

2020 #6

February 14, 2020

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CBER Announces 2020 Guidance Agenda

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has [published](#) its guidance calendar for 2020. The agenda outlines the guidance and draft guidance documents that CBER plans to issue throughout the year. Topics of note that the agency will look to address include:

- Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers; Guidance for Industry
- Blood Pressure and Pulse Donor Eligibility Requirements; Draft Guidance for Industry
- Alternative Procedures for Cold-Stored Platelets Intended for Transfusion; Draft Guidance for Industry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 Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria; Draft Guidance for Industry
- Revised Recommendations for Biological Product Deviation Reporting for Blood and Plasma Establishments; Guidance for Industry

The topics listed for Tissue and Advanced Therapies all involved gene therapy and chimeric antigen receptor T cell (CAR-T) therapies.

ABC has been advocating to the FDA on several of these issues and is pleased to see CBER addressing these topics of concern to our membership. A complete listing of the potential guidances is available on the FDA's [website](#).

(Source: FDA [Announcement](#), 2/14/20) ♦

FDA BPAC to Meet in April

The U.S. Food and Drug Administration (FDA) has [announced](#) that the next Blood Products Advisory Committee (BPAC) meeting will take place April 2nd-3rd at the FDA White Oak Campus, Silver Spring M.D. The agenda will include Zika virus (ZIKV) and Hepatitis B Surface Antigen (HBsAg) testing.

The committee will be asked to discuss and make recommendations about:

(continued on page 2)



FDA BPAC to Meet in April (continued from page 1)

- whether universal ZIKV testing of blood donations is still appropriate given the decline in the number of ZIKV cases in the U.S., and
- whether HBsAg testing can be discontinued in light of the sensitivity of hepatitis B nucleic acid tests in combination with hepatitis B core antibody testing.

America's Blood Centers (ABC) previously [encouraged](#) the FDA to discontinue ZIKV testing in December 2019 based on the recommendation of the ABC Science, Medical and Technical (SMT) Committee. The SMT will undertake a similar assessment of the science with respect to HBsAg testing in preparation for the BPAC meeting.

Members are asked to share their input with ABC by contacting [Ruth Sylvester](#). Individuals interested in making oral presentations to the BPAC must [notify](#) the FDA by March 16th, while individuals wishing to submit a written statement must [notify](#) the FDA by March 25th. Additional details are available on the FDA [website](#). The meeting is open to the public and will have a [webcast](#) for those who cannot attend in-person.

(Source: FDA [Announcement](#), 2/13/20) ♦

Upcoming ABC Webinars – Don't Miss Out!

- **ADRP Webinar: How NHS Blood and Transplant Solved the O- Problem** – February 27th from 1 – 2 p.m. (E.T.) [Register](#) today.
- **SMT Journal Club Webinar** – March 30th from 2 – 3 p.m. (E.T.) More information coming soon.

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 healthcare 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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AMERICA'S BLOOD CENTERS' 58TH ANNUAL MEETING

March 9-11 | Washington, DC

“Join us in Washington, D.C. for the only industry meeting dedicated solely to advocacy as decisionmakers, thought leaders, experts, and industry partners discuss trends and issues that impact community blood centers. Value exists for professionals of all experience levels with the opportunity to let your voice be heard in policy discussions with your peers, regulators, and legislators as we work collaboratively with all stakeholders to develop solutions that advance the industry.”

Kate Fry, Chief Executive Officer
America's Blood Centers



2020 ANNUAL MEETING SCHEDULE

- March 9** General Sessions, SMT Forum, Celso Bianco, MD Lectureship
- March 10** ABC Members Meeting, Public Awareness Forum, Advocacy Forum, 23rd Annual Awards of Excellence
- March 11** Capitol Hill Congressional Visits



Hotel Information
Ritz-Carlton (Pentagon City)
Hotel room rate: \$259



For registration information, visit http://bit.ly/abc_am20

For sponsorship opportunities, please contact Mack Benton at mbenton@americasblood.org.

INFECTIOUS DISEASE UPDATES

CORONAVIRUS

The World Health Organization (WHO) has officially named the coronavirus disease that continues to spread throughout China with confirmed cases around the world COVID-19. The number of cases continue to rise globally as 15 positive cases have been confirmed in the U.S. according to the Centers for Disease Control and Prevention (CDC) with more than 46,000 reported by the WHO with the vast majority in China. It is important to note that a significant increase in the number of cases has occurred this week due to changes in the manner in which cases are being reported. The agency stated that “China reported 13,332 clinically confirmed cases in Hubei province, and crucially, we understand that most of these cases relate to a period going back over days and weeks and are retrospectively reported as cases, sometimes back to the beginning of the outbreak itself. So, this increase that you’ve all seen in the last 24 hours is largely down to a change in how cases are being diagnosed and reported. So, in other words, in Hubei province only, a trained medical professional can now classify a suspected case of COVID-19 as a clinically-confirmed case on the basis of chest imaging, rather than having to have a laboratory confirmation. This allows clinicians to move and report cases more quickly, not having to wait for lab confirmation, ensuring that people get to clinical care more quickly, and also allows public health responses in terms of contact tracing and other important public health measures to be initiated. As you’ve noticed with suspect cases, there have been some backlogs in testing and this is also going to help ensure that people get adequate care and adequate public health measures can be taken. So we are not dealing, from what we understand, with a spike in cases of 14,000 on one day.”

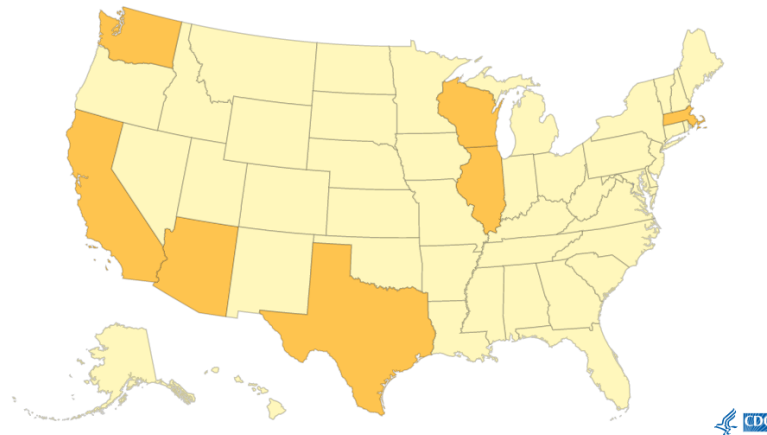
(continued on page 4)



INFECTIOUS DISEASE UPDATES (continued from page 3)

America's Blood Centers (ABC) issued a public [statement](#) last week on the novel coronavirus outbreak as well. It emphasized that the blood donation process is safe and encouraged all donors and sponsors of blood drives to schedule appointments and keep commitments to donate blood. ABC will continue to monitor the outbreak and provide timely updates to member blood centers.

States with Confirmed COVID-19 Cases



(Sources: WHO News [Release](#), 2/13/20, CDC [Update](#) 2/14/20) 💧

Donor Deferrals Due to Low Hemoglobin: Reasons and Mitigation

A common reason that prevents individuals from donating blood is due to being temporarily deferred for low hemoglobin (Hb). Limited data exist regarding the contribution of demographics, physical and environmental factors to a donor's risk of low Hb deferral (LHD). A meta-analysis published in *Transfusion Medicine Reviews* sought to identify new research findings since a 2013 review and reassess the impact of the aforementioned factors. The researchers examined a total of 2,518 records. From these, 76 independent studies were combined with 40 from the 2013 review for a total of 116 studies included in this review that delved into factors associated with LHD.

Previous Hemoglobin Level. Two European studies showed a reduced risk of LHD in donors who were not deferred at their previous visit. A third study found that men whose Hb increased between visits were less likely to be deferred. For donors in the Netherlands, "there was a higher risk of LHD for those whose Hb levels were stable across visits, whereas donors whose initial Hb levels were higher but experienced a sharper decline had a lower risk of deferral." In the U.S., "donors who had previous Hb levels below ≥ 14.5 g/dL had a higher risk of LHD."

Iron Status Intervention. One study in India provided dietary information and oral iron supplementation recommendations to deferred donors. "Of the 68.8 percent of donors who returned to donate, 85 percent were successful." While Danish researchers saw a significant decrease in the male LHD from 0.92 to 0.55 percent ($P = .03$) in a study that provided iron supplementation to participants. A U.S. randomized trial "of iron intervention strategies found that the LHD rate in donors who received daily oral iron (19 mg or 38mg) was lower (2.7 percent) than in those who received placebo (6.1 percent). Furthermore, the LHD rate in donors who received a ferritin status letter which either recommended they continue donation (ferritin >26 $\mu\text{g/L}$) or recommended they take iron supplementation/delay donation (ferritin ≤ 26 $\mu\text{g/L}$) was lower (4.1 percent) than in those who received a letter with no such information/advice (9.8 percent)."

(continued on page 5)



Donor Deferrals Due to Low Hemoglobin (continued from page 4)

Donation Characteristics. Two European studies reported that the number of previous donations correlated to decreased LHD risk in both men and women, with a greater association in men, though a third study found that LHD deferral increased as the number of donations increased in men. Multiple American studies and a Canadian study found that deferrals for low Hb decreased “significantly” with increases in the inter-donation interval.

Sex. LHD rates were higher in females across all studies, as those “studies that used universal Hb thresholds for both male and female donors showed a 14-fold increased risk of LHD for females (OR 14.62, 95 percent CI 12.43-17.19). An increased risk of LHD in females remained for those studies that applied lower Hb thresholds for female donors (OR 5.73, 95 percent CI 4.36-7.53).”

Ethnicity. For male donors most studies discovered a higher risk of LHD in African American/black donors when compared with white donors (OR 1.94, 95 percent CI 1.14-3.31). Female African American/black donors had a higher risk of LHD in all studies (OR 2.82, 95 percent CI 1.71-4.65), while “the combined risk across four studies was not significant” for Asian and white male donors. “A significantly higher risk of LHD was found in female Asian donors compared with white donors, (OR 1.63, 95 percent CI 1.31-2.03). A similar increased risk of LHD was found in female Hispanic donors compared with female white donors (OR 1.43, 95 percent CI 1.22-1.68).” In male donors, no evidence was found that Hispanic ethnicity was associated with an increased risk of LHD (OR 0.74, 95 percent CI 0.53-1.03).

Age. A trend seen across studies was that LHD rates increased in men with age, while fewer deferrals among women older than 50 years of age were seen when compared to women younger than 50.

Weight. “One U.S. study found that, compared to those who weighed between 68.0 to 79.3 kg, lighter men (OR 1.38) and women (OR 1.13) were deferred at a higher frequency, as were the heaviest women (weight >90.7 kg, OR 1.04).”

Donation Setting. A study from the United Arab Emirates reported LHD rates for fixed centers versus mobile sites of 25.3 and 14.4 percent. Meta-analysis of the remaining three studies demonstrated a significant increase in the risk of LHD for those who donated at fixed sites in comparison to mobile sites (OR 1.14).

Blood Group. “An African study found a significant association between LHD and AB blood group (AB vs O: OR 4.12, 95 percent CI 1.81-9.4)”. While a U.S. study observed a “significantly higher risk of deferral for group A+, whereas blood groups AB+ and B+ had a lower risk of deferral.”

The authors concluded that the meta-analysis “confirmed that clear differences exist in deferral rates between male and female donors irrespective of whether minimum Hb thresholds for donation were defined universally for male and female donors or whether [gender]-specific thresholds are used. Other potential factors that may influence LHD include diet, smoking, blood group, and genetic factors, but further evidence is required.” The paper expressed the need for large prospective studies that emphasize “collecting a wide spectrum of data on demographics, ethnicity, and donation characteristics to establish the combined effect on LHD in blood donors.”

Citation: Browne, A., Fisher, S.A., Masconi, K., *et al.* Donor deferral due to low hemoglobin—An Updated Systemic Review. *Transfusion Medicine Reviews*. 2020. Doi: [10.1016/j.tmr.2019.10.002](https://doi.org/10.1016/j.tmr.2019.10.002).

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



PEOPLE

Nancy Seay, RN MEDIC Regional Blood Center's Senior Director of Donor Services, retired in December after 39 years with the organization. Ms. Seay was a registered nurse who previously served as MEDIC's director of Nursing. She began her career as an intensive care unit nurse at the University of Tennessee Medical Center seeking an opportunity that would allow her to work in the nursing field with well people while continuing to save lives. Ms. Seay was a member of multiple organizations during her blood banking career including AABB. Additionally, she served on the board of the Tennessee Association of Blood Banks (TABB) in multiple roles including East Tennessee Representative, Treasurer, and President. She received multiple awards including the prestigious Grace Neitzer Memorial Lecture Award that recognized her distinguished service in the Excellence in Laboratory Medicine and Blood Banking.



(MEDIC Regional Blood Center Announcement, 2/11/20)



Be The Match® announced that **Amy Ronneberg, MBA** has been named acting chief executive officer following the departure of Randal Mills, PhD who succeeded Jeffrey Chell, MD in 2017. Ms. Ronneberg currently serves as the organization's chief financial officer and chief of staff. She joined the organization in 2013 after previously working as an audit manager at Ernst & Young and chief accounting officer and vice president of Finance at Capella Education Company. Ms. Ronneberg received a Master of Business Administration degree from Capella University, Minneapolis, Minn. and a Bachelor of Business Administration in Accounting from University of Wisconsin-Eau Claire.

(Source: Be The Match® News [Release](#), 2/11/20) ♦

ABC-ADRP PUBLIC AWARENESS FORUM

*ALIGNING EFFORTS TO CREATE
MEANINGFUL CHANGE*

March 10 | 8 am - 10 am
ABC Annual Meeting
Ritz Carlton - 2nd Floor
Pentagon City, VA

Shifts in blood donor demographics present short- and long-term challenges to a safe and sustainable blood supply. The evolving viewpoints and behavior of younger generations in relation to blood donation is of particular concern for continued resiliency and long-term sustainability. Join us for a national dialogue around blood donation, one that prioritizes increased education and awareness about the blood supply and external partnerships that support and align with blood center needs. Questions? Contact info@adrp.org

RSVP: <https://form.jotform.com/200265360462043>



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.

February Blood Bulletin Available

ABC's Scientific, Medical, and Technical (SMT) Publications Committee, has published the February 2020 Issue ([PDF](#) or [MS Word](#) versions) of the *Blood Bulletin*, titled "Transfusion-Associated Circulatory Overload (TACO): Underreported and Underappreciated."

The article was written by Richard Gammon, MD, Medical Director at OneBlood & Nanci Fredrich, RN, BSN, MM, Transfusion Safety & Blood Management Officer at Versiti. *Blood Bulletin* is reviewed and edited by ABC's SMT Publications Committee.

ABC publishes the *Blood Bulletin* for use by member blood centers in their educational programs as a value-added service for hospital customers. Current and previous issues can be accessed at any time on the ABC member [website](#).

Please note: The MS Word version may not display properly for users with older versions of MS Word. For those individuals, we recommend viewing and using the PDF version of this publication instead.

(Source: MCN [20-015](#))

ADRP Webinar: How NHS Blood and Transplant Solved the O- Problem

[Register](#) today for the Thursday, February 27th ADRP Webinar entitled "How NHS Blood and Transplant solved the O- problem." This webinar will take place at 1 p.m. eastern and feature Jon Latham, associate director of Donor Relationships at NHS Blood and Transplant. Attendees will receive information on how his organization increased the donor base and donor satisfaction, while lowering costs. ADRP subscribers may register for free and non-subscribers can participate for \$25.

(ADRP [Announcement](#), 2/10/20)

Register for the 2020 ABC Annual Meeting

[Registration](#) is open for America's Blood Centers' (ABC) 58th Annual Meeting in Washington, D.C. March 9th – 11th, 2020 at the Ritz-Carlton (Pentagon City). Join us for the premiere blood community meeting that brings blood center, regulatory, legislative, and medical leadership together to focus on key issues which will ultimately impact blood center bottom-lines. From implementation challenges for the new bacterial guidance to the operational complexities entailed in gender identification, the ABC Annual Meeting will provide you with the latest updates on these topics and more, along with the opportunity to help shape the association's advocacy and policy efforts. Additionally, attendees will have the chance to work collaboratively with their peers and ABC leadership in developing solutions that address internal and external needs ranging from health policy to donor motivations. This meeting also includes a day on Capitol Hill to let our voices be heard. Contact [Jeanette Brown](#) for available sponsorship opportunities and to see if hotel availability still exists at the group rate. Registrant substitutions are accepted any time at no charge. Registrations

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INSIDE ABC (continued from page 7)

cancelled after February 16 will be refunded, less \$200. No refunds after March 8. CME and P.A.C.E.® credits will be offered. Schedule at a glance:

- ABC Board Meeting (**open to ABC Members only*) (March 8th)
- General Sessions & SMT Forum & Celso Bianco Lectureship (March 9th)
- ABC Members' Meeting (**open to ABC Members only*) & Public Awareness Forum & Advocacy Forum (March 10th)
- 23rd Annual Awards of Excellence (March 10th)
- Advocacy Day – Capitol Hill Visits (March 11th)

(Source: MCN [19-086](#), 12/18/19)

ABC Survey on Donor Deferrals Due to Blood Pressure

The America's Blood Centers (ABC) Scientific, Medical, and Technical (SMT) Committee is evaluating the mandatory donor blood pressure and prescribed ranges set forth by the Final Rule in 21 CFR 630.10. Members of ABC have indicated that donors are unnecessarily being deferred for out of range blood pressure because of the requirement in 630.10(f)(2) that a "physician examines the donor and determines and documents that the health of the donor would not be adversely affected by donating." This cannot be delegated to the blood drive supervisor or other qualified staff per 630.5(b)(1)(i). Since doctors are not generally on mobile drives, any donors with blood pressures outside the established range are deferred. Member assistance is needed to measure the impact of this issue. A survey has been designed for ABC members to complete to objectively determine how many donors are being deferred because of blood pressure outside of the U.S. Food and Drug Administration's (FDA) established range and to estimate the impact on donors and staff time. ABC members can [access](#) a link to the survey and a copy of the survey questions in MCN 20-010. The survey will gather data on the number of donors with blood pressures outside of established ranges and how many of them are qualified or deferred. ABC understands that not all organizations are able to easily break that information down between donors with low or high blood pressures. Please provide as much data as possible completing the survey by February 28th. If you have any questions, please contact ABC Director of Regulatory Services [Ruth Sylvester](#).

(Source: [MCN 20-010](#), 1/29/20) ♦

MEMBER NEWS

The Knoxville Chamber of Commerce honored **MEDIC Regional Blood Center** (Knoxville, Tenn.) on February 7th with a Pinnacle Business Award in the Mid-Sized Business Excellence category. "This award is in recognition of the 62 years of service to our region, as well as the dedication and hard work of all of our employees," said MEDIC Regional Blood Center CEO Jim Decker DHA, FACHE. "We are humbled and grateful to be recognized with this award." MEDIC Regional Blood Center was chosen from more than 200 submissions for the award and was honored during the Knoxville Chamber of Commerce Pinnacle Award Gala.



(Source: MEDIC Regional Blood Center Announcement, 2/11/20)

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MEMBER NEWS (continued from page 8)



The Blood Connection, Inc. (Greenville, S.C.) will be holding a ribbon cutting ceremony on February 27th to celebrate the official opening of its North Charleston collection site. “The Lowcountry community has embraced us and we are so thankful to the donors who have joined us on our blood mobiles,” said The Blood Connection, Inc. President and CEO, Delisa English in a news [release](#). “Now donors have a beautiful, spacious blood center to enjoy while they help save the lives of their neighbors. We’re proud to be local and to serve this community through our hospital partners. This center opening is just the beginning of making Charleston our home.” The 15,000 square foot facility will

also serve as a distribution hub and reference lab .

(Source: The Blood Connection, Inc. News [Release](#), 2/11/20) 💧

GLOBAL NEWS

China’s largest news organization, Xinhua, [reported](#) that China’s General Office of the National Health Commission and the health arm of the Department of the Central Military Commission issued a circular encouraging awareness of risk prevention strategies and development of preparedness plans to maintain a safe and available blood supply in light of the ongoing novel coronavirus (COVID-19) epidemic that is impacting the country. The notice required the country’s blood collection entities to “implement blood donation appointments to avoid overcrowding” and encouraged being more stringent during the predonation process to ensure that health information inquiries and body temperature checks prevent individuals who are feeling ill or “have a history with the epidemic” from donating blood. No cases of transmission by blood or blood components of COVID-19 have been identified at this time, as the circular stated that “there is no evidence so far showing that [it] can be transmitted through blood.” According to the latest [figures](#) from the World Health Organization (WHO), more than 46,000 cases had been confirmed in China with close to 1,400 deaths.

(Source: Xinhua, China strengthens safety of blood supply amid epidemic, 2/11/20; WHO Situation [Report](#), 2/13/20)

The European Blood Alliance announced that the 4th “European Conference on Donor Health and Management” has issued a call for [abstracts](#). Interested individuals may submit their abstract by the May 22nd deadline in the following areas of interest:

- “research regarding donors, blood, blood products, organs, tissues, quality & management;
- diagnostics (serological, genetic, microbiological) in terms of donor health and eligibility;
- organizational or clinical management of donors and donated blood, blood products, organs and tissue; or
- management and strategy in working with donor health and donor relationship.

The conference will take place September 23rd-25th in Hamburg, Germany hosted by the German Red Cross Blood Donation Service and will explore recent developments in donor management science, policy, and experiences with a focus on blood donors. Additional information is available on the conference [website](#).

(Source: 4th European Conference on Donor Health and Management [Announcement](#), 2/10/20) 💧

CALENDAR

***Note to subscribers:** Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 393-1282. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)*

2020

Mar. 9-11. **2020 ABC Annual Meeting, Washington, D.C.** Registration is [open](#).

Mar. 25-26. **IPFA 5th Asia Workshop on Plasma Quality and Supply, Chonburi, Thailand.** More details available [here](#).

April 1. **U.S. Food and Drug Administration (FDA) Public Meeting on FDA’s Communications About the Safety of Medical Devices.** Silver Spring, Md. More details available [here](#).

April 2-3. **U.S. Food and Drug Administration (FDA) Blood Products Advisory Committee Meeting.** Silver Spring, Md. More details available [here](#).

April 14-15. **16th Annual FDA and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C.** More details available [here](#).

May 12-13. **AABB and Mayo Clinic Laboratories Transfuse 2020, Rochester, Minn.** More details available [here](#).

May 13-14. **IPFA/PEI 27th International Workshop on “Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal.** More details available [here](#).

May 19-21. **2020 ADRP Conference, Phoenix, Ariz.** More details available [here](#).

July 21-23. **2020 ABC Medical Directors Workshop and Summer Summit, Cleveland, Ohio.** More details coming soon.

Sept. 23-25. **4th European Conference on Donor Health and Management.** Hamburg, Germany. More details available [here](#).

Oct. 3-6. **2020 AABB Annual Meeting, Baltimore, Md.** More information available [here](#). ♦

ABC 2020 Meetings & Workshops				
Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees
2020 ABC Annual Meeting	March 9 th -11 th	Washington, D.C.	Ritz-Carlton (Pentagon City)	Registration now open!
ADRP 2020 Conference	May 19 th -21 st	Phoenix, Ariz.	Hyatt Regency	Registration now open!
2020 ABC Medical Directors Workshop and Summer Summit	July 21 st -23 rd	Cleveland, Ohio	Westin Downtown	More details coming soon!

Notes: For the most up-to-date information on all events, members of ABC may check the [calendar](#) on ABC’s Member Site. Non-members may attend all events; information will be updated on ABC’s [Public Site](#).





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

Hematologist/Medical Director. OneBlood is expanding its clinical practice offerings in the areas of outpatient transfusion medicine, therapeutic apheresis & phlebotomy, pre-op anemia management, cell therapy, treatment of blood disorders. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking/transfusion medicine, hematology and outpatient clinical services, IRL, therapeutic apheresis, cellular therapy, research, consider joining our medical team as a regional **Medical Director**. This position includes a highly competitive salary, benefits package, including the option of free medical coverage, retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, etc. The position is based out of the Ft. Lauderdale, Florida area. Qualified candidates should possess: minimum of three years' experience, M.D. or D.O. degree with board certification in Internal Medicine/Hematology and sub-specialty board certification in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Candidates must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. For more detailed information, visit OneBlood's *Careers* page at www.oneblood.org. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.

Vice President, Donor Services (RN). Kentucky Blood Center, located in Lexington, Kentucky, seeks a dynamic professional to direct the activities of the Blood Collections departments in accomplishing collection goals. Responsibilities will include the development of strategic plans, budgeting, and oversight of employee training, processes, and procedures in compliance with equipment manufacturer, FDA, AABB and EU guidelines/regulations. The position has oversight of employees at multiple locations throughout Kentucky, in addition to mobile blood drive operation. Qualified applicants must have a minimum of a four-year degree, Registered Nurse (RN), with a minimum of five years management experience. Must be knowledgeable of industry regulations including FDA, AABB, and EU. Must be proficient with MS Office, Outlook and Adobe with the ability to navigate web-based applications and other internal systems. Should possess proven data analysis skills and be highly organized, reliable, and have outstanding interpersonal skills. Strong written and oral communication skills, a do-what-it-takes work ethic, and a team player attitude are required. All resumes must contain a cover letter. To be

considered, candidate must reside in or be willing to relocate within 1 hour of the Lexington area. Relocation assistance available. Competitive salary and benefits package. Click [here](#) to apply.

Vice President of Technical Operations (Oklahoma City, OK). The Vice President of Technical Operations provides planning, operational management, budgeting and leadership to the Oklahoma Blood Institute. It will oversee and direct the operational and quality systems in the Testing Laboratory, Manufacturing Laboratory, Quality Control Laboratory, Logistic & Distribution, and Client Relations & Contracting departments. He/She will develop and administer capital expense budgets and operating budgets. This position requires a thorough understanding of regulations and laws applying to Oklahoma Blood Institute. Qualifications: Requires a Bachelor of Science degree in Medical Technology, master's degree strongly preferred, minimum of eight years progressive management in a related medical industry. Salary Range: Competitive salary and excellent benefits package including health, dental, vision, life insurance, long term disability, 401(k), paid time off, etc. How to apply: <http://obi.org/careers/>.

Assistant Director of Quality Assurance. This position at Shepard Community Blood Center assists the Director of QA in management and implementation of organizational Quality Plan. Monitors regulatory compliance in all areas of operation and reviews new and revised regulations, standards and other compliance documents. Assists in management of corrective and preventative action, change control, document control, record storage, equipment and validation. Coordinates and facilitates center training and competency programs. Serves as resource for quality and compliance issues for staff. Qualifications: bachelor's in laboratory science or related discipline required; three to five years' experience in blood bank or transfusion service, management experience, working knowledge of PC software using Windows, Microsoft Word, Excel and other software programs as required, familiarity with FDA/AABB Regulations/Standards, OSHA and CLIA requirements; working knowledge of regulations and standards for biologics to include blood and blood products. Working knowledge of donor suitability criteria and infectious disease testing. Must maintain knowledge of and perform according to Standard Operating Procedures (SOPs) and policies. Must maintain knowledge of cGMP, CLIA regulations, applicable OSHA rules, and current industry

(continued on page 12)

POSITIONS (continued from page 11)

standards. Licenses/Certifications: MT or MLT with appropriate certification preferred or BS-RN acceptable with appropriate work experience. Please upload cover letter, resume, relevant documentation and complete an application at www.shepardblood.org.

Outside Sales Representative/Event Planner. Oklahoma Blood Institute (Ada, O.K.) Account Consultants/Outside Sales Representatives must develop new partnerships with targeted decision makers in community organizations, educational & religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing & promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, life insurance, long term disability, 401(k), paid time off, etc. Apply at: <http://obi.org/careers/>.

Assistant Manager, Donor Testing. Innovative Blood Resources (St. Paul, Minn.) is seeking an Assistant Manager for Donor Testing. Join our team today and start making a difference in the community and saving lives. Provide day-to-day supervision of personnel in their shift and laboratory area and responsible for the engagement of Donor Testing staff through proper personnel management, training, development and evaluation of staff. Work with all of IBR management to ensure that organizational needs are being met. Promote the Mission, Vision, Values, and strategic objectives of the organization. Requirements: a Bachelor Degree in Medical Technology/Clinical Laboratory Science highly preferred; BS degree in chemical, biological, or CLIA equivalent (Associates of Science Degree/MLT plus four years related experience) with relevant leadership experience acceptable; graduate of a CLIA approved degree program where laboratory experience was obtained and accompanies a working knowledge of good laboratory

practices in addition to a minimum of three plus years' experience in the Donor/Clinical Testing Laboratory; must possess attention to detail, accurate in transcription of numbers, good written and oral communication skills, and computer input/retrieval skills, ability to work in a team environment or independently, good decision making skills, ability to work irregular hours or overtime as dictated by departmental needs. Must comprehend and apply clinical laboratory procedures and theory. View full job descriptions at: <https://innovativebloodresources.org/careers/>.

Director, Regulatory Affairs. America's Blood Centers (ABC), North America's largest network of community-based, independent blood programs, is seeking a Director, Regulatory Affairs. The position will be actively involved and accountable for the development, implementation, execution and advancement of the ABC regulatory agenda before federal agencies and other stakeholders. In addition, the position will assist in the facilitation of member education, evaluation and coalescing of member input in the development of industry positions, data collection from internal and external sources, and primary and secondary research. The position will report directly to the Senior Director, Federal Government Affairs, providing strategic guidance on regulatory affairs and public policy issues pertaining to the nation's blood supply. A bachelor's degree is required for the position, which is based in Washington, D.C. This individual should: have a thorough understanding of the federal regulatory processes and landscape, particularly with the FDA; have knowledge of and experience in health policy; blood industry knowledge preferably (but not required); be able to collect, analyze, and synthesize information from varied sources; have strong critical thinking, analytical, and problem-solving skills; be self-motivated and goal oriented; have the ability to multitask and determine priorities; be able to network and collaborate effectively with colleagues and volunteers; have strong communication skills - verbal, written, and presentation; and be able to travel, sometimes at short notice. ABC offers a salary commensurate with experience as well as an excellent benefit package including medical, dental, LTD, and 401k contribution. We are a hybrid virtual office that promotes a flexible work environment. This is a full-time staff position including benefits and a stipend for internet and telephone services. ABC prohibits discrimination and provides equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws. The full job description is available [here](http://careers@americasblood.org). Interested applicants should send a cover letter and resume to careers@americasblood.org. ♦