



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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INSIDE:

WORD IN WASHINGTON	2
RESEARCH IN BRIEF	3
ABC Launches Meetings Survey	4
Elks Lodges Partner with ABC to Host Blood Drives throughout August	4
ABC Partners to Attempt World Record Blood Drive	4
PEOPLE	5
MEMBER NEWS	5
GLOBAL NEWS	5
COMPANY NEWS	6
CALENDAR	7
EQUIPMENT AVAILABLE	8
POSITIONS	8

Clinical Practice Guidelines for COVID-19 Convalescent Plasma Published

Authors in the *Annals of Internal Medicine* have [published](#) “Clinical Practice Guidelines from the Association for the Advancement of Blood and Biotherapies (AABB): COVID-19 Convalescent Plasma” (CCP). The guidelines include five recommendations for the appropriate use of CCP and state that “CCP is most effective when transfused with high neutralizing titers to infected patients early after symptom onset.” The recommendations are:

- “[for] CCP transfusion in addition to the usual standard of care for outpatients with COVID-19 who are at high risk for disease progression (weak recommendation, moderate-certainty evidence);
- against CCP transfusion for unselected hospitalized persons with moderate or severe disease (strong recommendation, high-certainty evidence). This recommendation does not apply to immunosuppressed patients or those who lack antibodies against SARS-CoV-2;
- [for] CCP transfusion in addition to the usual standard of care for hospitalized patients with COVID-19 who do not have SARS-CoV-2 antibodies detected at admission (weak recommendation, low-certainty evidence);
- [for] CCP transfusion in addition to the usual standard of care for hospitalized patients with COVID-19 and preexisting immunosuppression (weak recommendation, low-certainty evidence); [and]
- against prophylactic CCP transfusion for uninfected persons with close contact exposure to a person with COVID-19 (weak recommendation, low-certainty evidence).”

An accompanying [editorial](#) by Jason Baker, MD, MS and H. Clifford Lane, MD identify lessons the authors feel should be learned in the aftermath of the blood community’s experiences with CCP during the COVID-19 pandemic. “[I]n response to increasing demand and the sense that it was reasonable to believe the product was effective, the Food and Drug Administration issued an EUA in August 2020. At that time, the EUA limited CCP treatment to unselected, hospitalized patients. Ironically, although it seemed plausible at the time that CCP might be of value to hospitalized patients, the eventual trials showed otherwise. An important lesson for future responses to emerging infectious diseases is that although it is important to rapidly provide therapies that ‘may be effective,’ it is essential that those therapies are evaluated in robust trials as soon as possible. As additional data became available, the Food and Drug Administration modified the EUA for CCP in

(continued on page 2)

CCP Guidelines Published (continued from page 1)

February 2021 to limit use to high-titer CCP units for patients who were early in the disease course or had impaired humoral immunity. In December 2021, the EUA further limited use to immunocompromised patients in either outpatient or inpatient settings.” The editorial concludes “[t]he experience with CCP during this pandemic provides at least two important lessons as we prepare for the next emerging infectious disease. First, despite how logical and available an intervention may appear, we cannot determine its benefit absent evidence from scientifically robust, ethically sound clinical trials. Second, it is incumbent on government, academia, and professional groups to ensure that, in our haste to provide treatments that may be of benefit, we make sure clinical evidence is generated as quickly as possible to determine whether they are of benefit.”

Citations: Estcourt, L.J., Cohn, C.S., Pagano, M.B., *et al.* [Clinical Practice Guidelines From the Association for the Advancement of Blood and Biotherapies \(AABB\): COVID-19 Convalescent Plasma](#). *Annals of Internal Medicine*. 2022.

Baker, J.V. and Lane, H.C. [The Fast and the Furious: Chasing a Clinical Niche for COVID-19 Convalescent Plasma](#). *Annals of Internal Medicine*. 2022. ♡

WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) [approved](#) the first “cell-based gene therapy treatment” for use in individuals with beta-thalassemia who require regular blood cell transfusions. “Today’s approval is an important advance in the treatment of beta-thalassemia, particularly in individuals who require ongoing red blood cell transfusions,” said Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research in an agency news release. “Given the potential health complications associated with this serious disease, this action highlights the FDA’s continued commitment to supporting development of innovative therapies for patients who have limited treatment options.” The therapy is a one-time single-dose treatment customized “using the patient’s own cells (bone marrow stem cells) that are genetically modified to produce functional beta-globin (a hemoglobin component)... The safety and effectiveness of [the gene therapy] were established in two multicenter clinical studies that included adult and pediatric patients with beta-thalassemia requiring regular transfusions. Effectiveness was established based on achievement of transfusion independence, which is attained when the patient maintains a pre-determined level of hemoglobin without needing any red blood cell transfusions for at least 12 months. Of 41 patients receiving [the therapy], 89 percent achieved transfusion independence. The most common adverse reactions associated with [the therapy] included reduced platelet and other blood cell levels... There is a potential risk of blood cancer associated with this treatment; however, no cases have been seen in studies of [the therapy].”

(Source: FDA [News Release](#), 8/17/22)

A [report](#) in *Politico*, states that the U.S. Department of Health and Human Services (HHS) plans to extend the COVID-19 public health emergency (PHE) “for another 90 days in mid-October.” HHS Secretary Xavier Becerra, JD previously [extended](#) the COVID-19 PHE effective July 15, 2022. The PHE has been in effect since January 2020 and extended in 90-day increments as required by law. It allows several pandemic response measures and flexibility to continue. This includes multiple donor deferral changes made by the FDA early in the pandemic, such as reducing blood donor deferral for men who have sex with other men (MSM) to three months, which are currently in effect until 60 days after the end of the PHE. HHS has committed to providing no less than 60-day notice prior to terminating the PHE declaration.

(Source: *Politico*, [HHS says it plans to extend Covid-19 public health emergency](#), 8/17/22) ♡



RESEARCH IN BRIEF

Application of Standardized Culture Criteria for Suspected Septic Transfusion Reactions. The goal of a study published in the *American Journal of Clinical Pathology* “was to retrospectively compare the strict application of the Biomedical Excellence for Safer Transfusion (BEST) criteria to clinical practice to determine the potential impact that adoption of these criteria might have on culture rates at a single academic tertiary care medical center.” The authors explained that “[a] retrospective, study examining transfusion reaction records from 2013 to 2020 was performed...During this period, culture of residual components was reflexively performed if the patient had a 2°C or higher rise in body temperature and/or if ‘hypotension’ was reported on the transfusion reaction reporting form [BEST criteria]...Cultures were also performed outside of these criteria upon request of the Transfusion Medicine Service physician...All adult patients with acute transfusion reactions reported during or within 24 hours following transfusion were included.” The investigators noted that “during the study 1,068 [transfusion reactions] were evaluated...[A] total of 200 had residual product cultures performed...Concordance between actual culture and BEST criteria recommendation was 62 percent for cultured components and 79 percent for components that were not cultured...The actual decision to culture (i.e., the culture rate) during the study period was 19 percent, a statistically significant difference from the 28 percent rate predicted per strict application of BEST criteria (P < .0001).” The authors stated that “[f]ollowing the BEST criteria would have resulted in an over 50 percent increase in the rate of cultured residual components or 103 additional component cultures...The highest rate of concordance was in reactions with hypotension, with 56 percent of the reactions meeting BEST criteria cultured in actual practice...Reactions meeting the remaining BEST criteria had less than 40 percent concordance with the decision to culture in actual practice...Comparison of the decision to culture across blood product types revealed that the concordance between actual practice and BEST culture recommendations was similar.” The study concluded that “BEST culture criteria provide objective recommendations for culturing transfusion reactions, but strict application of these criteria may result in increased culture rates with an unclear effect on diagnostic yield.”

Citation: Ruby, K.N., Khan, J., Martin, I.W., Dunbar, N.M. [Application of Standardized Residual Component Culture Criteria for Suspected Septic Transfusion Reactions Would Increase the Component Culturing Rate at a Single Academic Medical Center.](#) *Am J Clin Pathol.* 2022.

Contributed by Richard Gammon, MD, Medical Director at OneBlood 💧



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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize 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.

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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.

ABC Launches Meetings Survey

America's Blood Centers (ABC) recently distributed a [survey](#) evaluating all of our in-person meetings and workshops. We encourage participation from all individuals. Your feedback is considered an important part of the evaluation process and will be used to design meeting programs that best serve the needs of attendees. All responses are valuable whether you a member or non-member of ABC, regularly attend ABC meetings and/or workshops, or have not yet had the opportunity do so. Please submit your responses to the survey by Friday, August 31st. Contact [us](#) with any questions.

(Source: MCN 22-071, 8/10/22)

Elks Lodges Partner with ABC to Host Blood Drives throughout August

ABC and Elks Lodges recently announced a collaboration as part of ABC's national partnership with the Student Leadership Council (SLC), a Department of Veteran Affairs Student Volunteer program. Through this collaboration, Elks Lodges agreed to host blood drives during the month of August as "SLC students have chosen blood donation as part of their national volunteer initiative." ABC is assisting them to host blood drives in their local community to compliment the VA's national blood drive initiative. A blog post on the partnership written by ABC Chief Executive Officer Kate Fry, MBA, CAE was published on the Elks National Veterans Service Commission [Blog](#) on August 8th. Please contact ABC Director of Strategic Communications and National Partnerships [Jeff Gohringer](#) with any questions.

(Source: Elks National Veterans Service Commission [Blog](#), 8/8/22)

ABC Partners to Attempt World Record Blood Drive

America's Blood Centers (ABC) recently [announced](#) a partnership with [Who is Hussain](#), a global not-for-profit community service organization that is partnering with blood centers internationally and across the U.S. in an attempt to break the world record for blood donations from a single group in a 24-hour period. This event serves the dual purpose of increasing blood donations and blood donation awareness, while educating individuals about the need for blood donation worldwide from new and diverse donors. The current world record stands at 33,000 blood donations worldwide. Their global goal is to generate more than 50,000 donations on August 27, 2022 – a day they are calling #GlobalBloodHeroes Day. Some ABC member centers are already working directly with Who is Hussain on this effort as they attempt to connect prospective donors to local, participating blood centers. We are inviting all interested members to join this effort. Note that you do not need to be listed on their website to take part. Each participating blood center should confirm their donation figures via email to Official World Record, a verification body recognized by the Council of Notariats of the European Union. More information about the confirmation process is available to ABC members in MCN 22-069. Please contact ABC Director of Strategic Communications and National Partnerships [Jeff Gohringer](#) with any questions.

(Source: MCN 22-069, 8/9/22) 💧



PEOPLE



Lina Barbieri, CFRE has been named Chief Philanthropy Officer at Miller-Keystone Blood Center. In this role she will be “responsible for all operations of the blood center’s fund development department, including but not limited to, individual giving, corporate and community partnerships, special events, grant applications,” according to a company news release. “She will also play an integral role in maintaining and extending the blood center’s brand in the communities it serves.” The news release added that “Ms. Barbieri graduate[d] [from] DeSales University (Center Valley, PA) with a degree in Business Communications, and received her certification as a Certified Fund Raising Executive (CFRE) in 2013. Prior to joining the Blood Center, she served as Associate Vice President of Annual Giving at DeSales University. She also was owner of Lina Barbieri Public Relations for five years and has held marketing and communications positions with DeSales University, Cabrini College, Muhlenberg College, and Binney & Smith.”

(Source: Miller-Keystone Blood Center News Release 8/16/22) ◆

MEMBER NEWS

LIFELINE Blood Services recently kicked off its 75th [anniversary](#) celebration. “We are excited to celebrate our 75th Anniversary,” said Melinda Reid, marketing manager at LIFELINE, according to WNWS. “The need for blood remains as relevant now as it did 75 years ago, and we are proud to serve West Tennessee and continue to provide safe blood products for the communities we serve. We look forward to celebrating our 75th throughout the next 12 months in the communities we serve with our donors and supporters.” The blood center first opened its doors in August 1947 as Jackson Medical Laboratory and Blood Bank and has been a community staple ever since. “What was once just a vision of Jack and Martha Smythe’s has turned into something very special,” said John B. Miller, chief executive officer of LIFELINE and president of America’s Blood Centers. “Our mission is to provide a safe and adequate supply of blood and its components to every area patient in need. For 75 years, we’ve been successful in doing that and it’s all thanks to the generosity of donors in the communities we serve.”

(Source: WNWS, [LIFELINE Blood Services celebrates 75th anniversary, Thursday](#), 8/17/22)

Gulf Coast Regional Blood Center has [joined](#) the Blood Emergency Readiness Corps (BERC) becoming its 33rd member. “Unfortunately, there’s a growing number of disasters across our communities and nation,” said Theresa Pina, vice president of Operations at Gulf Coast Regional Blood Center and President of the ADRP Advisory Board in the announcement. “We are proud to join [BERC] to extend our life-saving mission in critical times.” BERC was founded in 2021 as a coalition of blood centers joining forces to prepare to meet the immediate transfusion needs when faced with a large-scale emergency situation that requires blood. The participating blood centers “commit to collecting extra units on a rotating “on-call” schedule to create an available supply of blood for emergency needs.”

(Source: Gulf Coast Regional Blood Center [Announcement](#), 7/15/22) ◆

GLOBAL NEWS

The World Health Organization (WHO) [announced](#) the publication of its initial guideline for Ebola virus disease therapeutics. The guideline includes “strong recommendations for the use of two monoclonal antibodies [mAb114 (Ansuvimab; Ebanga) and REGN-EB3 (Inmazeb)]... The two recommended

(continued on page 6)

GLOBAL NEWS (continued from page 5)

therapeutics have demonstrated clear benefits and therefore can be used for all patients confirmed positive for Ebola virus disease, including older people, pregnant and breastfeeding women, children, and newborns born to mothers with confirmed Ebola within the first seven days after birth. Patients should receive recommended neutralizing monoclonal antibodies as soon as possible after laboratory confirmation of diagnosis. There is also a recommendation on therapeutics that should not be used to treat patients: these include ZMapp and remdesivir.” The agency added that in spite of the strong recommendations for the two monoclonal antibody treatments, “there is a need for further research and evaluation of clinical interventions, as many uncertainties remain.”

(Source: WHO [News Release](#), 8/19/22)

The BBC reported this week that the Isle of Man, part of the British Isles, is planning to revise its current lifetime blood donor deferral policy for sexually active gay and bisexual men. According to the news outlet, “Health Minister Lawrie Hooper said there was a ‘willingness’ to change the eligibility criteria to individual assessments.” He added, “[t]he Isle of Man to this day does not allow gay men to donate blood, an archaic rule that was placed into force at the height of the AIDS pandemic... Ultimately the aim is absolutely to move to that position of equality where the ability of give blood is based on whether or not the blood is safe to be used.”

(Source: *BBC*, [Isle of Man to update blood donation rules for gay men](#), 8/17/22)

The WHO “convened” global experts who have “[agreed](#) on new names for the monkeypox virus variants.” According to the announcement from the WHO, experts approved identifying the virus and variants, or clades, with Roman numerals. The agency stated, “[c]onsensus was reached to now refer to the former Congo Basin (Central African) clade as Clade one (I) and the former West African clade as Clade two (II). Additionally, it was agreed that the Clade II consists of two subclades... [T]he new naming convention comprises Clade I, Clade IIa and Clade IIb, with the latter referring primarily to the group of variants largely circulating in the 2022 global outbreak. The naming of lineages will be as proposed by scientists as the outbreak evolves. Experts will be reconvened as needed. The new names for the clades should go into effect immediately while work continues on the disease and virus names.”

(Source: WHO [News Release](#), 8/12/22) 💧

COMPANY NEWS

Novavax, Inc. [announced](#) the submission of an application to the U.S. Food and Drug Administration (FDA) for emergency use authorization (EUA) of its COVID-19 vaccine as a “homologous and heterologous booster in adults aged 18 and older.” According to a company news release, “the application for EUA is supported by data from Novavax’s Phase 3 PREVENT-19 trial conducted in the United States and Mexico, and from the United Kingdom-sponsored COV-BOOST Phase 2 trial. As part of an open-label booster phase of the PREVENT-19 trial, a single booster dose of the Novavax COVID-19 Vaccine, Adjuvanted was administered to healthy adult participants at least six months after their primary two-dose vaccination series of the Novavax COVID-19 Vaccine, Adjuvanted. The third dose produced robust antibody responses comparable to or exceeding levels associated with the efficacy data in the primary series Phase 3 clinical trials. In the COV-BOOST trial, the Novavax COVID-19 Vaccine, Adjuvanted induced a significant antibody response when used as a heterologous third booster dose. In the PREVENT-19 trial, following the booster, local and systemic reactions had a median duration of approximately two days. Safety reporting of

(continued on page 7)

COMPANY NEWS (continued from page 6)

reactogenicity events showed an increasing incidence across all three doses of the Novavax COVID-19 Vaccine, Adjuvanted, reflecting the increased immunogenicity seen with a third dose. Medically attended adverse events, potentially immune-mediated medical conditions, and severe adverse events occurred infrequently following the booster dose.” The FDA previously [authorized](#) Novavax’s COVID-19 vaccine last month for emergency use in adults as a two-dose primary vaccination series to prevent COVID-19.

(Source: Novavax, Inc. [News Release](#), 8/15/22)

The FDA has [accepted](#) a biologics license application (BLA) submission for priority review from **Gamida Cell Ltd.** for the company’s investigational cellular therapy for “patients with blood cancers in need of an allogeneic hematopoietic stem cell transplant.” Data accompanying the BLA “is supported by the statistically significant results from Gamida Cell’s pivotal Phase III study, the results of which were [published](#) in *Blood*...Results for the study’s primary endpoint, the median time to neutrophil engraftment in patients with hematologic malignancies undergoing allogeneic bone marrow transplant with [the investigational therapy] compared to standard umbilical cord blood (UCB), demonstrated a median time to neutrophil engraftment of 12 days for patients randomized to omidubicel compared to 22 days for the comparator group ($p < 0.001$). The secondary endpoints of this Phase III study were all achieved and were statistically significant. These secondary endpoints were platelet engraftment, the rate of infection, and days alive and out of hospital. [The investigational cellular therapy] was generally well tolerated in the Phase III study.” The company reported that the FDA “has set a Prescription Drug User Fee Act (PDUFA) target action date of January 30, 2023...and is not planning an advisory committee meeting as part of the BLA review” at this time.

(Source: Gamida Cell [News Release](#), 8/1/22) 💧

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.)*

2022

Aug. 29-30. **NHLBI of the National Institutes of Health (NIH) and the Office of the of the Assistant Secretary of Health (OASH) of the Department of Health and Human Services (HHS) 2022 State of the Science in Transfusion Medicine Workshop (Virtual)**. Registration is [open](#). More information available [here](#).

Sept. 19-22. **American Association of Tissue Banks Annual Meeting, San Antonio, Texas**. More information available [here](#).

Sept. 21-22. **28th IPFA/ Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Porto, Portugal**. Registration is [open](#). More information available [here](#).

Sept. 28-29. **2022 ADRP Master Class (Virtual)**. Registration is [open](#).

Sept. 28-29. **BEST Meeting LXIV, Cocoa Beach, Fla.** More information available [here](#).

Oct. 1-4. **Association for the Advancement of Blood & Biotherapies Annual Meeting, Orlando, Fla.** Registration is [open](#). More information available [here](#).

Nov. 15-16. **The Biomedical Advanced Research and Development Authority (BARDA) Industry Day (Virtual)**. More details available [here](#).

(continued on page 8)

CALENDAR (continued from page 7)

2023

Mar. 6-8. **ABC Annual Meeting, Washington, D.C.** More information coming soon.

May 9-11. **2023 ADRP Conference, Charlotte, N.C.** More information coming soon. 💧

Upcoming ABC Webinars – Don't Miss Out!

- **ABC HIPAA & Privacy in Blood Banking Webinar** – September 13 from 3-4 PM EDT. More information coming soon.
- **ABC Cybersecurity Threats & Mitigation for Blood Centers Webinar** – September 20 from 3-4 PM EDT. More information coming soon.

EQUIPMENT AVAILABLE

For Sale. New and Unused CompoMat G5 Units. The Blood Bank of Alaska has three new and unused CompoMat G5 Units for sale. These units have not been validated or used. If interested, please contact Bryan Baynard at bbaynard@bbak.org or (907) 222-5664.

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

POSITIONS

Divisional Director. The Blood Connection, formerly Carolina-Georgia Blood Center, is expanding our operations into Augusta, Georgia! We are one of the fastest growing blood centers in the country and we are looking to hire a Divisional Director who will be responsible for our day-to-day operations and help direct our expansion of services into this new territory. The ideal candidate is a results-focused self-starter with progressive leadership experience and the drive to help fulfill the needs of our community partners. We offer a generous benefits package including a great 401k match, tuition reimbursement, yearly increases, company bonus, cell phone stipend, and 30 days PTO. Join our team and help make an impact in your community today! Click [here](#) to apply.

Donor Testing Laboratory Director. LifeSouth Community Blood Centers and The National Blood Testing Cooperative (NBTC) are currently seeking a skilled individual for the Donor Testing Laboratory Director position in the NBTC owned Donor Testing Laboratory in **Stone Mountain, GA**. This position is responsible for the strategic planning, development, organization, coordination, management, and daily oversight of all activities associated with a blood testing laboratory. This

position will also ensure the laboratory performs in accordance with all regulatory requirements and will possess the oversight and responsibility of all standard operating procedures (SOPs) within the lab. Must have bachelor's degree in: chemical, physical, biological, clinical laboratory science, or medical technology. Scientific and technical knowledge from current sources, such as the AABB Standards and relevant guidances related to FDA, CLIA, and CMS, both state and federal. Minimum of four years of management/supervisory experience required; Equivalent combination of demonstrated work experience and education may be considered. Starting salary range is \$135,000 - \$150,000 annually. Click [here](#) to apply.

Quality Assurance Specialist - R2219597 (Stanford Blood Center). Responsibilities: Cover the quality essentials and perform regulated tasks addressing organization, resources, equipment, supplier & customer issues, process control, document and records, deviations and adverse events, assessments, process improvement,

(continued on page 9)

POSITIONS (continued from page 8)

and facility & safety. Assist in training appropriate personnel pertaining to QRA and safety activities. Ensure compliance to current regulations, accreditation standards, guidance documents and policies and procedures consistent with the latest releases of Code of Federal Regulations, California Code of Regulations, Health & Safety Codes, Business and Professions Code, AABB Blood Bank and Transfusion Services and College of American Pathologist accreditation standards including local Bills (Assembly and Senate Bills) and applicable County Directives. Perform regulated document reviews of standard operating procedures, forms, training plans, other pertinent documents, change controls, and validations. Also, review and monitor incident and deviation management through the different Quality Management System applications. Act as member of the safety committee member and perform designated roles as Emergency Response Team (ERT), Assembly Point Coordinator (APC). Facilitate external inspection conducted by inspectors. Qualifications: Bachelor's degree required. Three plus years to five years in blood banking, laboratory, or manufacturing with solid familiarity of GMP, safety in a manufacturing setup, and CAL-OSHA regulations required. Please click [here](#) to view the full job description and apply.

Sr. Vice President, Contracting and Business Development (Blood Centers of America). Blood Centers of America (BCA) is a national cooperative comprising over 50 blood center members. BCA is seeking an individual with industry experience to serve as a Sr. Vice President, Contracting and Business Development. Candidate will be responsible for identifying and pursuing opportunities that meet the company's objectives for growth and /or savings. Position negotiates agreements with healthcare manufacturers, distributors and other suppliers that support the operations of the BCA membership. In addition, this position seeks and establishes relationships and contracts with Cell Therapy companies, CRO's, Cell Banks and Academic Researchers and Plasma companies. Candidate should have eight to 10 years of experience in business development in the healthcare products industry or progressive managerial experience in health care or blood center industry. Candidate should have an in-depth knowledge of blood center operations, and strong negotiation skills. Position requires approx. 20-30% overnight travel. Submit resume to careers@bca.coop. Click [here](#) to view the detailed job description. 💧