America's Blood Centers®
It's About Life.

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

2024 #5 **February 9, 2024**

INSIDE:

ABC Announces 2024 Advocacy Agenda

America's Blood Centers (ABC) has published its 2024 Advocacy Agenda. The federal legislative and regulatory priorities that are most important to community blood centers are reflected within the ABC Advocacy Agenda which also includes clearly defined legislative and regulatory solutions that will guide the work of the association on behalf of its member blood centers. The Advocacy Agenda has been developed in consultation with the ABC Board of Directors, Policy Council, and input from member blood centers. It will guide the work of the association on behalf of its member blood centers as ABC continues to urge the Administration, Congress, and industry stakeholders to promote the value of blood to patients, communities, and the healthcare system by:

- ensuring patient access to blood by streamlining product licensure;
- increasing the number of blood donors nationwide through the funding of local awareness programs;
- ensuring blood transfusions are available to patients when and where they need blood;
- supporting a robust donor base by prioritizing blood donation as a national imperative through the establishment of targeted federal initiatives to support increased diversity in the donor base; and the establishment of funding research on the predictive social and psychological factors in blood donor motivation to attract and retain donors;
- committing federal resources in support of the vital role of blood in the healthcare system by exploring federal funding mechanisms to facilitate implementation of mandated safety and technological measures by regulators, increasing federal resources for data gathering, collection, and utilization of blood components as needed, and advocating for programs and funding that increase surge capacity of the nation's blood supply; and
- reducing unnecessary and burdensome regulation to support innovation and blood product availability by applying evidence-based decision making to U. S. Food and Drug Administration testing requirements, revisiting regulator policy on the acceptance of international data for use in the approval of new products or technologies, lowering the U.S. platelet content requirement (PCR) to expand platelet availability and alignment with international standards, and implementing a rational and flexible approach to the regulation of plasma products, advocating regulators for licensure of recovered plasma to give blood centers the ability to convert plasma from transfusable to further manufacture without requiring expiration for more effective blood inventory management.

(continued on page 2)

ABC Advocacy Agenda Published (continued from page 1)

ABC thanks its members and partners who have and continue to help advance the priorities and work of independent community blood centers. Please contact ABC Senior Director of Federal Government Affairs Diane Calmus, JD for questions or additional information.

(Source: MCN 24-010, 2/6/24)

CBER 2024 Guidance Agenda Announced

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has published its guidance agenda for 2024. The agenda outlines the guidance and draft guidance documents that CBER "is considering for development" throughout the calendar year. Topics of note that the agency will look to address include:

- "Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma; Guidance for Industry;
- Considerations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method; Draft Guidance for Industry;
- Collection of Platelets by Automated Methods; Draft Guidance for Industry;
- Blood Pressure and Pulse Donor Eligibility Requirements; Compliance Policy; Guidance for Industry; [and]
- Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry."

Topics categorized as therapeutic products that may be of interest included:

- "Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry;
- Considerations for the Development of Chimeric Antigen Receptor T Cell Products; Guidance for Industry;
- Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Draft Guidance for Industry;
- Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry;

(continued on page 3)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognizes the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the health care system; promote partnerships, policies, and programs that increase awareness about the need for blood donation; and serve as a thought leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

America's Blood Centers
Chief Executive Officer: Kate Fry
Chief Medical Officer: Jed Gorlin
Editor: Mack Benton
Subscriptions Manager: Leslie Maundy
Annual Subscription Rate: $420

Send subscription queries to
memberservices@americasblood.org
America's Blood Centers
1717 K St. NW, Suite 900, Washington, DC 20006
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

CBER 2024 Guidance Agenda Announced (continued from page 2)

- Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Guidance for Industry;
- Potency Assurance for Cellular and Gene Therapy Products, Guidance for Industry;
- Recommendations to Reduce the Risk of Transmission of Mycobacterium tuberculosis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Guidance for Industry; [and]
- Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Guidance for Industry."

America's Blood Centers will continue to provide updates to member blood centers on its advocacy efforts regarding the CBER guidance agenda as they become available. Please contact ABC Director of Regulatory Affairs and Public Policy Justine Coffey, JD, LLM with questions. The complete listing of the potential guidances is updated periodically throughout the year and always available on the FDA's website.

(Source: FDA Announcement, 1/29/24)

PEOPLE

Liz Culler, MD has been named president and chief executive officer (CEO) of Blood Assurance (Chattanooga, Tenn.). She most recently served as chief medical officer. According to *The Tullahoma News*, Dr. Culler's career at the blood center began in 2006 as medical director. "During her tenure, [she]has played a pivotal role in Blood Assurance's expansion in the region and was instrumental in the organization's establishment of a research and cellular therapy program, OurCEL Solutions. Dr. Culler also helped Blood Assurance become one of the first blood centers in the country to collect convalescent plasma for COVID-19 patients…[She] has a degree in Chemistry from the University of South Carolina, and a Doctor of Medicine degree from the Medical University of South Carolina. She completed a residency in Clinical Pathology, and a fellowship in Transfusion Medicine at Emory University…She serves on the board of Commonwealth Transfusion Foundation, where she supports the mission of providing students educational opportunities in laboratory careers." Dr. Culler succeeds J.B. Gaskins, "who is retiring this summer after spending over 40 years in the blood banking industry," according to the publication. Mr. Gaskins added, "Dr. Culler is one of the most dedicated professionals that I have ever had the opportunity to work with. I am confident that she is more than ready to take the reins, and lead Blood Assurance to even greater heights."

(Source: *The Tullahoma News*, "Blood Assurance appoints Culler as President and CEO," 2/6/24)

REGULATORY NEWS

The U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) issued a news release announcing the agency's, "intent to initiate the reclassification process for most high risk *in vitro* diagnostics (IVDs)." In the news release, CDRH Director Jeff Shuren, MD, JD explained that specifically, "the Center intends to initiate the reclassification process for most IVDs that are currently class III (high risk) into class II (moderate risk). The majority of these tests are infectious disease and companion diagnostic IVDs. Reclassification would allow manufacturers of certain types of tests to seek marketing clearance through the less burdensome premarket notification (510(k)) pathway rather than the premarket approval pathway, the most stringent type of FDA medical device review." He added that, "Such reclassifications may support the potential for more manufacturers to develop these tests, which can increase competition and increase access to these important tests. CDRH intends to propose

(continued on page 4)

REGULATORY NEWS (continued from page 3)

reclassification of devices for which we believe there is sufficient information to establish special controls that, together with general controls, provide a reasonable assurance of safety and effectiveness for these tests." The agency previously recommended in September 2023, "[the] potential future reclassification from class III to class II with special controls of three types of infectious disease diagnostic tests [that included] nucleic acid and serology-based IVDs to aid in the diagnosis of Hepatitis B Virus (HBV) infection."

(Source: CDRH News Release, 1/31/24)

RESEARCH IN BRIEF

Clinical effectiveness of Mirasol-treated platelets. In *Transfusion*, a study designated that, "the Mirasol-treated Apheresis platelets (PLTs) in Patients with Hypoproliferative Thrombocytopenia (MiPLATE) trial was designed to assess the clinical effectiveness and hemostatic efficacy of Mirasol® platelets (PLTs) compared to standard PLTs in plasma using a novel clinical endpoint of days with World Health Organization (WHO) ≥Grade 2 bleeding in participants with hypoproliferative thrombocytopenia requiring PLT transfusions." The authors explained that this, "was a prospective, multicenter, controlled, randomized, non-inferiority trial," in which, "[p]articipants in the experimental arm received Mirasol-treated plasma stored Apheresis PLTs (MIRASOL) while those in the [c]ontrol arm (CONTROL) received conventional plasma stored Apheresis PLTs." The trial's stated, "primary outcome was the number of days with WHO ≥Grade 2 bleeding from the first post-randomization PLT transfusion (Day 0) through 28 days following the first transfusion or until transfusion independence (10 days without PLT transfusion) prior to Day 28." The authors noted that, "[a] total of 297 participants (MIRASOL = 145 and CONTROL = 152) received at least one study transfusion and were part of the modified intention-to-treat (mITT) [s]et…The primary efficacy endpoint demonstrated a 2.74-fold increase in days of ≥Grade 2 bleeding from MIRASOL (95 percent confidence interval (CI) 1.66–4.53). The lower limit of the two-sided 95 percent CI for the relative risks (RR) exceeded the non-inferiority (NI) margin of 1.6." The researchers explained that, "[i]n the mITT [s]et, the proportion of participants with ≥Grade 2 bleeding was 40 percent (n = 58) in MIRASOL and 30.26 percent (n = 46) in CONTROL. The corresponding relative risk of ≥Grade 2 bleeding for MIRASOL versus CONTROL was 1.32 (95 percent CI 0.97–1.81; p = .08)...There were 22 percent more PLT transfusions per participant (RR = 1.22, 95 percent CI 1.05–1.41) in MIRASOL than CONTROL. Similarly, the mean days between PLT transfusion episode was shorter (MIRASOL = 0.96 day vs. CONTROL = 1.29 days). Furthermore, the proportion of participants with PLT refractoriness was greater (corrected count increments (CCIs) < 5,000, RR = 2.15, 95 percent CI 1.32–3.49) with lower mean corrected count increments (CCIs) at one-hour post-transfusion (MIRASOL = 7,070 vs. CONTROL = 10,149, p < .01) in MIRASOL. There was no difference in the days of PLT support (HR = 0.86, 95 percent CI 0.68–1.08)." It was concluded that, "[t]his study did not support that MIRASOL was non-inferior compared to conventional platelets using the novel endpoint number of days with ≥Grade 2 bleeding in MIRASOL when compared to CONTROL." The researchers further explained that, "the increase in number of days with grade ≥2 bleeding observed in MiPLATE [potentially] reflects lower CCI's observed in all pathogen reduction (PR) clinical trials and potentially decreased hemostatic function inherent in pathogen reduction technology (PRT)…Another potential explanation for the increase in number of days with grade ≥2 bleeding in MIRASOL may be due to PLT damage from the combination of the PR process followed by irradiation." They also noted that, "[d]espite finding an increase in the number of days with grade ≥2 bleeding in participants receiving Mirasol PLTs, there was no difference between the study arms in red blood cell (RBC) transfusions (RR = 1.12, 95% CI 0.91–1.37) or days of PLT support similar to previous PR trials [suggesting] the use of Mirasol PLTs does not increase the amount of clinically significant bleeding that would lead to longer hospitalization or interventions."

Citation: Koepsell, S.A., Stolla, M., Sedjo, R.L., *et al*. Results of clinical effectiveness of conventional versus Mirasol-treated Apheresis Platelets in Patients with Hypoproliferative Thrombocytopenia (MiPLATE) trial. *Transfusion*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

WORD IN WASHINGTON

Sen. Bill Cassidy, MD (R-L.A.), the ranking member of the Senate Health, Education, Labor and Pensions (HELP) Committee and Sen. Bob Casey (D-Penn.) announced the introduction of a bill to increase bone marrow and blood donations and reduce the barriers to donation of each. According to the news release, "The Lifesaving Leave Act ensures potential bone marrow and blood donors can take leave from work to undergo donation activities, which could vastly expand the pool of eligible donors." Sen. Cassidy stated in news release, "Americans deciding to make a lifesaving bone marrow or blood cell donation should not have to worry about losing their job. Patients with life-threatening conditions depend on them. This legislation makes it easier for Americans to provide these crucial donations to save lives." Sen. Casey added, "[t]oo many people waiting for bone marrow transplants can't find a match because donors can't take time off from work. I'm fighting for this bill because every potential donor has the opportunity to save a life, and we must ensure the fear of losing your job is not a barrier to doing so."

(Source: Senate HELP Committee News Release, 1/30/24)

The Human Resources and Services Administration (HRSA) recently provided an update regarding the agency's "Organ Procurement and Transplantation Network (OPTN) Modernization Initiative to improve transparency, performance, governance, and efficiency of the U.S. transplant system." HRSA announced that the request for proposals (RFP) is open, "to support multiple different contract awards. This action will increase competition ensuring patients and their families benefit from best-in-class vendors." Additionally, the agency's update included:

- "releasing a contract solicitation to create an independent OPTN Board of Directors, including supporting a special election to seat a new Board of Directors within six months of contract award;
- launching the discovery and development phase of the transition to a modernized OPTN Information Technology (IT) matching system that leverages industry-leading IT standards and practices; [and]
- taking action to address 'pre-waitlist' inequities in the organ waitlist process and reduce variations in referrals to transplant and in organ procurement practices."

(Source: HRSA Announcement, 2/6/24)

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) will hold a webinar on March 7th titled, "Considerations for the Development of CAR T Cell Products." According to an agency announcement, the webinar will, "discuss a recently finalized guidance document on considerations for the development of Chimeric Antigen Receptor (CAR) T cell products. This guidance is intended to assist industry and academic sponsors that are developing ex vivo-manufactured CAR T cell products." Registration is currently open.

(Source: FDA Announcement, 1/29/24)

America's Blood Centers®
It's About *Life.*

INSIDE ABC

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

ABC Bylaws Town Hall Set for Feb. 16th

America's Blood Centers (ABC) will be hosting a Bylaws Town Hall on Friday, February 16th at 12 p.m. EST. The purpose of this virtual event is to, "present and discuss proposed changes to the ABC Bylaws, specifically the nomination and composition of the ABC Board of Directors." A link to register is available to ABC members in MCN 24-009. Please contact us with questions.

(Source: MCN 24-009, 2/1/24)

Save the Date: SMT Journal Club on March 29th

The next ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar will take place on March 29th from 12-1 p.m. EST. The webinar is free to all ABC members. An email announcement with a registration link and the articles to be reviewed on the webinar will be available soon.

ABC Announces Corporate Partner Council

ABC recently introduced the formation of the Corporate Partner Council, an initiative that convenes blood center and industry leadership to discuss, strategize, and advance solutions to the most pressing needs and challenges of the blood community. ABC Corporate Partners are companies and organizations that support ABC's mission and vision and have a vested interest in helping them come to fruition. Thank you to the inaugural 2024 Corporate Partners for their generous support. Premium Council Partners include Abbott, Grifols, Roche, and Terumo Blood and Cell Technologies. Council Partners are Cerus Corp., Fresenius Kabi, Healthcare-ID, Macopharma, and Velico. The inaugural in-person meeting of the council will take place on Monday, March 3rd at the ABC Annual Meeting.

(Source: MCN 24-007, 1/29/24)

ABC HR Education Webinar Announced

The next ABC Human Resources (HR) Education Webinar will take place on February 20th at 3 p.m. EST. The webinar will cover:

- "Developing Leaders for Tomorrow;" and
- "Employee Conflict Resolutions."

Featured speakers include Maria Brcka of LifeServe and Stephanie Rue of SunCoast Blood Centers. The webinar is not only intended for HR professionals, but also all ABC members who would like to learn more about developing their staff and strengthening professional interpersonal skills. More information, including a link to registration, is available to ABC members in MCN 24-006. Please contact ABC Director of Scientific and Technical Operations Betzy Gonzalez, MS, BB(ASCP) with questions.

(Source: MCN 24-006, 1/26/24)

(continued on page 7)

INSIDE ABC (continued from page 6)

Program Available for 2024 ABC Annual Meeting

Registration is open for the ABC 2024 Annual Meeting and the program is available. The meeting will take place March 4th-6th in Arlington, Va. at the Ritz-Carlton in Pentagon City and features several exciting changes, including expanded content offerings and a new format. With a focus on advocacy, leadership, operations, and science and medicine, the program will feature a mix of general and breakout sessions, external speakers, blood center-led case studies, committee and council meetings, networking events, and more. *Awards of Excellence* (AoE) winners will be recognized throughout the Annual Meeting and at a reception on Capitol Hill, where we can celebrate their achievements with fellow meeting attendees, members of Congress and their staff, our federal agency partners, Blood Advocacy Week partners, and more. Secure your room today to take advantage of the group rate. The deadline to book a room is February 16th. Sponsorship opportunities are also available. Contact us with any questions.

Registration Is Open for 2024 ADRP Annual Conference

Register today for the 2024 ADRP Annual Conference! Join more than 400 blood center professionals in St. Louis, Mo. May 14th-16th at The St. Louis Union Station Hotel. This year's conference will feature keynotes Jason Kotecki, an expert at helping people "Escape Adulthood" in order to beat burnout and become more innovative and creative by breaking rules that do not exist, and Candy Whirley, a recognized motivational speaker, leadership, and team building expert. The 2024 ADRP Annual Conference is your opportunity to gain insights into industry trends, exchange ideas, and share information with your peers, while taking advantage of networking opportunities. Attendees will be able to participate in pre-conference workshops, educational sessions, roundtables, and have access to an expansive exhibit hall. Learn more about available exhibitor and sponsorship opportunities. Remember to book your hotel room by April 19th for the discounted rate. Please contact us with questions.

COMPANY NEWS

Blood Centers of America, Inc. (BCA) and **Calimex USA** have partnered to provide, "BCA members with cutting-edge information technology (IT) solutions," according to a news release. BCA Vice President of Information Services Greg Bishop added in the news release, "it's great to have another IT agreement in the BCA portfolio of offerings to our members. Calimex is a trusted partner to many centers, and we are proud to introduce their products and services across the BCA cooperative."

(Source: BCA, Inc. & Calimex USA Joint News Release, 2/1/24)

Upcoming ABC Webinars & Virtual Events – Don't Miss Out!

- **America's Blood Centers (ABC) Bylaws Townhall** – Feb. 16th. More information available to ABC Members including a link to registration in MCN 24-009.
- **ABC Human Resources (HR) Education Webinar: Developing Leaders for Tomorrow & Employee Conflict Resolution** – Feb. 20th. More information available to ABC Members including a link to registration in MCN 24-006.
- **ADRP, the Association for Blood Donor Professionals Webinar: Whole Blood-Derived Platelets - Maximize Every Donor's Gift** – Feb. 21st Registration is open. More information available here.
- **ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar** – Mar. 29th. More information coming soon.

America's Blood Centers® It's About Life.

ADRP The Association for Blood Donor Professionals

NEW on Coll*ABO*rate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC Coll*ABO*rate Online Member Community include:

- Hospital Satisfaction Survey (ALL MEMBER FORUM)
- Hematology Proficiency Testing Program (TECHNICAL DIRECTORS)
- Downtime Questionnaire (QUALITY BYTES)
- Travax Malarial Maps (QUALITY BYTES)
- Alternative Blood Mobiles (COLLECTIONS & DONOR SERVICES)
- Donor Notification of Test Results (QUALITY BYTES)
- One Dad Can (COMMUNICATIONS & DONOR RECRUITMENT)

ABC members are encouraged to login and join the conversations today!

CALENDAR

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

2024

Feb. 16. **America's Blood Centers (ABC) Bylaws Townhall (Virtual).** More information and a link to registration are available to ABC members in MCN 24-009.

Feb. 20. **ABC Human Resources Education Webinar: "Developing Leaders for Tomorrow & Employee Conflict Resolution."** More information and a link to registration are available to ABC members in MCN 24-006.

Feb. 21. **ADRP, the Association for Blood Donor Professionals Webinar: "Whole Blood-Derived Platelets - Maximize Every Donor's Gift."** Registration is open. More information available here.

Mar. 4-6. **ABC Annual Meeting. Arlington, Va.** Registration is open. More information available here.

Mar. 7. **U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Webinar: "Considerations for the Development of CAR T Cell Products."** Registration is open. More information available here.

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

April 11-12. **International Haemoviglance Network Symposium. Athens, Greece.** Registration is open. More information available here.

April 12-13. **BEST Meeting. Amsterdam, Netherlands.** More information is coming soon.

April 16-17. **International Plasma Protein Congress. Athens, Greece.** Registration is open. More information available here.

April 17-18. **ABC Quality and Technical Workshop. St. Louis, Mo.** Registration is open. More information available here.

May 3-4. **California Blood Bank Society (CBBS) Annual Meeting.** More information is coming soon.

May 14-16. **2024 ADRP Annual Conference. St. Louis, Mo.** Registration is open. More information available here.

May 15-16. **International Plasma and Fractionation Association/Paul-Ehrlich Institut[e] 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Aarhus, Denmark.** Registration is open. More information available here.

June 7-8. **2024 South Central Association of Blood Banks (SCABB) Annual Meeting and Exhibit Show. Orlando, Fla.** More information is coming soon.

June 23-27. **38th International Society of Blood Transfusion (ISBT) Congress. Barcelona, Spain.** Registration is open. More information available here.

Sept. 4-6. **American Society for Clinical Pathology (ASCP). Chicago, Ill.** More information is coming soon.

Sept. 30- Oct. 3. **American Association of Tissue Banks (AATB). Denver, Colo.** More information is coming soon.

Oct. 19-22. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Houston, Texas.** More information is coming soon.

(continued on page 10)

CALENDAR (continued from page 9)

2025

May 20-21. **International Plasma Protein Congress. Warsaw, Poland.** More information is coming soon.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** More information is coming soon.

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 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

POSITIONS

Medical Laboratory Technologist. The Medical Laboratory Technologist will report to the Manager of Technical Services and is responsible for performing lab procedures such as compatibility testing, reference lab work, specimen processing, test performance, and reporting test results. They also may perform computer aided labeling, component production, and distribution. They will be responsible for the maintenance and storage of blood components including temperature monitoring, labeling of blood, biohazard disposal, component preparation, daily orders, blood shipments and returns. The laboratory duties will include qualifications of Apheresis Platelets and Plasma, lot release, blood grouping, compatibility testing, antibody detection and emergency release of products. The distribution duties will include daily orders, blood shipments and returns, shipping recovered plasma, resource management, and irradiation of blood products. Please click here to view the full job description and apply.

Chief Operating Officer. As we enter our 50th year of service, ImpactLife is seeking a talented and passionate individual to join our executive leadership team as the Chief Operating Officer (COO). As a member of the Executive Leadership Team, the COO will oversee and lead the operational aspects of the organization to include all marketing and public relations activities as well as blood recruitment, collection, patient services, manufacturing, and distribution activities. Additional responsibilities include departmental budgeting and development of control systems to ensure that organization objectives are met. Qualifications include bachelor's degree with preference given to candidates with a graduate degree and blood center and/or hospital executive leadership experience. This position can be located anywhere within the ImpactLife service territory extending into four states: Illinois, Iowa, Missouri, and Wisconsin. At ImpactLife we keep our mission, vision, and values at the forefront as we lead our teams. As a leader you will lead, inspire, and mentor with clear communication leading to collaboration within your team and across the organization remaining focused on achieving our tactical goals and fulfilling our strategic initiatives. Click here to apply. EOE: M/W/V/D

Quality and Regulatory Services Manager. The Quality and Regulatory Services Manager reports to the Director of QRS and is responsible for the quality and regulatory affairs, duties, and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, and validations, and assist with the development, as necessary. Reviews applicable regulations and standards from FDA, AABB, CLIA, OSHA, NRC, State of Tennessee, and manufacturers to ensure compliance. Personnel Training: Perform Good Manufacturing Practice (cGMP) and safety training and assist in inter-departmental training and competency evaluation. Maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports when required. Document Control: Maintain proficiency in Document Control within MediaLab. Able to revise and create SOPs, Forms, and Job Aids. Create, perform, and review validations.

(continued on page 11)

POSITIONS (continued from page 10)

Manage the overall deviation management program to include investigation, root cause, analysis, corrective and preventative actions, and documentation. Responsible for developing, tracking, monitoring, and reporting quality indicators. Monitor and conduct trend analysis of quality indicators. Process improvement, including change control and corrective/preventative actions. Please click here to view the full job description and apply.

Medical Laboratory Technologist. The Medical Laboratory Technologist will report to the Manager of Technical Services and is responsible for performing lab procedures such as compatibility testing, reference lab work, specimen processing, test performance, and reporting test results. They also may perform computer aided labeling, component production, and distribution. They will be responsible for the maintenance and storage of blood components including temperature monitoring, labeling of blood, biohazard disposal, component preparation, daily orders, blood shipments and returns. The laboratory duties will include qualifications of Apheresis Platelets and Plasma, lot release, blood grouping, compatibility testing, antibody detection and emergency release of products. The distribution duties will include daily orders, blood shipments and returns, shipping recovered plasma, resource management, irradiation of blood products. Please click here to view the full job description and apply.

Donor Recruitment Manager. Blood Assurance is seeking a **Donor Recruitment Manager** to lead field recruitment efforts that build new and existing business in our Chattanooga and North Georgia region. Primary responsibilities include direct leadership of Account Managers in expanding blood drive activity on mobiles primarily, and in facilities as needed, based on growth strategy in a specific type of blood product recruitment and collection. Assist in developing long-term community business partnerships, and coordinating internally with all leadership levels to support or expand Blood Assurance recruitment efforts. Work closely with Donor Services leadership to ensure recruitment and collection teams are working together toward meeting overall product collection goals. Qualified applicants will have: Bachelor's degree-preferably in business, marketing, or related field. Sevent to 10 years sales experience, preferably in blood banking. Three to five years sales staff management. Advanced communication skills. Public presentation and networking skills. Advanced organizational, customer service and teamwork skills. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Paid Time Off, 401K, Wellness Program and Relocation Assistance. Qualified candidates are encouraged to submit an online application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Environment.

Director, Laboratory Services. The Director, Laboratory Services reports to the Chief Medical Officer/CLIA Laboratory Director and is responsible for facilitating the design and implementation of the delivery of laboratory services, developing, and recommending strategies to improve services and clinical outcomes, reaching established goals, maintaining satisfactory outcomes, and contributing to the business plans and financial goals of the organization. The Director, Laboratory Services will provide oversight of San Diego Blood Bank's clinical and research laboratories. Educational requirements include MD or MD/PhD (doctoral-degree scientist) and board certification in anatomic/clinical pathology or clinical pathology (preferred). Eight years of progressively responsible and demonstrated experience in high-level management at a reference or health system laboratory is preferred, participation in FDA, State, Federal, and accrediting agency inspections with knowledge of regulatory accreditation and licensing requirements, and application of quality assurance principles. Please click here to view the full job description and apply.

Transfusion Lab Supervisor Needed! Join Florida's leading blood center, OneBlood, as a Blood Bank Lab Supervisor in Lakeland, FL. Bring your leadership, technical expertise, and management experience to support the transfusion testing procedures on patient and/or donor samples. Qualified candidates should possess three (3) or more years' experience in a clinical laboratory, preferably blood banking environment, including one (1) or more years' experience in supervision and management experience, as well as a valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking; Supervisor license strongly preferred. To apply and view a complete Job Description of this Lab Supervisor position, visit www.oneblood.org/careers. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Vice President, Quality & Regulatory Affairs (VPQRA). The Vice President, Quality & Regulatory Affairs (VPQRA) leads the Organization's adherence to regulations and standards established by governing agencies (AABB, FDA, CLIA, State, OSHA, NRC, EU, etc.). Kentucky Blood Center is seeking qualified candidates to fill this key executive leadership role which is responsible for our Quality Assurance (QA) program and regulatory compliance activities. The position has oversight of the QA department and team, and reports to the CEO. Qualifications include MLS/CLS (ASCP) with preference given to candidates with a graduate degree, and blood banking experience. Relocation to the Lexington, Kentucky area required (assistance provided). For more

(continued on page 12)

POSITIONS (continued from page 11)

information or to apply, visit https://www.kyblood-center.org/about-us/careers.

Manager of Donor Resources. The Blood Connection is expanding our operations into Virginia! We are one of the fastest growing blood centers in the country and we are seeking a Manager of Donor Resources who will provide management and oversight of the Donor Resources department as we expand into this new territory. The ideal candidate for this position possesses strong leadership and organizational skills with a proven ability to meet organizational goals. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community. *This role is based in Roanoke, VA. Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Resources Application.