

# Partnering with AABB: Advancing Biotherapies by Accelerating Your Goals

In 1947, a group of leaders in blood banking and transfusion medicine formed AABB, then known as the American Association of Blood Banks. From its inception, the Association focused on improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide. For more than 75 years now, AABB has been at the forefront of blood therapy research, clinical care, quality standards and industry support.

Before AABB was formed, there were no standards for what have become one of the most reliable therapeutics in the world: blood transfusion and cell transplant. These products now move readily from one health system to another and internationally using voluntary consensus standards.

AABB's expertise in blood banking and transfusion medicine has allowed the Association to seamlessly move into the broader biotherapies space. In a sense, blood transfusion can be considered one of the first biotherapies. Our name change to the Association for the Advancement of Blood and Biotherapies in 2021 reflects our commitment to the development of, research on, production of, and care with biotherapies.

Throughout the past three-quarters of a century, AABB's standards, accreditation, regulatory expertise, education, professional development and industry support have become synonymous with excellence in biotherapies.

## SOLUTIONS FOR CHALLENGES COMPANIES FACE TODAY

AABB's wealth of experience and expertise allows us to provide solutions to both industry challenges and those are unique to companies in this rapidly changing space. By partnering with AABB, biotherapies companies can profit from our years of knowledge and know-how harmonizing the field of biotherapies.

From standards and consulting to regulatory know-how and educational opportunities, we help you overcome any and all of these challenges. Just a few of our high-value results include:

- Identifying geographically desirable suppliers with the right capabilities.
- Streamlining the supplier qualification process.
- Gaining assurances of trustworthy sources of regulatory information.
- Achieving workforce readiness and capacity.
- Improving speed to market for products.
- Benefiting from essential resources and networking.

## DRIVING INNOVATION

Innovation drives the basic science and therapeutic developments that have revolutionized patient care, offering more hope where previously there were many treatment challenges. Research breakthroughs and new production techniques require support though. AABB partners with companies that offer innovative solutions to critical needs. AABB also fuels innovation in the biotherapies space by awarding grants for promising basic science research.

This publication highlights the many advantages of partnering with AABB in the biotherapies space and outlines the ways that we can help biotherapy companies succeed and grow — whether your company is in start-up mode, at the commercial stage or in between.

## HOW AABB CAN HELP BIOTHERAPY COMPANIES

AABB has been intricately involved in biotherapies since the beginning of modern transfusion medicine. We work with nearly all — and accredit many — cell collectors in the United States. We help biotherapies companies make those key connections with critical suppliers.

Our expertise in the regulatory realm can help companies reduce regulatory hurdles and approval time, as well as minimizing compliance burdens at commercialization by streamlining processes to manage the regulatory landscape. We can also help companies maintain regulatory requirements during start-up and commercialization; and identify then adapt to regulatory changes in their organization, particularly with regard to staff and departments.

AABB can support established companies grow and expand in current and additional markets by helping quickly scale manufacturing capability/capacity to support commercialization, reduce costs and raise capital and funds.

## QUALITY SYSTEMS FRAMEWORK

AABB has led the way in quality systems for more than 75 years through standards, accreditation and reliable educational resources.

AABB Standards provide the foundation for the Association's internationally recognized accreditation program. Accreditation consists of independent facility audits conducted by expert professionals to objectively ensure compliance with AABB Standards every two years. Accreditation allows for the identification and resolution of any process issues. Accreditation can also help streamline the supplier qualification process. By using an AABB-accredited facility, you can count on the highest levels of compliance, quality and safety. In addition, AABB accreditation also helps identify geographically desirable suppliers with the right capabilities for your products.

### Standards

You could say that AABB has written the books on quality control systems in the biotherapies space. AABB Standards represent current best practices and state of the science. AABB Standards are based on the AABB quality system framework, which leads the field in quality standards worldwide. Our Standards incorporate both technical and quality systems standards to ensure that all facets are reviewed — from specification of equipment, materials management, and organizational structure to documents, resource management and program assessment.

Each edition of AABB's Standards are developed by a team of experts who volunteer their time as a member of a Standards Committee. Each edition is based on best clinical practice, scientific data, principles associated with good manufacturing practices, quality assurance and applicable regulations. Each revision cycle — conducted every two years — includes a public comment period that seeks input from active professionals throughout the world.

## Regulatory Compliance

Federal regulations can be challenging to track, interpret and implement under most circumstances. The rapidly evolving world of biotherapies makes this even more difficult. AABB has a long history of helping members navigate new regulations, updates and related supporting materials (such as donor history questionnaires). Our close interaction with our member experts and federal agencies affords AABB a unique position, from which to represent and support our membership, businesses partners and patients.

Our experts monitor changing and expanding issues related to federal regulations and recommendations. They also track federal agency practices and procedures. For decades, AABB has worked closely with the U.S. Food and Drug Administration, the U.S. Centers for Disease Control and Prevention and other government agencies to promote safety, such as identifying and mitigating emerging threats to the safety of blood and biotherapies. For example, AABB experts offer interpretation of proposed and final regulatory guidances. Regulatory updates and interpretations are included in AABB's *Weekly Report* as they happen.

AABB also collaborates with regional and international biotherapies organizations to define terms and harmonize best practices, data standards, quality measures, outside of federal regulations that encourages innovation and discovery.

## Consulting

AABB offers consulting services featuring insight and guidance from AABB's world-renowned expert consultants. AABB Consulting Services brings decades of experience as a leader in developing innovative strategies and solutions for the field of transfusion medicine and biotherapies to your project. We know that each facility is different, and our innovative assessment methods are effective in identifying specific challenges and opportunities unique to each facility. AABB experts provide exceptional results while guiding clients to achieve sustainable goals.

AABB Consulting Services reviews, interviews and performs gap analyses. These services help different types of facilities — blood, plasma and tissue collection and/or management facilities; clinical laboratories; and biotherapies facilities — improve their quality management and process improvement systems.

Our consultants are real-world experts with on-the-ground experience. They have a passion for biotherapies and the promises they bring. They are dedicated to improving quality, meeting regulatory requirements, enhancing facility-wide systems. Your consulting team will be uniquely tailored to your needs. Our staff of experts are up to date on regulatory changes, compliance issues, emerging risks and more impacting your facility.

## ADVOCACY

AABB provides the biotherapies community with current information, resources and interpretive guidance for healthcare professionals, patients and regulators. These efforts improve patient access and facilitates harmonization worldwide.

Success and growth in biotherapies rely in part on government support, whether through R&D monetary support or through favorable policies, to improve patient access. AABB has been and continues to be a leading voice in advancing policies that support the development of novel biotherapies, as well as and donor and patient safety and care.

AABB represents the transfusion medicine and biotherapies community before a variety of federal and Congress, advocating for the biotherapies industry. In addition, the Association works with other professional societies, hospitals, health care organizations, and payers to advance private sector policies to improve transfusion medicine and biotherapies care to drive policies that ensure patient access, advance research, increase the supply and safety of biological products and expand coverage for these transformative therapies. AABB policy priorities in the biotherapies space include supporting patient access to safe, medically appropriate treatment; encouraging research related to biotherapies; and advancing a sustainable supply of cellular starting materials.

Recently, AABB has provided comment on several critical issues in the field, including:

- Laboratory workforce needs
- FDA discussion paper on distributed manufacturing and point-of-care manufacturing of drugs
- FDA Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies Draft Guidance for Industry
- The U.S. Centers for Medicaid and Medicare Services in response to Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proposed Rule
- FDA considerations for CAR T cell products manufacturing
- Analysis of bill establishing regulatory framework for laboratory-developed tests

AABB works closely with corporate and individual members to identify, understand and advocate for specific needs of the biotherapies industry and translates this into actionable policies. AABB puts your concerns and issues about speeding products to market front and center in the legislative and regulatory spaces.

## **Workforce Development**

While the rapid discovery and growth of the biotherapies field increases the chance for effective therapies for patients, the field continues to face workforce shortages that limit research, manufacturing and delivery of biotherapies. AABB is keenly aware of these issues and is working to help the field to address workforce shortages and related issues. We are committed to providing resources to help mitigate these challenges.

## **Certification**

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, denoting that that qualified professionals have demonstrated – through a certification exam – that they have the necessary knowledge to credibly practice in the field of biotherapies. This certification benefits the entire biotherapies field by establishing minimum standards of competence, identifying qualified and proficient professionals, while advancing safety and quality. It provides an opportunity to recognize high-performing professionals among peers, patients, health care organizations and more. Professionals with the CAPB credential are the staff that you can count on to support your organization with quality and expertise.

## Certificates

AABB offers the Cellular Therapies Certificate Program in collaboration with The George Washington University. The program is intended for — but not limited to — those with a background in basic biology or medical science who desire to further their professional development and advance in the field of blood and biotherapies. The program caters to busy professionals, with 12 self-paced online modules containing professionally narrated presentations, videos, and additional reading resources. Our renowned and award-winning certificate programs are developed and directed by leading experts in the field and designed to offer in-depth information for learners. Participants can earn continuing education credits and those who pass each module's assessment with a score of 80% or higher will earn a Certificate of Completion.

## Educational Materials

AABB's education programs and publications are developed, led, and written by renowned experts in the field. AABB offers myriad opportunities for continuing education credits and has education programs and publications aimed at every career level.

AABB offers workforce leaders a video series focused on innovative ways to meet biotherapy industry needs. The series features Dr. Don Siegel, a pioneer in the biotherapies field, who outlines employee retention challenges, and the initiatives he implemented to help significantly increase employee retention among the cellular therapies technical staff at the University of Pennsylvania.

In addition to offering educational opportunities for established biotherapies professionals, AABB is doubling down on initiatives to cultivate the field's future leaders. These efforts include certification opportunities, e-education (Meetings on Demand, e-casts, online courses), publications, news and other resources.

AABB has hours of educational materials available in a wide range of topics related to biotherapies that those already in the field — and those just entering the field — to improve their knowledge of specific areas and increase their skill set. AABB members have access to Meetings on demand, hot topic discussions, live e-Casts, other courses and, of course, educational content from our Annual Meetings.

## Professional Exposure

AABB offers those in the biotherapies field the chance to show off their expertise and background through a number of exposure opportunities that allow them to meet peers and leaders in the field, including several opportunities during our annual meeting. For those just starting their careers in biotherapies, AABB offers a mentoring program. This informal, 6-month program pairs experienced AABB members with colleagues who have worked in biotherapies for less than five years. Mentors and mentees communicate at least once per month by phone. AABB also hosts a job board to match biotherapy companies with the right hires.

## Publications and Curated Biotherapies Library

AABB is a premier publisher of books to support biotherapies. Our relevant and distinct publications include standards, guidelines, reference books, and other resources that reflect the dynamics of the field. All of AABB's publications are written and edited by leading experts and are designed to spread knowledge and share resources to promote the advancement of the biotherapies field. We offer books for professionals at and for facilities that want to have a well-stocked library for their staff.

Through our website, AABB provides additional biotherapies-specific resources, including a Circular of Information for CT Products; “Facts About Cellular Therapies;” cellular therapy ISBT 128 resources, and many more.

AABB’s curated biotherapies library, comprising exclusive products and resources that have been curated or created by experts with a specific focus on the benefit they offer to professionals in the biotherapies field. The library includes expert-developed training programs with a biotherapies focus, including a flow cytometry course, and a new course — Foundations in Cell Therapy.

### **News and AABB Community**

Partnering with AABB also provides you with the latest biotherapies news and in-depth analysis of the major issues facing the field — giving you an edge. AABB’s *Weekly Report* and the AABB Newsfeed provide news as it happens and are the best places to keep up with regulatory and advocacy activities. *AABB News*, our flagship members-only monthly magazine, tackles the hot topics that have implications for the future of biotherapies. The AABB Community provides a space for sharing best practices, asking questions, and learning from your peers.)

Subspecialty working groups — always looking for volunteers — focus on specific issues or needs within the field and offer the opportunity for members to learn, share knowledge and best practices and develop resources to advance the field.