

2023 #9

March 3, 2023

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**Please Note:** The ABC Newsletter will not be published on Mar. 10<sup>th</sup>. We will resume regular publication on Mar. 17<sup>th</sup>. Thank you for your continued interest.

## Blood Community Proposes Solutions to CBER in Support of Supply Chain Challenges

America's Blood Centers (ABC), the Association for the Advancement of Blood & Biotherapies (AABB), the American Red Cross, and Blood Centers of America (BCA) sent a [joint letter](#) to the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) this week outlining supply chain challenges facing blood centers, and both ongoing and potential future remedies to promote "long-term stability of the blood supply chain." In the March 1<sup>st</sup> letter, the blood community thanked CBER for collaboration, "open discussions and sharing of information" that impacts the nation's blood collectors throughout the pandemic.

The organizations suggest collaborative solutions to prevent future supply chain challenges in the form of:

- "[e]xpeditied FDA Licensure of the Fresenius Kabi Hořátev site: Emergency Use Authorization (EUA) is currently set to expire in December 2023. To avoid blood centers having to validate another bag option and hospitals having to ready for yet another new bag, we request licensure occur as soon as possible;
- [e]xpeditie FDA evaluation and licensure of apheresis kits and solutions to meet critical supply shortfalls to ensure clinical needs for platelets can be met;
- [a]llowing solutions already in use in Europe a faster path for FDA approval in the U.S. (e.g., buffy coats);
- [e]nsured capacity and business continuity for key suppliers in the blood industry; [and]
- [s]trategic reserves of key supplies supported by the federal government."

Additionally, the blood community also lists measures taken by blood centers to offset supply chain challenges in the letter while describing the staff time required and the incremental costs associated in undertaking such steps as:

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## INSIDE ABC

*The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.*

### Save the Date: ABC Summer Summit & MD Workshop

Mark your calendars for the America's Blood Centers (ABC) [Summer Summit and Medical Directors Workshop](#) in St. Louis, Mo. The meeting will take place August 1<sup>st</sup>-3<sup>rd</sup>. Hotel [reservations](#) can be made now through the ABC block at Live! by Loews (St. Louis). Over the course of two days, attendees will hear case study rounds, engaging discussions, and have networking opportunities to connect with peers and colleagues. Additional details including registration information and a preliminary agenda are coming soon.

### Participate in ABC's Blood Advocacy Week

ABC is hosting the inaugural [Blood Advocacy Week](#) April 24<sup>th</sup>-28<sup>th</sup>. This initiative reinforces ABC's commitment to advocacy and advancing policies that assist community blood centers. This virtual event aims to bring together members of the blood community, legislators, agency decision makers, advocates, providers, patients, and more to learn about and advance ABC's advocacy efforts on behalf of member blood centers. It includes the following:

- Monday, April 24th will be dedicated to discussing the current [status](#) of the nation's blood supply and trends impacting the collection and utilization of blood;
- Tuesday, April 25th will be dedicated to promoting the awareness of FDA donor [eligibility](#) changes impacting veterans and gay and bisexual men;
- Wednesday, April 26th will be ABC's virtual "Day on Capitol Hill." [Registration](#) is now open.
- Thursday, April 27th will be dedicated to examining changes that will expand early and increased access to blood, including in [pre-hospital](#) and [hospice](#) settings;
- Friday, April 28th will be dedicated to highlighting why increased [diversity](#) – racial, ethnic, and age – is important to patient care.

Additional updates will be provided in the coming weeks. If you or your organization is interested in becoming an official [advocacy partner](#), please contact [Jeff Gohringer](#), director of Strategic Communications and National Partnerships at ABC. ABC also encourages all member blood centers to register for the [2023 "Day on Capitol Hill"](#) on April 26<sup>th</sup>. This "virtual" day provides an opportunity for member blood centers to connect with members of Congress and their staffs to discuss the ongoing work at the blood center and the work done collectively by ABC and community blood centers to advance the ABC Advocacy Agenda. This event is a chance for individuals to let their voice be heard as ABC will arrange the virtual meetings for member blood centers with their members of Congress and provide additional resources to help inform them and their staff about the latest policies impacting the blood community. Take advantage of this opportunity to easily meet with your local Congressional leaders and build relationships. Each person from the blood center who would like to participate in the "Day on Capitol Hill" must register individually. ABC will arrange for group meetings but will need information for each person in attendance. Additional details, including the 2023 Advocacy Agenda, will be forthcoming. Please direct any questions to ABC Senior Director of Federal Government Affairs [Diane Calmus, JD](#).



## MEMBER NEWS

Héma-Québec has [announced](#) a joint virtual symposium with Canadian Blood Services on April 20<sup>th</sup> that will “focus on the strategies to mitigate the risk of transfusion-transmitted infections following the removal of deferral criteria related to sexual orientation.” [Registration](#) is free and open to all and the [agenda](#) for the symposium is available as well. Stated objectives include:

- hearing “experts from countries which have moved to a gender-neutral, individualized risk assessment share their experience, including the steps that were undertaken to document the impact of this paradigm shift;”
- discussing “the impacts of various risk mitigation strategies on blood safety and costs, the impacts on the size of the donor pool, how these strategies are perceived by new donors, and how these changes have been monitored;
- “key stakeholders, including governmental partners, [sharing] their views on the risk of transfusion-transmitted infections following the removal of deferral criteria related to sexual orientation and what challenges lie ahead; [and]
- to shed light on other future or immediate needs regarding blood safety, key stakeholders will discuss measures implemented to mitigate the risks associated with pre- or post-exposure prophylaxis (oral or injectable) among new eligible donors, post-implementation surveillance, and the potential use of pathogen reduction technologies to remove behavi[o]ral, individualized donor screening questions.”

(Source: Héma-Québec [Announcement](#), 2/27/23) 💧

## PEOPLE



**Brian Rollefson** has been named vice president of Human Resources and Staff Development at Community Blood Center (Appleton, Wis.) According to a blood center news release, Mr. Rollefson has “more than 24 years of experience leading team-based operations in time-sensitive and high-stakes situations in the private sector and military. He spent 21 years on active duty in the United States Air Force [and] [m]ost recently, he led the human resources team that works with operations within the Defense segment of Oshkosh Corporation. Mr. Rollefson is also a leadership cohort facilitator at the Center for Exceptional Leadership at St. Norbert College in De Pere, Wis.” John Hagins, president and chief executive officer of Community Blood Center added in the news release, “we are thrilled to have Brian join our team. His expertise, leadership and knowledge will be great assets to our senior leadership team and organization as a whole.”

(Source: Community Blood Center News Release, 3/3/23)

## WORD IN WASHINGTON

The Administration [unveiled](#) its “[National Cybersecurity Strategy](#)” on March 2<sup>nd</sup>. The strategy is developed on five key pillars:

- “defend critical infrastructure;
- disrupt and dismantle threat actors;
- shape market forces to drive security and resilience;
- invest in a resilient future; and
- forge international partnerships to pursue shared goals.”

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## WORD IN WASHINGTON (continued from page 6)

Also this week, a report from *Bank Info Security*, [stated](#) that the healthcare and public health were the most targeted sectors for ransomware attacks according to data from the Federal Bureau of Investigation (FBI).

(Sources: Administration [National Cybersecurity Strategy](#), 3/2/23; *Bank Info Security*, [Health care most hit by ransomware last year, FBI finds](#), 2/27/23) 💧

## CALENDAR

*Note to subscribers: Submissions for a free listing in this calendar (published weekly) are welcome. Send information to [newsletter@americasblood.org](mailto:newsletter@americasblood.org). (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

### 2023

Mar. 14. **U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Advanced Manufacturing and Analytical Technologies (AMAT) for Regenerative Medicine Therapies (RMT) Workshop (Virtual)**. [Registration](#) is open. More information available [here](#).

Mar. 29. **ABC Scientific, Medical, and Technical Committee Journal Club Webinar**. More information coming soon.

April 20. **End of Selection Criteria Based on Sexual Orientation – International Symposium on Alternatives to Donation Deferral (Virtual)**. [Registration](#) is open. More information available [here](#).

April 24-28. **ABC Blood Advocacy Week**. More information available [here](#).

April 26. **ABC Day on Capitol Hill**. [Registration](#) is open. More information available [here](#).

April 26. **FDA Blood Products Advisory Committee (BPAC) Meeting (Virtual)**. More information available [here](#).

April 27. **FDA's CBER Office of Tissues and Advanced Therapies (OTAT) Public Listening Meeting: Methods and Approaches for Capturing Post-Approval Safety and Efficacy Data on Cell and Gene Therapy Products (Virtual)**. [Registration](#) is open. More information available [here](#).

May 9-11. **2023 ADRP Conference, Charlotte, N.C.** [Registration](#) is open. Additional information is available [here](#).

May 10-11. **29<sup>th</sup> IPFA/ Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Bologna, Italy**. More information available [here](#).

Aug. 1-3. **ABC Medical Directors Workshop and Summer Summit, St. Louis, Mo.** More information available [here](#).

Sept. 17-20. **American Association of Tissue Banks Annual Meeting, National Harbor, Md.** More information available [here](#).

Sept. 20-21. **2023 ADRP Master Class (Virtual)**. More information coming soon.

Oct. 9-11. **Advanced Medical Technology Association (AdvaMed) The MedTech Conference, Anaheim, Calif.** More information available [here](#).

Oct. 14-17. **AABB Annual Meeting, Nashville, Tenn.** More information available [here](#). 💧

## CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for ABC Newsletter subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: [newsletter@americasblood.org](mailto:newsletter@americasblood.org)

## POSITIONS

**Registered Nurse.** If you have a passion to join a team that is providing specialized and focused, cutting-edge therapeutic apheresis procedures in a one-on-one patient care environment, consider joining OneBlood as a **Registered Nurse.** OneBlood, a proven leader in blood banking, also needs dedicated nurses to join our organization to provide their exceptional nursing skills to the hospital's we support and their patient care needs. This position includes a competitive benefit package, 403(b) retirement plan with company contribution PLUS a company match, paid time off, cell phone stipend, mileage reimbursement, tuition assistance, professional growth and much more. This position will be based out of the St. Petersburg/Tampa area, close to some of the most gorgeous beaches in the nation! If you want to join our life saving mission and team of dedicated employees, visit our **Careers** page at [www.oneblood.org](http://www.oneblood.org) to learn more. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

**Medical Technologists Needed with experience working in a Molecular Lab!** OneBlood is currently recruiting for a Medical Technologists to work in our Reference Lab in St. Petersburg, Florida. This position will perform basic through advanced testing serologic and molecular (ex: HEA, HLA, RHD, RHCE, NGS) procedures on patient and/or donor samples and interpret results in accordance with regulatory guidelines and organizational policies and procedures. Applicants must have a bachelor's degree in a biological science or related scientific field from an accredited college or university or an equivalent combination of education, certification, training and/or experience. Applicants must also have a valid and current Florida Clinical Laboratory Technologist license, or eligible, in Immunohematology or Blood Banking. To apply and view a complete Job Description of these positions, go to [www.oneblood.org](http://www.oneblood.org) and click on the **Careers** tab. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

**Manager of Donor Resources.** The Blood Connection is seeking a Manager of Donor Resources in Asheville, NC, Raleigh, NC, and Greenville, SC to provide oversight to our recruitment teams within these divisions. This position directs Account Managers and Business Development Representatives to strategically manage our existing portfolio of blood donor groups and new business to reach collection targets. The Manager of Donor Resources monitors progress to goal proactively and effectively coaches and manages the team to success. The ideal candidate will have a strong background in territory management and team building. Candidates must possess excellent interpersonal, analytical, and strategic planning abilities. We offer an exceptional benefits package including a generous 401k match, 30 days PTO, company bonuses, tuition reimbursement, cell phone stipend, and

yearly increases. Join one of the fastest growing blood centers in the country and help make an impact in your community today! How to apply: [Manager of Donor Resources](#)

**Director of Finance.** LifeSouth Community Blood Centers is seeking an experienced CPA for our Director of Finance position in Gainesville, FL. The Director is responsible for ensuring the stability of LifeSouth's finances through planning, directing, and controlling financial functions, including establishing appropriate control environments, preparing financial reports for management, financial analysis, overseeing development and implementation of effective financial and accounting systems. This position oversees all staff in the Accounting and Purchasing departments. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position and to apply. <https://www.lifesouth.org/work-at-lifesouth/>

**Compensation and Benefits Manager.** LifeSouth Community Blood Centers is seeking an experienced Compensation and Benefits Manager to join our Human Resources team at our headquarters in Gainesville, FL. This position is responsible for facilitating the organization's compensation and benefits programs as well as providing strategic leadership for its administration, including enrollment, maintenance, and compliance with regulations. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position and to apply. <https://www.lifesouth.org/work-at-lifesouth/>

**Regional Manager.** LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Regional Manager for McDonough, Ga. is responsible for overseeing daily operations of the region, is organized and decisive, and can motivate the team to reach daily and long-range collection goals. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position and to apply. <https://www.lifesouth.org/work-at-lifesouth/>

**Executive Director, Operations – Eastern Wisconsin/UP Michigan.** The Community Blood Center (CBC) (a division of Midwest Blood Centers, Inc. (MBC)) is looking to hire an Executive Director, Operations – Eastern Wisconsin/UP Michigan. Responsible for achieving the organizational objectives of the business unit within (CBC). This includes collaborating with executive-level management in the development, oversight and expansion of blood recruitment, collections, manufacturing and

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## POSITIONS (continued from page 8)

hospital services activities. Accountable for ensuring operations are compliant with all applicable regulations, standards, and organizational policies. Create an engaged, collaborative and productive culture while ensuring blood donors and blood drive sponsors receive exceptional service. At CBC, we lead our teams while keeping our mission, vision, and values at the forefront of all that we do. As a leader, you will inspire, train and collaborate with those in your department accordingly in addition to focusing on the organization's strategic goals. Essential duties include develop, implement and monitor day to day operational systems and processes in the areas of field donor recruitment, blood donor collections, manufacturing and hospital services. Participate in strategic and annual planning of the organization. Provide the processes, infrastructure, staff and training to ensure exceptional, skillful and knowledgeable services are provided. Effectively initiates, implements and manages change within the organization. Read full job description and apply: <https://www.communityblood.org/currentopenings/executive-director-operations/>.

**Medical Director (Oklahoma City, Oklahoma).** The Our Blood Institute, a large, successful blood center servicing Oklahoma, Arkansas, Texas and beyond, seeks qualified candidates for the position of **Medical Director**. Successful applicants must be **board-certified AP/CP or CP-only pathologists with board certification/eligibility** in Blood Banking/Transfusion Medicine. The Medical Director will work with the Chief Medical Officer (CMO) and other Medical Directors to direct and supervise key staff with the obligation to ensure that the quality of all products manufactured is in compliance with all regulatory requirements. In conjunction with the CMO and other staff, the Medical Director exercises control over the Institute's operations regarding all matters relating to compliance. The FACT Facility Medical Director shall have postgraduate training in cellular therapy practices and two years of practical experience in product collection, preparation, and clinical use of cell therapy products. If you are a doctor looking both to deliver excellence patient and donor care via multifaceted transfusion medicine organization and to reimagine the mission of blood banking in meeting community needs for connectivity, compassion, altruism and healing, this could be the perfect job for you. Salary Range: Competitive salary with excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. **How to apply:** <http://obi.org/careers>

**Territory Sales Consultant (Tulsa, Oklahoma).** Territory Sales Consultants must develop new partnerships with targeted decision makers in community organizations, educational & religious institutions, and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing & promoting

blood donation events; assessing, developing, and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. How to apply: <http://obi.org/careers/>.

**Director, Scientific and Technical Operations.** America's Blood Centers (ABC), North America's largest network of community-based, independent blood programs, is seeking a **Director, Scientific and Technical Operations**. The position will lead the association's evaluation and response to new Scientific, Medical, Technical Operations, Quality and Regulatory (SMTQR) developments, including the development of programs and resources. The position will report directly to the Senior Director, Federal Government Affairs, providing strategic guidance on emerging trends in the blood community and transfusion medicine to help shape strategies that leverage the ABC membership to drive ABC's advocacy work. Primary Responsibilities: Direct the development of programs and resources that support member activities in SMTQR and operational areas, including Journal Club, *Blood Bulletin*, workshops, and webinars. Convene ABC members to share best practices and collaborate in advancing ABC's advocacy agenda and hot topics of importance to blood centers. Assist in the analysis of new standards, guidelines, and regulations. Provide consultative services to ABC member requests for information and assistance in SMTQR areas. Serve as the primary staff liaison to the ABC Quality Committee and subcommittees, and Quality and HR Forums. Oversee ABC's research, benchmarking, and survey programs, including the use of the data to improve member blood center operations and the identification of best practices. Educational Requirements: Bachelor's required. Experience, Knowledge, Skills, and Abilities: A

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## POSITIONS (continued from page 9)

minimum of five years of experience in blood banking, with emphasis in any of the areas of scientific, medical, quality, technical operations, and/or regulatory affairs. Blood center operational experience a plus. Possesses demonstrated analytic and communication skills. Strong customer service orientation and ability to navigate and respond to sensitive/difficult situations. Self-motivated, flexible, creative, innovative, and goal oriented. This position is virtual. Click [here](#) to view the full job description. Interested applicants should send a cover letter and resume to [careers@americasblood.org](mailto:careers@americasblood.org).

**Chief Executive Officer (Flowood, MS).** Mississippi Blood Services makes a difference in people's lives every day. With the support of the community and voluntary blood donors, we have been serving the needs of hospital patients since 1979. To help us meet our mission, as part of a planned retirement, we are looking for a new Chief Executive Officer with the necessary expertise to direct all functions of the corporation in accordance with Board directives and regulatory guidelines in order to attain strategic objectives. The CEO will provide leadership to provide exceptional service and products to hospitals giving maximum consideration to the safety and efficiency of those products and services, direct overall operation of the corporation, ensure implementation of established policies and acts as liaison with the Board of Directors, and maintain positive relationships with the business and medical community, civic groups, and other blood banking organizations. Education and/or Experience: Bachelor's degree (B.A.) or higher from a four-year college or university; 10 years of related experience preferably with either large nonprofits or blood services/products organizations; or equivalent combination of education and experience. Click [here](#) to view the full job description. Mississippi Blood Services is an equal opportunity employer and makes employment decisions without regard to race, color, sex, religion, national origin, age, disability, veteran status, genetic information, sexual orientation or gender identity. Please submit cover letter, resume and salary requirements to Kiffany Lee, Director of Human Resources [klee@msblood.com](mailto:klee@msblood.com). 💧

