



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2022 #17

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Grant Funding Opportunities Analysis for Blood Centers Available to ABC Members

America's Blood Centers (ABC) is providing a new resource to member blood centers. The Grant Funding Opportunities Analysis is tailored for ABC member centers and was commissioned by ABC to identify targeted federal grant programs for which ABC member centers may be eligible to apply.

The final Grant Funding Opportunities Analysis is available to ABC member blood centers in MCN 22-042. This comprehensive document contains:

- an overview of grants including searching and competing for grants, grant compliance and lifecycle considerations, and best practices;
- a review of specific grant programs. The identified programs were included based on the type of projects blood centers may be undertaking and the fact that blood centers may be eligible for funding under these grant programs;
- and resources about where to look for grants and how to navigate the Grants.gov website (which must be used for federal grant applications).

This Grant Funding Opportunities Analysis was completed exclusively for the benefit of ABC member centers and should not be shared outside of ABC membership. Please provide any feedback, questions, or concerns, to ABC Senior Director of Federal Affairs [Diane Calmus, JD](#).

At the ABC Annual Meeting in March 2022, a one-day Advocacy Workshop took place that included a session on federal funding opportunities, both grants and earmarks. Attendees received an overview on federal grants and discussions took place to gather information, which laid the foundation for this report to meet the specific needs of independent community blood centers.

(Source: MCN 22-042, 5/6/22)

CBER Updates 2022 Guidance Agenda

This week, the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has [published](#) an updated guidance agenda for 2022. The agenda outlines the guidance and draft guidance documents that CBER "is considering for development" throughout the calendar year. The agency added two topics that were not included in the January announcement of the agenda:

(continued on page 2)

CBER Updates Guidance Agenda (continued from page 1)

- “Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components; Guidance for Industry; [and]
- Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry.”

Other topics of note that the agency intends to address that remain from the earlier announcement include:

- “Blood Pressure and Pulse Donor Eligibility Requirements; Compliance Policy Draft Guidance for Industry;
- Alternative Procedures for Cold-Stored Platelets Intended for Transfusion Draft Guidance for Industry;
- Collection of Platelets by Automated Methods; Guidance for Industry;
- Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; Draft Guidance for Industry; [and]
- An Acceptable Circular of Information for the Use of Human Blood and Blood Components: Guidance for Industry.”

The topics listed for tissue and advanced therapies included:

- “Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) – Small Entity Compliance Guide; Guidance for Industry; [and]
- Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry; [and]
- Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft 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 [Jill Mastin](#) with questions.

(Source: FDA [Announcement](#), 5/9/22) 💧

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The [calendar of events](#) includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

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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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RESEARCH IN BRIEF

Platelet Transfusion and Outcomes after Massive Transfusion Protocol Activation. A study published in *Anesthesia and Analgesia* emphasized that a hospital's "laboratory can return an emergency hemorrhage panel of conventional coagulation tests within 15 minutes." The authors noted that [this] study aimed to describe early (first 4 hours) platelet transfusion practice in massively transfused (MT), severely injured trauma patients and to assess any association between early platelet transfusion and in-hospital mortality." The "hypothesis was that platelet transfusion in resuscitation of severe trauma can be guided by rapid turnaround platelet counts without excess mortality." Included were "all trauma patients aged ≥ 15 years admitted between October 1, 2016 and September 30, 2018 who had been triaged to a trauma team activation, suggesting life-threatening injury...[The] massive transfusion protocol (MTP) response include[d] transport of six units of red blood cells (RBCs), six units of thawed or never-frozen liquid plasma, and a unit of apheresis platelets to the bedside in < 5 minutes in a portable blood transporter...Blood product use for 469 patients met the definitions of MT, and these patients were included in [the] final study cohort. The authors observed that, "[r]eceiving platelets in the 1st 4 hours was strongly positively associated (all P values $\leq .001$) with increased Injury Severity Scores (ISS), shock index, base deficit, blood lactate concentration, and international normalization ratio (INR), and strongly negatively associated with admission blood pH, hemoglobin, and platelet count (all P values $< .001$)...Overall blood product use differed markedly between early platelet recipients and later/nonrecipients, most early platelet recipients (175 of 250, 70 percent) received their first platelet transfusion in the first hour of care...Among the 219 patients who did not receive platelets in the first 4 hours, 46 (21 percent) received 5 or more units of RBCs in the first 4 hours." The study "saw no difference in 4-hour (8 vs 7.8 percent; P = 0.4), 24-hour (16.4 vs 10.5 percent; P = 0.06), or in-hospital mortality (30.4 vs 23.7 percent; P = 0.1) between platelet recipients and nonrecipients." The authors concluded that "early platelet transfusion guided by protocol-based clinical judgment and rapid-turnaround platelet counts was not associated with increased mortality."

Citation: Aichholz, P.K., Lee, S.A., Farr, C.K., Tsang, H.C., Vavilala, M.S., Stansbury, L.G., Hess, J.R. [Platelet Transfusion and Outcomes After Massive Transfusion Protocol Activation for Major Trauma: A Retrospective Cohort Study.](#) *Anesth Analg.* 2022.

Contributed by Richard Gammon, MD, Medical Director at OneBlood 

Upcoming ABC Webinars – Don't Miss Out!

- **The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Need-ASCP Blueprint Webinar** – July 20th from 3-4 PM EDT. More information coming soon.
- **ABC SMT Journal Club Webinar** – August 10th from 3-4 PM EDT. More information coming soon.

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.



WORD IN WASHINGTON

The House Energy and Commerce Committee has drafted the U.S. Food and Drug Administration (FDA) user fee legislative package. According to AgencyIQ, “Section 802 of the bill contains language that “would streamline FDA requests for feedback on blood donation. Under this provision, Congress would exempt the FDA’s solicitations for ‘views and perspectives of patients’ on blood donation policies from the Paperwork Reduction Act requirements for information collection. Overall, this would lessen the burden for regulators seeking information that would ‘support the development of recommendations’ about blood donation. The FDA is currently looking at alternatives to the time-based deferral system for blood donation eligibility – although research in that area was delayed by the Covid-19 pandemic.”

(Source: AgencyIQ Announcement, 5/10/22)

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services (HHS) has published a report titled “Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce: Challenges and Policy Responses.” According to a news release announcing the report, the publication “combines a survey of the literature and primary analysis of data from the Census Bureau, Bureau of Labor Statistics, and other sources, with a focus on the hospital and outpatient clinician workforce, in order to describe workforce shortages both prior to and during the pandemic, COVID-19 impacts on the mental and physical health of the health care workforce, and an overview of federal interventions and investments to support the health care workforce during the pandemic.” Topics addressed in the report include:

- healthcare workforce shortages and maldistribution;
- healthcare workforce burnout and mental health;
- healthcare workforce physical health;
- federal efforts to support health care workforce during the pandemic; and
- future opportunities moving forward for the health care workforce.

(Source: ASPE [News Release](#), 5/3/22)

Kaufman Hall has released a “Special Workforce Edition” of its “National Hospital Flash Report: The Financial Effects of Hospital Workforce Dislocation.” The report describes how the pandemic exacerbated a national shortage of healthcare workers and increased expenses for hospitals. Findings of the report include:

- nationally, hospital labor expenses increased by more than one-third from pre-pandemic levels;
- the largest increases were in the South and West, while the highest expense levels consistently were in the West and Northeast/Mid-Atlantic;
- contract labor as a percentage of total labor expenses increased more than five times the rate from pre-pandemic levels;
- as of March 2022, the median wage rate for contract nurses had risen to more than three times that of employed nurses; and
- in the first three months of 2022, hospitals saw dramatic declines in YTD operating margin in a perfect storm of expense, volume, and revenue pressures attributable largely to the effects of COVID.

(Source: Kaufman Hall [Announcement](#), 5/11/22) ◆



PEOPLE

Daniela Hermelin, MD has been [appointed](#) Chief Medical Officer of ImpactLife. Dr. Hermelin will assume her new role on July 1st as current Chief Medical Officer Louis Katz, MD transitions to emeritus status. “We are very fortunate to introduce Dr. Hermelin as our new chief medical officer,” said Mike Parejko, president and chief executive officer of ImpactLife in a news release. “She is a highly regarded specialist in transfusion medicine who brings a wealth of experience from her previous roles with Saint Louis University and SSM Health. I have great confidence in her ability to succeed Dr. Katz in this critical leadership role. According to the news release, “Dr. Hermelin is currently an assistant professor of Pathology at St. Louis University School of Medicine and the medical director of Transfusion Services at SSM Health St. Louis University Hospital and SSM Health Cardinal Glennon Children’s Hospital...[She] completed a residency in Anatomic and Clinical Pathology in 2019, followed by a fellowship in Transfusion Medicine at SSM Health St. Louis University Hospital...Dr. Hermelin was a recipient of an AABB 2019 President’s Award recognizing her use of social media to share her knowledge in the fields of Blood Banking and Transfusion Medicine with students and fellow practitioners. [She] serves as the social media editor for *Transfusion Medicine Reviews* as well as an associate editor of ‘The Blood Bank Guy Essentials Podcast and Transfusion News.’ Additionally, Dr. Hermelin is an active member of numerous professional associations including the Association for the Advancement of Blood and Biotherapies (AABB), The American Society for Apheresis (ASFA), The College of American Pathologists (CAP), American Society for Clinical Pathology, and the International Society of Blood Transfusion (ISBT).”



(Source: ImpactLife [News Release](#), 5/12/22) ♦

NEW on CollABORate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC [CollABORate](#) Online Member Community include:

- [Historical Antigen Typing Criteria Question](#) (ALL MEMBER FORUM)
- [MSM Trends](#) (MEDICAL ISSUES)
- [Customer Service Investigations](#) (COLLECTIONS & DONOR SERVICES)
- [Documentation of Customer Service](#) (QUALITY BYTES)
- [Issue with rWBC Testing](#) (TECHNICAL DIRECTORS)

ABC members are encouraged to [login](#) and join the conversations today!



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 staff only, unless otherwise specified.

ABC MD Workshop and Summer Summit

Mark your calendar for the [ABC Medical Directors Workshop and ABC Summer Summit](#) taking place August 2-4 in Minneapolis, Minn. Over the course of two days, attendees will hear case study rounds, engaging discussions, and have many networking opportunities to connect with peers and colleagues. [Hotel reservations](#) can be made now through the ABC block. 💧

MEMBER NEWS

Héma-Québec has [reported](#) its findings from the fourth phase of a seroprevalence study of blood donors that estimates “more than one in four Québec adults developed antibodies to COVID-19 due to infection” in the first quarter of 2022. A news release explaining the findings stated, the “analyses were done with tests able to identify antibodies present in people recently infected by SARS-CoV-2. The approach compares the level of antibodies in the same individual, based on two samples taken at different times. A first sample was collected prior to the arrival of the Omicron variant of concern and another was collected from the same person in 2022, once the Omicron wave was well underway. Using plasma donated to the PLASCOV project, this study estimated that 27.8 percent of the adult Québec population had contracted COVID-19 between the end of 2021 and March 2022.”

(Source: Héma-Québec [News Release](#), 5/9/2022)



Photo courtesy of ImpactLife

ImpactLife recently [welcomed](#) Bob Barnes of Syracuse, N.Y. who is in the process of biking cross-country to visit all 50 state capitols over 12 months to raise awareness for blood donation. Mr. Barnes donated platelets at an ImpactLife donor center in Cedar Rapids, Iowa on May 11th and intends to donate again with ImpactLife in Madison, Wis. as he is more than 12,000 miles through his journey. “I don’t have a lot of means financially, and blood is something I can give and anybody who is eligible should give because I think it’s the human thing to do,” said Mr. Barnes to *The Gazette*. According to the publication, Mr. Barnes “started the trip Aug. 1 last year, and plans to make it to Juneau, Alaska, by Aug. 1, then fly to Hawaii. After pedaling from the airport to the state capitol, Barnes said he plans to

spend some time in Hawaii as a reward for the yearlong endeavor.”

(Source: *The Gazette*, [New York man stops in Iowa on cross-country bike tour to encourage blood donations](#), 5/13/22) 💧

GLOBAL NEWS

The Lithuanian Health Ministry has [revised](#) its donor history questionnaire for blood donors. According to a report in *The Baltic Times*, all individuals who present to donate blood will be asked “the same question about unprotected sexual relations they have had in the last six months” as a question asking men about sexual contact with other men was removed as of May 1st. “By making it possible for [gay and bisexual men] to become blood donors, Lithuania is coming out of the fear and closed-mindedness,” said Tomas Vytautas Raskevicius, a Lithuanian lawmaker. “A person’s ability to become a blood donor is not determined by their sexual orientation but by their behavior and health.”

(Source: *The Baltic Times*, [Lithuania changes rules for homosexual blood donors](#), 5/2/22) 💧

COMPANY NEWS

Terumo Blood and Cell Technologies has been [awarded](#) a \$10.6 million contract to continue its works on freeze-dried plasma, which “can be kept at room temperature and is ready in minutes after reconstituting it with medical-grade water.” According to a company news release, the contract partners Terumo Blood and Cell Technologies with the Medical Technology Enterprise Consortium (MTEC), a 501(c)(3) “biomedical technology consortium collaborating under an Other Transaction Agreement (OTA) with the U.S. Army Medical Research and Development Command, and is sponsored by the Defense Health Agency (DHA) and managed by the Naval Medical Research Center (NMRC) to drive healthcare advances for the battlefield.” Terumo Blood and Cell anticipates using the funds to further “product development” as it prepares for future “clinical studies and continued verification testing.” Currently, the company is developing bags that resemble standard blood bags to reconstitute the freeze-dried powder quickly.” Chetan Makam, general manager of Global Blood Solutions at Terumo Blood and Cell Technologies added in the news release, “[y]ou can only imagine that it’s nearly impossible to carry a giant freezer with frozen plasma into a conflict or trauma zone. And at home many hospitals outside major urban settings do not have plasma readily available because of the logistics of managing it. We envision a day when clinicians can use our freeze-dried, shelf-stable plasma to provide the same level of therapy for severe bleeding no matter where it happens — whether it’s on a battlefield or a remote highway, in a midsize hospital or at a top-tier academic medical center.”

(Source: Terumo Blood and Cell Technologies [News Release](#), 4/26/22)

Grifols recently finalized the [acquisition](#) of **Biotest AG**, a European healthcare company specializing in innovative hematology and clinical immunology. A news release announcing the acquisition stated the transaction “expands and diversifies” Grifols’ plasma supply, while allowing the companies “to jointly increase the global availability of plasma-derived therapies.” The acquisition also adds 29 Biotest plasma centers under Grifols’ umbrella of plasma centers making it the largest private European network of plasma centers.

(Source: Grifols [News Release](#), 4/25/22) 💧

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

June 4-8. **37th Annual International Congress of ISBT (Virtual)**. More information available [here](#).

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CALENDAR (continued from page 7)

June. 7-9. **U.S. Food and Drug Administration (FDA) Virtual Public Workshop — Building Medical Device Supply Chain Resilience: A Healthcare and Public Health Ecosystem-wide Collaboration.** More information available [here](#).

June. 6-10. **FDA Regulatory Education for Industry (REdI) Annual Conference 2022 (Virtual).** More information available [here](#).

June. 9-10. **FDA Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) Meeting (Virtual).** More information available [here](#).

Aug. 2-4. **ABC Summer Summit and Medical Directors Workshop, Minneapolis, Minn.** More information coming [soon](#).

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

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

2023

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

May 9-11. **2023 ADRP Conference.** More information 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 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

Director of Recruitment (Bradenton, FL). SunCoast Blood Centers is accepting applications for a Director of Recruitment to work at our Lakewood Ranch Head Quarters. This position directs and oversees mobile, fixed site and concierge recruitment activities. Other duties include: Designs and directs a comprehensive donor recruitment and retention plan for the organization. Counsels and evaluates the performance of direct reports. Oversees processes related to the coaching and mentoring of recruitment management staff to assure a well-functioning team. Manages the data base of blood donors and donor groups to assure successful strategies to meet collection goals, standards, and efficiency measures, and other duties as required to fulfill the organizations mission and vision. Qualified applications should possess a bachelor's degree in public relations, marketing, or other equivalent experience. Applicant must have five years recruitment, healthcare sales, or marketing, plus three years in a senior leadership role. To apply and view a complete

job description of this position please visit <https://sun-coastblood.org/careers/>. EOE. Applicant drug testing required.

Chief Administrative Officer (Shreveport, LA). LifeShare Blood Center (LSBC) is seeking an experienced human resource, risk management or business administration professional as our **Chief Administrative Officer (CAO)**. Reporting to the President & CEO, the CAO develops and administers Company-wide policies and practices to facilitate business operations and manage risk exposures; ensures compliance with applicable laws, standards and regulations governing various areas of responsibility; provides executive leadership of human resources, health, safety, benefit plan, commercial and professional liability insurance, donor claims management, and other risk management efforts; provides

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POSITIONS (continued from page 8)

executive oversight of the IT infrastructure, including computer software systems, servers and networks, enterprise systems, data integrity and security, and business continuity protocols; provides direction of quality assurance and regulatory affairs to ensure achievement of goals and objectives and compliance with standards and regulations governing the blood banking industry. Oversees LifeShare Phlebotomy School operations to ensure all accreditation requirements are met. Degree in human resources, business management or related field; 10 years management experience in HR, legal compliance, or risk management. LSBC offers a competitive beginning salary, commensurate with experience and a generous benefits package. **Join us in our important mission to connect blood donors and the lives they impact!** Apply at [Careers Page](#).

Area Operations Director – Donor Recruitment and Blood Collections (south Louisiana regions). LifeShare Blood Center is seeking an Area Operations Director to provide leadership and strategically direct all donor recruitment and blood collection operations of our south Louisiana regions (Baton Rouge, Lafayette, Lake Charles, LA and Beaumont, TX). Relocation assistance may be available for the right candidate. The Area Director will provide guidance, oversight, and supervision to regional directors in the execution of donor recruitment strategies and achievement of red cell, platelet, and plasma collection goals, ensuring compliance with company policies, standard operating procedures, and applicable regulatory and accreditation guidelines. The ideal candidate holds a bachelor's degree in a healthcare or business-related discipline and at least six (6) years of progressively responsible operations management experience, preferably in a blood banking setting, plasma center or manufacturing center; demonstrated experience in leading teams in a regulatory environment preferred; working knowledge of FDA regulations governing blood collection establishments, OSHA and cGMP guidelines for laboratory operations preferred. LifeShare offers a competitive beginning salary, commensurate with experience and a generous benefits package. **Join us in our important mission to connect blood donors and the lives they impact!** Visit our [Careers Page](#) to apply.

Regional Operations Director. LifeShare Blood Center is seeking an Operations Director to oversee blood collection and donor recruitment operations in the Monroe, LA region. Relocation assistance may be available for the right candidate. The Operations Director will develop and implement strategic and tactical plans for donor recruitment and collections within the donation center and community-based activities; direct, develop and coach teams for achievement of established goals and KPI's; develop relationships with community leaders and groups to promote our mission and business needs; ensure operations adhere to standards and regulations governing the

blood banking industry; and model LifeShare's mission and values, integrating them into daily decisions, behaviors, and actions. The ideal candidate has a bachelor's degree in a healthcare or business-related discipline, plus at least five (5) years of operations management experience, including supervisory experience in the direction and coaching of other employees; working knowledge of FDA regulations governing blood collection establishments, OSHA and cGMP guidelines for laboratory operations preferred. LifeShare offers a competitive salary, commensurate with experience plus incentive bonus opportunities, as well as a generous benefits package. **Join us in our important mission to connect blood donors and the lives they impact!** Visit our [Careers Page](#) to apply.

Director of Regulatory Affairs and Quality Compliance. Director of Regulatory Affairs and Quality Compliance. The Blood Connection is looking for a Director of Regulatory Affairs and Quality Compliance. This is a newly created position reporting to the Vice President of Quality Systems. The Director of Regulatory Affairs and Quality Compliance would be responsible for providing leadership with regulatory guidance ensuring ongoing compliance for the organization. This role will monitor the release of new or revised regulations and standards, evaluating the impact on current processes and practices, and recommend changes if necessary to ensure continual compliance. The Director will evaluate investigations of incidents/occurrences reported and participate in the investigation, root cause analysis, and development of corrective action plans. This role will lead the Quality Unit staff by coaching, managing, monitoring, and evaluating compliance activities and promoting ongoing compliance and effective processes ensuring adherence to applicable regulations and standards. We offer a generous benefits package including a great 401k match, tuition reimbursement, yearly increases, company bonus, cell phone stipend, and 30 days PTO. How to apply: <https://thebloodconnection.org/about-us/careers/> ♦