

Please Note: The *ABC Newsletter* will not be published on July 8th. We will resume regular publication on July 15th. Thank you for your continued interest.

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2022 #24

July 1, 2022

ABC-HOSA Partnership Kicks Off at HOSA's International Leadership Conference

America's Blood Centers (ABC) and HOSA – Future Health Professionals a 260,000 member-led organization in 5,000 schools and colleges across 48 states, previously announced a [partnership](#) focused on encouraging and nationally recognizing HOSA students involved in blood donation as well as promoting careers at community blood centers.

During the recent HOSA 2022 International Leadership Conference in Nashville, Tenn., ABC and HOSA formally commenced the partnership which included a blood drive conducted by ABC member blood center Blood Assurance. The drive resulted in close to 350 units being donated potentially saving an estimated 1,040 lives.



“The response we saw from the more than 300 attendees was nothing short of remarkable,” said J.B. Gaskins, chief executive officer (CEO) of Blood Assurance in an upcoming joint news release from ABC, Blood Assurance, and HOSA. “Our sincere thanks to HOSA and ABC for allowing us to be part of this awe-inspiring event. In a time when many longtime blood donors are becoming blood recipients, it gives us hope to see that there are so many altruistic young people who understand the importance of being someone’s hero by donating the gift of life. This past weekend, countless lives were saved because of them.”

ABC CEO Kate Fry, MBA, CAE added, “[t]his blood drive’s astounding success exceeded all expectations. HOSA students are tomorrow’s health care professionals, but they are already changing lives for the better today through their decision to take time out of their conference to donate blood. This is a strong start to our new

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ABC-HOSA Partnership Kicks Off (continued from page 1)

national partnership as we work to build the next generation of lifelong blood donors and promote careers across the blood community.”

As a part of this partnership, ABC will recognize HOSA chapters and state associations for outstanding achievements in the collection of blood at HOSA’s annual International Leadership Conference beginning with their 2023 event in Dallas, Texas.

For more information on the partnership please contact ABC Director of Strategic Communications and National Partnerships [Jeff Gohringer](#). 

High-titer CCP Trial Reopens in the UK

NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom (UK) [announced](#) this week that the first patient “has been treated” in a randomized reopened trial “seek[ing] to confirm evidence” that COVID convalescent plasma with very high antibody levels “from recovered ‘super donors’ benefits immunosuppressed people with coronavirus.” Trial participants include “[m]ore than 15 hospitals across all four countries of the UK [using CCP] supplied by donations to NHSBT. According to the NHSBT news release, “Only plasma with a very high antibody threshold, which is about ten times the threshold used in the original trials, will be used. The plasma will only come from people who have had both coronavirus and the vaccine, as they were found to have the highest antibody levels and the broadest reactivity against viral variants.”

Investigators added that the “highest antibody level recorded so far in the reopened trial came from a man in his 20s who had just over 100,000 units of antibodies per millilit[er], a figure around 100 times higher than that typically seen during the first wave of coronavirus.”

Additionally, the CCP donation will only come from the “existing donor base and there is no public appeal for new donors. Several hundred units are being donated at Birmingham and Twickenham. Further plasma will come from nearly 300 suitable units still in storage from the original trials. The units will be issued to participating hospitals on a named patient basis.”

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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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High-titer CCP Trial Reopens in the UK (continued from page 2)

Professor Lise Estcourt, who leads the clinical trial unit at NHSBT and serves as chair of this trial added in the news release, “[t]here’s a signal from [REMAP-CAP](#) [trial] that convalescent plasma can help immunosuppressed people but only if it comes from super donors with very high antibody levels. It would be a valuable treatment because some immunosuppressed people do not respond to the vaccine and monoclonal antibodies – which are often given to immunosuppressed people - may not work against emerging variants. It could also be of particular use in the developing world, where access to more expensive treatments is limited. Only a full, randomised controlled trial can provide a definite answer.”

Anthony Gordon, the UK chief investigator for REMAP-CAP, added, “[t]he REMAP-CAP trial was designed to be adaptive, providing high quality evidence to guide best treatments for severely ill patients with COVID-19 around the world. As we move to a different stage of the pandemic, we are pleased to be able to provide that evidence to ensure high-risk patients continue to receive the right combination of treatments.”

(Source: NHSBT [News Release](#), 6/30/22) ♦

REGULATORY NEWS

The U.S. Food and Drug Administration’s (FDA) Center for Biologics Evaluation and Research (CBER) has published its 2021 annual summary of Biological Product and Human Cells, Tissues, and Cellular Tissue-based Product (HCT/P) Deviation [Report](#). Deviations potentially affecting “safety, purity, or potency, as well as unexpected events that occur during the manufacturing of blood and blood products” must be reported to CBER in accordance with 21 CFR 606.171 or 1271.350(b). In addition, manufacturers of non-reproductive HCT/Ps regulated by FDA are “required to submit [deviation] reports” involving distributed products if “the deviation or the unexpected event is related to a core Current Good Tissue Practice requirement and related to the prevention of communicable disease transmission or HCT/P contamination.” The annual summary provides an overview of the reports FDA received during the most recent fiscal year, including detailed information regarding the number and types of deviation reports received. FDA combined data received over the last three fiscal years to compare data and highlight changes. During fiscal year 2021, Oct. 1, 2020 to Sept. 30, 2021, CBER entered 14,556 deviation reports into its database, a 52.9 percent decrease from FY 2020. “The total number of reporting establishments increased from 2,133 in FY20 to 2,152 in FY21. Compared to FY20, there were 28 more blood and [s]ource [p]lasma establishments, four fewer manufacturers of licensed biological products other than blood and blood components, and one more 361 HCT/P manufacturer reporting in FY21.”

(Source: CBER Biological Product and HCT/P Deviation [Reports](#) – Fiscal Year 2021, 6/28/22) ♦

WORD IN WASHINGTON

More than 20 Senators [signed](#) a June 24th [letter](#) sent to U.S. Food and Drug Administration Commissioner (FDA) Robert Califf, MD and U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra, JD requesting an update on the review of the FDA’s current donor deferral policy for men who have sex with other men (MSM). The letter states that the existing deferral policy is “outdated and discriminatory” and that a change is “a long overdue step that would dramatically increase the eligible donor base.” The Senators recognized and “applauded” the change that the FDA implemented during the COVID-19 public health emergency (PHE) and acknowledged the ongoing work of the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study.” However, they feel that “given the ongoing nationwide shortage of blood and blood products, it is critical that FDA take further

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WORD IN WASHINGTON (continued from page 3)

action...it is absolutely essential for FDA to take steps to increase the availability of blood and blood products to prioritize patient care. Following the conclusion of the ADVANCE study, we expect that FDA will utilize this new evidence to work expeditiously and develop an evidence-informed policy based on individualized risk factors that meets the urgent demands of the moment. The United States remains in a nationwide blood supply crisis for the first time. Now is the time for a new donor deferral policy that allows all potentially eligible donors to contribute free of stigma. Thank you for your attention to this important issue.”

Senators who signed the letter included:

- Tammy Baldwin (D-Wis.);
- Kirsten Gillibrand (D-N.Y.);
- Elizabeth Warren (D-Mass.);
- Jeff Merkley (D-Ore.);
- Bernie Sanders (I-Vt.);
- Sherrod Brown (D-Ohio);
- Bob Casey (D-Penn.);
- Richard Blumenthal (D-Conn.);
- Cory Booker (D-N.J.);
- Martin Heinrich (D-N. Mex.);
- Ed Markey (D-Mass.);
- Christopher Coons (D-Del.);
- Bob Menendez (D-N.J.);
- Mazie Hirono (D-Hawaii);
- Catherine Cortez Masto (D-Nev.);
- Ben Cardin (D-Md.);
- Ron Wyden (D-Ore.);
- Tammy Duckworth (D-Ill.);
- Angus King (I-Maine);
- Jacky Rosen (D-Nev.);
- Tina Smith (D-Minn.);
- Amy Klobuchar (D-Minn.);
- Tim Kaine (D-Va.);
- Michael Bennet (D-Col.); and
- Brian Schatz (D-Hawaii).

Earlier this year, Sen. Baldwin [led](#) similar efforts asking the FDA to revise the deferral policy.

(Source: Senate [Letter](#) to FDA and HHS, 6/24/22) 💧

RESEARCH IN BRIEF

Predictors of Pica in High-Intensity Blood Donors. Investigators from the National Heart, Lung, and Blood Institute’s (NHLBI) Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) program conducted the “Red Blood Cell (RBC)-Omics study to “investigate the quality of RBC units from blood donors. The study, whose results have been published in *Transfusion Medicine*, explored genomic and metabolic attributes of [RBC] units, and obtained detailed questionnaire data about pica symptoms [from donors] consisted of 13,403 [individuals] from four [U.S.] blood centers.” It featured “1,748 high-intensity donors who gave nine or more units of whole blood in the preceding two years.” The study “characterized

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RESEARCH IN BRIEF (continued from page 4)

the demographic, clinical, and biochemical predictors of pica in high-intensity donors and compared these to the remainder of the RBC-Omics population.” The authors explained that “[t]he study (n = 1,693) consisted of 1,112 males and 581 females between 18 and 87 years old...Donation frequencies ranged from nine to 13 units...At enrollment, a complete blood count (CBC) was obtained while plasma ferritin concentrations were measured.” Criteria for pica classification was: “consumed 8 oz or more ice at least daily and/or, consumed non-ice substances regardless of amount and frequency.” All (26/26) “of the donors with pica had ferritin <50 ng/ml...[A] general decline in pica behaviors was observed from younger to older donors ranging from 4.3 percent in 18–40-year-old donors to 0.4 percent in donors >70-years old (p = 0.001)...[There] was a higher prevalence of pica behaviors in obese donors (BMI ≥30, 2.5 percent, 14/ 565) than in normal/underweight (BMI 17.5–25, 1.3 percent, 6/490)...CBC parameters with iron deficiency positively associated with pica included lower hematocrit (p = 0.005), lower mean corpuscular volume (p < 0.001), and higher RBC distribution width (p = 0.007).” The authors noted that “variables were analyzed for associations with pica [and] hematocrit (OR = 0.835, p = 0.020) was independently associated...[H]igh-intensity donors were white, older (59 y vs. 44, p < 0.001), male[s] (66 vs. 47 percent, p < 0.001), [who] donated blood more frequently two years prior to enrollment (10.5 vs. 2.0, p < 0.001), and [were] more likely to have severe iron deficiency with ferritin <12 ng/ml (34.3 vs. 18.9 percent, p < 0.001)...[P]ica behaviors were less common among high-intensity donors (1.5 percent) compared to 2.2 percent in less frequent donors.” The study concluded that the “findings emphasize the need to continue to implement iron replacement programs, to reduce pica among donors and maintain a robust pool of frequent donors.”

Citation: Liu, H., Burns, R.T., Spencer, B.R., *et al.* [Demographic, clinical, and biochemical predictors of pica in high-intensity blood donors](#). *Transfusion Medicine*. 2022

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

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!





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.

ADRP Webinar: “School Is in Session!”

[Register](#) today for the Wednesday, July 27th ADRP webinar titled “School Is in Session!” This webinar will take place at 1 p.m. ET and feature Kenda Burnham (Community Blood Center of the Ozarks), Pete Lux (ImpactLife), and Brad Terry (Community Blood Center of the Ozarks) sharing their experiences with high school donor groups and strategies to mitigate risk, ensuring return invitations to schools.

(Source: ADRP [Announcement](#), 6/30/22)

Recording and Slides Available for U.S.-Wide Red Blood Cell Antibody Exchange Project Webinar

A recording and slides of the May 10th America’s Blood Centers (ABC) webinar on the “U.S.- Wide Red Blood Cell Antibody Exchange Project” are now available to ABC members. The webinar featured Jeanne Hendrickson, MD, medical director of the Apheresis Service and associate medical director of the Transfusion Medicine Service at Yale New Haven Hospital, providing background information and a status update on the project and its future direction. This project focuses on antibody exchange at the hospital level. ABC members can find the recording and slides in MCN 22-051. Contact [us](#) to receive a copy of the MCN.

Registration Opens for MD Workshop and Summer Summit

[Registration](#) is open for the [ABC Medical Directors Workshop and ABC Summer Summit](#) taking place August 2-4 in Minneapolis, Minn. A [preliminary program](#) is available. 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 until July 8th to receive the group rate. ♦

PEOPLE



Rob Van Tuyle has assumed the new role of chief operating officer (COO) at Vitalant. In this role Mr. Van Tuyle will provide executive leadership for blood services, all laboratory and clinical services, sales, and corporate marketing and communications. He will also help Vitalant leverage its sales and marketing talent across the organization and provide the infrastructure to support new product and service development. Mr. Van Tuyle is also the current America’s Blood Centers Board of Directors President-elect.

(Source: Vitalant Announcement, 6/29/22)

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PEOPLE (continued from page 6)

Steve Ferraiuolo has also been promoted to senior vice president of blood services operations. In this role, he will be responsible for Vitalant’s five blood services divisions, manufacturing, and hospital services. Mr. Ferraiuolo “joined Vitalant in 2017 and has more than 25 years of experience in the blood services industry. He’s held leadership roles in all aspects of operations, acquiring a broad understanding and essential knowledge to impart at Vitalant.”



(Source: Vitalant Announcement, 6/29/22) ◆

COMPANY NEWS

Terumo Blood and Cell Technologies and **GenCure**, a subsidiary of BioBridge Global [announced](#) a “new collaborative agreement to extend and unify cell and gene therapy solutions.” According to a news release, the agreement allows the organizations “to combine technologies and expertise to cater to the demand across the cell and gene therapy (CGT) industry for smart systems that are automated and closed. These smart-systems allow for real-time response and refinement to the living therapies being produced inside the systems.” The multi-phase collaboration is set to last three years. BioBridge Global Chief Executive Officer (CEO) Martin Landon added in the news release, “[a]cross the cell and gene therapy sector, collaborations are now proving vital to the rapid development of solutions to a number of key challenges. Our donor-to-patient solutions, which include cell collection, manufacturing, and testing, require the best technologies and expertise available in the market. Working with an innovator like Terumo Blood and Cell Technologies will allow us to provide a leading-edge end-to-end solution for cell and gene therapy manufacturing that will be vital to deliver advanced therapies to patients.”

(Source: Terumo Blood and Cell Technologies and GenCure Joint [News Release](#), 6/28/22)

Precision BioSciences, Inc. and **Novartis Pharma AG** have [partnered](#) to develop an investigational gene therapy to treat sickle cell disease and beta thalassemia. According to the announcement, the exclusive agreement between the two companies Precision BioSciences “will develop a custom [treatment using its proprietary genome editing technology] that will be designed to [be] insert[ed], *in vivo*,” to treat patients with certain hemoglobinopathies.

(Source: Precision BioSciences, Inc. [News Release](#), 6/21/22) ◆

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

July 19-20. **U.S. Department of Health and Human Services (HHS) Tick-Borne Disease Working Group Meeting, Washington, D.C.** More information available [here](#).

Aug. 2-4. **ABC Summer Summit and Medical Directors Workshop, Minneapolis, Minn.** Registration is [open](#). More information available [here](#).

Aug. 29-30. **National Heart, Lung, and Blood Institute (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).** More information coming soon.

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**CALENDAR** (continued from page 7)

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).** More information coming soon.

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](#).

2023

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

May 9-11. **2023 ADRP Conference.** More information coming soon. 💧

Upcoming ABC Webinars – Don't Miss Out!

- **ADRP Webinar: School Is In Session** – July 27 from 1-2 PM ET. [Register](#) today!
- **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.
- **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.

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

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.

POSITIONS

Director, Human Resources. National Blood Testing Cooperative is now interviewing for a Director of Human Resources who through direct or delegated oversight, ensures financial feasibility, customer, and employee desirability of business decisions, strategic planning, development, and execution of all human resource systems. The Director of Human Resources will create and foster a collaborative environment in the organization that allows all employees to work together to further the mission and vision of the organization to ensure that the organization is increasing customer value, growing in a smart and efficient manner, driving operational efficiency, inspiring the talent base and continually reinventing the business. A BA in Business Administration, Human Resources Management, or the equivalent in related work experience and current PHR or SHRM-CP designation required. Current SPHR or SHRM-SCP designation preferred. Minimum four years required in Management/Supervisory experience with emphasis on employee development, performance evaluations, coaching and counseling and daily work management and involvement in strategic planning and execution and a minimum six years of Human Resource experience, with emphasis on employee relations, recruitment and selection, training/organization development; AAP/EERO; and policy and procedure development. Knowledge and experience in employment law (federal, state, local), management practices and approaches, needs assessments, and training and design. A valid driver's license and good driving record are also required. If you meet the above qualifications, please apply by sending your resume to: mharper@nbtccoop. EOE/AEE

Regional Account Manager. The essential element of the *Regional Account Manager* position is to develop, maintain, and expand professional relationships with community businesses and organizations through quality customer service with the goal of adding donations from new groups and increasing donations from existing groups. The Regional Account Manager is responsible for all aspects of the blood drive recruitment process within an assigned territory in order to ensure successful drives and achieve collection goals. This includes, but is not limited to booking the drive, education, marketing, and coordination of the drive. This position comes with a company car. Recruits donor groups within the assigned territory to run blood drives. Develops and maintains positive and professional relationships with blood drive coordinators and organizations. Provides the highest level of customer service to internal and external customers. Click [here](#) to view the full job description and apply. LifeStream is a full-service blood bank serving approximately 80 hospitals in six Southern California counties. We distribute over 150,000 products a year, have an AABB accredited reference laboratory, a thriving therapeutic apheresis service and offer specialty products not

provided by other blood banks in the area. For more information about LifeStream Blood Bank, please visit our website at: <https://www.lstream.org/>.

Manager, Component Manufacturing. LifeStream Blood Bank is seeking a Manager of Component Manufacturing. This role is responsible for the daily leadership and oversight of all manufacturing, labeling storage, and release of blood components, derivatives, and resale products. Establishes proper weekly production schedules to best meet local demand based on current inventory levels and hospital usage. Ensures operations in manufacturing are in compliance with all applicable Federal, State, AABB, OSHA and CLIA guidelines. Oversees the daily and monthly quality control program to ensure products and components are in compliance with established requirements. Responsible for the proper labeling and release of all components based on established Standard Operating Procedures. Ensures team provide the highest level of customer service to internal and external customers. Education: Four-year bachelor's degree (BA or BS) or equivalent. Experience: Three years laboratory experience in either Blood Banking or a Hospital. Management and/or Supervisory experience preferred. Please click [here](#) to view the full job description and apply.

QRA Supervisor (Stanford Blood Center). Responsibilities: Quality Assurance/Training/ GMP/GTP/GLP: Lead the department's quality activities, initiatives, and process improvement activities. Perform training on QRA core functions and activities, Good Manufacturing Practice/Good Tissue Practice/Good Laboratory Practice, and safety. Compliance: Ensure compliance to current regulations and accreditation requirements by federal, state, county, and accreditation agencies. Team Leadership: Manage the performance of direct reports. Set team objectives, priorities, and resources to align staff with Blood Center objectives. Safety: Lead the safety, emergency, and disaster management of the organization. Quality Management System: Provide oversight on the appropriate use of the quality management tools in handling the various documents, records, and activities of the blood center. Registration and Licensure: Ensure all licenses, permits and certificates are current and regulatory requirements are met. Qualifications: Bachelor's degree required. One to two plus years supervisory experience in a regulated or GMP (Good Manufacturing Practice) required. Please click [here](#) to view the full job description and apply.

Medical Technologist – Overnight/Shift Differential. LifeSouth Community Blood Centers is currently seeking a skilled individual for a **Medical Technologist** position in our Immunohematology Reference Laboratory (IRL) in **Jacksonville, FL**. This position is responsible for performing and interpreting clinical laboratory tests that require the exercise of independent judgment. **We are**

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POSITIONS (continued from page 9)

looking to fill an overnight/third shift. Starting salary range is \$27.00 - \$32.40 an hour. Shift differential of 15 percent – 20 percent may apply for working overnight hours. Applicants should apply [here](#).

Director of Finance. LifeSouth Community Blood Centers is currently seeking an individual to join our team as the Director of Finance in Gainesville, FL. This position is charged with ensuring the stability of LifeSouth's finances through planning, directing, and controlling financial functions, including establishing appropriate control environments, financial reports for management on the company's financial status, preparing financial reports and analysis, and overseeing the development and implementation of effective financial and accounting systems. The selected candidate will also manage the Purchasing and Accounting departments. Applicants should apply [here](#). 💧