: B,D
 - Competent Authorities -- 21CFR610.12 (FDA)
6. Correct Answer: D
 - Cellular Therapy: Principles, Methods, and Regulations - ed Areman-Loper -- p 95 section “labeling”
7. Correct Answer: D
 - <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271>
 - <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-E/section-1271.350>

AABB (Association for the Advancement of Blood & Biotherapies) is an international, not-for-profit organization representing individuals and institutions involved in the fields of transfusion medicine and biotherapies. The Association works collaboratively to advance the field through the development and delivery of standards, accreditation and education programs. AABB is dedicated to its mission of improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.



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