AABB
Leadership Certificate in Blood Banking and Transfusion Medicine

Association for the
Advancement of
Blood & Biotherapies

AABB Leadership Certificate in Blood Banking and Transfusion Medicine

Specialized Leadership Training for Emerging Laboratory Leaders

Syllabus

Program Description

In response to well-documented shortages of laboratory supervisors in the field, AABB developed the Leadership Certificate in Blood Banking and Transfusion Medicine. This unique program seeks to educate the next generation on the core concepts necessary to cultivate effective leaders in the blood and biotherapies field.

Featuring self-paced, multi-media online leadership training, specifically in the context of blood banking and transfusion medicine:

- The program was developed in accordance with ANSI/ASTM E2659-18, Standard Practice for Certificate Programs.
- The curriculum was developed through an extensive needs analysis in the field and with the input of expert advisory panels.
- The content and learning experience use the ADDIE (Analyze, Design, Develop, Implement and Evaluate) model of instructional design.
- A leading instructional design company – which was also responsible for the development of the AABB and Canadian Blood Services Individual Donor Assessment modules – was engaged to create the interactive eLearning experience.

The certificate program is presented with 27 modules which encompasses seven domains. Additional exercises and resources are also included within the program:

- **Domain 1: Blood Banking and Transfusion Medicine Fundamentals**
- **Domain 2: Quality**
- **Domain 3: Regulatory Compliance**
- **Domain 4: Operations Management**
- **Domain 5: Administration**
- **Domain 6: Information Technology (IT) Systems**
- **Domain 7: Personnel Leadership and Management**

Prerequisites

While there are no prerequisites for the program, learners working in the laboratory of blood banking and biotherapies field will benefit most from the content. Learners are encouraged to complete the domains in order as information builds upon preceding lessons.

Learning Objectives

Following completion of this program, the learner should be able to meet the learning objectives listed in each domain.

Domain 1: Blood Banking and Transfusion Medicine Fundamentals

The Blood Banking and Transfusion Medicine Fundamentals domain focuses on ensuring the safe and effective use of blood products in transfusion medicine. This includes identifying blood types and antibodies to prevent mismatches, selecting appropriate blood products for patients, and following regulations and standards for collection, storage and transfusion. This domain also covers patient and recipient communication, including explaining the blood donation and transfusion process and notifying donors, recipients and their families regarding abnormal findings in a manner accessible to non-professionals.

This domain is broken into four modules. Upon completion of this domain, the learner should be able to:

Determining Appropriate Blood Products Module

- Ensure proper identification of donor/patient blood types and antibodies.
- Determine appropriate blood products/components for transfusion based on patient needs and available inventory.
- Request required blood products/components based on patient needs.

Determining Donor Eligibility Module

- Determine donor eligibility based on relevant requirements, standards, needs and timeframes.

Defining the Process: From Collection to Transfusion Module

- Demonstrate basic knowledge of entire process from blood collection to transfusion.

Describing Appropriate Communication and Referrals Module

- Explain relevant considerations in the blood donation and transfusion process to patients and their families in a manner accessible to non-professionals.
- Identify and communicate abnormal findings requiring donor/recipient notification.
- Recognize when patient needs exceed lab capabilities and identify the appropriate referral.

Domain 2: Quality

The Quality domain covers the leader's role in ensuring quality and safety in a blood bank or transfusion medicine setting. You will explore conducting root cause analyses, implementing corrective actions, directing safety training, and conducting internal assessments to improve quality systems. Additionally, Quality involves tracking and evaluating corrective actions, managing non-conforming products and ensuring compliance with relevant guidelines and regulations such as AABB, CLIA and FDA.

This domain is broken into six modules. Upon completion of this domain, the learner should be able to:

Quality Management Plan Module

- Recognize the importance of a quality management plan.
- List and describe the agencies responsible for maintaining quality standards and regulations.
- Create a quality management plan according to AABB, CLIA and FDA guidelines.

Conducting Assessments Module

- Define and recognize the qualities of an internal assessment.
- Conduct periodic internal assessments to improve quality systems, operations, equipment and material initiatives.

Conducting Internal Audits Module

- Define and recognize the qualities of an internal audit.
- Schedule and conduct an internal audit to ensure compliance with SOPs, regulations and standards.

Conduct Root Cause Analysis Module

- Conduct root cause analyses to identify sources of variance, threats to quality and/or barriers to improvement.
- Take appropriate corrective action based on root cause analysis, utilizing effective quality management techniques and tools to improve processes.
- Use statistical analysis tools to interpret reports and identify corrective actions.
- Track and evaluate effectiveness of Corrective and Preventive Actions (CAPA).

Describe Safety Training and Safety Data Sheets (SDS) Module

- Direct safety training activities in compliance with standards.
- Ensure Safety Data Sheets (SDS) are available for all chemicals.

Identify Patient or Donor Complaints Module

- Identify and evaluate potential and actual complaints.
- Describe regulatory and accrediting agency requirements for the handling of complaints.
- Explain investigation actions to prevent harm and promote health and safety.

Domain 3: Regulatory Compliance

The Regulatory Compliance domain involves ensuring compliance with regulatory requirements and standards in the blood banking and transfusion medicine environment. Topics include registering and updating FDA licenses, implementing process changes and reporting them to regulatory bodies and ensuring current practices align with regulations. The domain also covers identifying and implementing new regulatory requirements, ensuring staff competence, overseeing supplier audits and managing product usage in accordance with SOPs and manufacturer instructions, among other responsibilities.

This domain is broken into three modules. Upon completion of this domain, the learner should be able to:

Managing Registration and Reporting Module

- Effectively manage FDA registration and/or licensure and annual reporting requirements.
- Deliver timely, accurate updates to FDA.
- Prepare timely, accurate and complete reporting to FDA of biological product deviations.

Staying Compliant Module

- Ensure current practices are in compliance with existing regulatory requirements and standards.
- Identify and implement new or revised regulatory requirements and standards affecting blood/biotherapy processes and product specifications.
- Ensure staff are qualified and competent in performing their duties.
- Ensure all devices, supplies, reagents, and biological products are used in accordance with SOPs, the manufacturers' instructions for use or the Circular of Information.
- Identify the criteria for market withdrawal, recall and lookback.

Managing Inspections and Assessments Module

- Prepare for inspections and accreditation assessments.
- Support regulatory inspections and accreditation assessments by acting as primary contact, responsible party, and providing documents or other information as requested.
- Formulate responses to inspection findings and audit/assessment citations.

Domain 4: Operations Management

The Operations Management domain focuses on ensuring efficient blood inventory management, staff scheduling, assessing risk and preparing for disaster, and qualifying and maintaining equipment in blood banking or transfusion medicine settings. Tasks discussed include tracking inventory, adjusting blood product levels and scheduling staff to maintain efficient workflow. It also includes developing disaster plans, drafting policies, and ensuring training and competency. Additionally, this domain discusses applying standard manufacturing techniques to blood products and ensuring validations and testing are completed.

This domain is broken into three modules. Upon completion of this domain, the learner should be able to:

Scheduling Staff and Managing Inventory Module

- Track blood inventory to forecast/anticipate needs.
- Adjust inventory levels and composition based on anticipated needs.
- Apply and adapt manufacturing/process control techniques to the collection, production, labeling and issuance of blood products.
- Describe the Proficiency Testing Program.

Maintaining Your Equipment Module

- Recognize the importance of equipment maintenance.
- Define the terms qualification, verification, and validation and recognize why it is necessary to qualify your lab's equipment.
- Identify situations when qualification should be performed or considered.
- Describe the steps involved in planning and performing a validation.
- Explain how to develop maintenance schedules for your equipment.

Managing Risks and Planning for Disaster Module

- Identify relevant risks to operations, develop and initiate risk mitigation strategies relative to operations.
- Develop and test a disaster management plan for areas of responsibility.

Domain 5: Administration

The Administration domain discusses managing administrative functions in a blood banking and transfusion medicine facility. This includes managing vendor and customer relationships and contracts, ensuring expenses align with the operating budget, and recommending capital investments based on analysis and operational goals. Additionally, it involves completing billing and invoice procedures, identifying operational risks, and developing risk mitigation strategies. This domain also covers ensuring facility maintenance and safety standards are met.

This domain is broken into three modules. Upon completion of this domain, the learner should be able to:

Managing Vendor Contracts Module

- Explain the basics of contracting and the contracting process.
- Describe how to manage contracts.
- Define common contracting terms.

Managing Your Budget and Expenses Module

- Describe a laboratory operating budget–Non-personnel.
- Describe a laboratory operating budget–Personnel.
- Describe a laboratory capital budget.
- Describe laboratory purchasing and accounts payable.

Laboratory Health and Safety Module

- Ensure safe practices by following Occupational Safety and Health Administration (OSHA), AABB and other industry regulatory guidance.
- Describe how to prepare team members for fire and chemical emergencies.
- Explain the laboratory's role in disease prevention and maintaining a clean and safe working environment.

Domain 6: Information Technology (IT) Systems

The Information Technology Systems domain covers how to manage Information technology systems and processes in a blood banking and transfusion medicine facility. This includes working with IT to establish and maintain a reporting system that meets regulatory requirements and supports operational evaluation. Additionally, it involves ensuring compliance with electronic record management and document control policies, identifying IT needs, and coordinating solutions. This domain also covers developing and testing downtime protocols for Laboratory Information Systems (LIS) or Blood Establishment Computer Systems (BECS).

This domain is broken into three modules. Upon completion of this domain, the learner should be able to:

Determining IT Requirements Module

- Identify departmental IT needs and coordinate solutions to meet regulatory requirements and/or operational needs.
- Recommend and work with IT to establish, validate and maintain a reporting system that satisfies regulatory requirements and provide data to evaluate operations in a timely manner.
- Ensure electronic records/documents are in compliance with regulatory requirements and document control policies.

Developing Downtime Protocols Module

- Develop and periodically test downtime protocols for Laboratory Information System (LIS) or Blood Establishment Computer System (BECS).

Other IT Considerations Module

- Work with IT in data management and security.
- Ensure Artificial intelligence (AI) meets operational needs and satisfies regulatory requirements.

Domain 7: Personnel Leadership and Management

The Personnel Leadership and Management domain discusses building strong relationships, managing teams and developing personnel. This domain involves fostering relationships with stakeholders, managing teams to meet objectives, and evaluating team members for competency and career development. It also includes coordinating student rotations, mentoring new employees and conducting effective employment interviews. Additionally, this domain covers leading team meetings, ensuring staff education and certification, managing employee retention and labor rights and resolving conflicts, among other people leadership competencies.

This domain is broken into five modules. Upon completion of this domain, the learner should be able to:

Building Constructive Working Relationships Module

- Develop constructive working relationships.
- Employ appropriate conflict resolution.

Managing Employee Labor Rights Module

- Manage employee labor rights by identifying and addressing potential labor law violations in the workplace and escalating them to HR and/or your legal department when appropriate.

Hiring and Onboarding Module

- Employ effective employment interview techniques.
- Conduct new staff on-boarding activities.
- Utilize effective employee retention strategies and make appropriate recommendations regarding staff compensation.

Managing Performance Module

- Manage a team/work unit to meet performance and productivity objectives.
- Establish, monitor and revise measurable performance benchmarks.
- Evaluate team members for competency, performance and career development.
- Lead team meetings.
- Manage projects/initiatives to completion.
- Prepare and review all reports required for successful performance of responsibilities.

Developing Employees Module

- Prepare and deliver effective staff in-service training.
- Ensure employees perform continuing education and maintain certification.
- Serve as a mentor to new employees by providing constructive feedback and resources.
- Coordinate student rotations and teach students, residents and/or fellows.

Program Content Accessibility

The program 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. Each module also provides a written script for the hearing impaired.

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. It is recommended to first view the material in each module in its intended order for best understanding. You will always be able to return to slides for review as many times as you wish during your access period.

Knowledge checks are provided within each module to provide feedback to see how well you have understood information as you work through the content. They are designed to reinforce your learning. Learners are encouraged to review the appropriate sections of the module when questions are missed to ensure a better understanding of the content.

Activities for Successful Completion of the Certificate Program

Read and study all materials for each module and complete each activity as presented. Follow the modules in order as information builds upon preceding lessons. Since this is a self-paced program, learners may decide how much time is needed to review and study the materials. It is estimated that it will take approximately 25-35 hours to complete the program. A suggested strategy is to create a study plan or timeline for completing each domain. Follow that plan to ensure timely completion within the year that you will have access to the program.

Assessments and Grading to Obtain Certificate

For successful completion of the program resulting in conferral of the AABB Leadership Certificate in Blood Banking and Transfusion Medicine:

1. Read and carefully study each slide in each module.
2. Complete all the activities within each module.
3. After each domain, you will be provided with an assessment. Answer all of the assessment questions; scoring 80% or higher. The assessment is a pass/fail exercise where learners will have two (2) opportunities to achieve 80% or higher. There is no grade provided for each assessment; rather an opportunity to reinforce your understanding of the content provided in the program. On each assessment:
   - Learners will receive questions (i.e., multiple choice, true-false questions) and asked to select the correct answer.
   - Learners will receive feedback as to whether an answer choice is correct or incorrect.
4. Complete the Leadership Certificate in Blood Banking and Transfusion Medicine Program Post-Program Evaluation (*Certificate of Completion issued*).
5. Claim continuing education (CE) credit type (*CE certificate issued*).

Continuing Education Credits

This program is eligible for 30 continuing education credits/contact hours for California Nurses, California Lab Personnel, Florida Lab Personnel and General Participation credit, which can be used for ASCP maintenance of certification. The number and type of credits awarded for this program was determined by the estimated program completion time. This program is not eligible for continuing medical education (CME) credit. For more information on each credit type, please visit the AABB **Continuing Education Credits webpage**. A continuing education certificate of completion will be immediately provided to learners upon reviewing all seven domains and their applicable modules, successful completion of all domain assessments, completion of the program evaluation and claiming your continuing education credit type.

Program Access & Retakes

Access to the program in the AABB Education Platform will be available to you for one (1) year from the date of registration for the program (immediate access is granted upon registration). This program is self-paced; however, learners must complete all modules, assessments and a program evaluation within the year to receive the Certificate of Completion. If learners are unable to complete the program within the one-year period and still wish to complete the program, they must either re-purchase the program at full price if your access has been removed or submit a retake form (includes a reduced fee), which will provide an additional 12 months of access and two additional attempts on any failed module assessment(s). It is recommended to complete all the modules and module assessments before submitting a retake as the retake will provide a retake for any and all failed module assessments. Questions related to registration should be directed to **eLearning@aabb.org**.

Certificate Program Faculty & Contributors

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

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Instructional Design

A leading instructional design company, Canadian Management Centre (CMC), was engaged to create the interactive eLearning experience. CMS was also responsible for the development of the AABB and Canadian Blood Services Individual Donor Assessment modules.

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