

2018 #21

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CBER Publishes Revised Guidance Calendar for 2018

The U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) [published](#) a revised guidance calendar for 2018. It contains topics that currently lack an associated guidance and includes topics where updated guidances may be beneficial and topics for which CBER has previously issued Level I draft guidance documents. CBER notes that it is not bound to this list of topics, nor required to issue each guidance on this list. The agency may address guidance documents topics that are not listed. Guidance documents to be issued regarding blood and blood components include:

- Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry (*Revised Draft*);
- Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Guidance for Industry;
- Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Draft Guidance for Industry;
- Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Draft Guidance for Industry;
- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry; and
- Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibody to Human T-Lymphotropic Virus Types I and II; Draft Guidance for Industry.

The calendar also [lists](#) guidance documents to be released regarding tissues and advanced therapies. To date in 2018, CBER has published the following guidances relevant to ABC member blood centers:

- [Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry \(Updated May 2018\)](#)

(Source: U.S. Food and Drug Administration, CBER 2018 [Guidance Calendar](#), 6/21/18) ◆



OUR SPACE

Sameer Ughade, Director, Information Technology & Business Intelligence, ABC

Better Privacy Regulation and Increasing 'I Accept' Boxes on Websites

I am sure everyone is now aware of the European General Data Protection Regulation (GDPR) that went into effect last month. Consequently, we were inundated with email messages from our favorite websites and service providers requesting us to accept and be aware of their data privacy policies. Even though GDPR is only directly affecting organizations having a presence or providing services to European Union (EU) citizens, there is a possibility of a ripple effect of new, similar data privacy regulations in the U.S. We are already noticing this trend with proposed or passed state level regulations in California, New York, Massachusetts, and Colorado. Some are part of consumer privacy regulation, others are specific to certain industries, and a few are related to data breaches. No matter the approach, they are all designed with the intent of protecting and empowering consumers and their data privacy. GDPR is different than existing federal and state privacy regulations in the U.S. because it fundamentally changes the way privacy is perceived. It empowers consumer rights, such as providing explicit consent for usage of personal consumer data that can be withdrawn at any time. It also allows consumers the ability to not only see and obtain their data, but also to correct and erase it at any time. GDPR has also tremendously increased the fines for violations to 4 percent of global revenue or 20 million euros, whichever is higher. A recently published *New England Journal of Medicine* article provides some specific examples of the impact within the healthcare sector including patient consent for clinical trials, patients' rights to correct and erase electronic health records, and a mechanism for patients to know which data end up in health registries and public health databases along with its purpose.

These changes, along with increased awareness amongst consumers due to frequent headlines of data breaches and organizations losing private data, will only cause additional similar regulations to be implemented in the U.S. Though ABC member blood centers operate in a unique environment, it will be prudent to be aware and possibly prepare for the impact, if any, of such privacy regulations on donors. Most centers already have privacy policies on their websites. However, these need to be simplified and the consent process for it modified towards explicit consent. A much broader impact will be the need for blood centers to evaluate their data collection, retention, and usage policies and practices to ensure they are designed with consumer privacy in mind. Most internet-based service providers have modified their services to support GDPR or have tools that are built to help meet the privacy requirements of clients, but this will take time to implement industry-wide as vendors will have to modify or redesign their applications with consumer privacy at its core. This is especially needed to erase records and tracking data lineage to the source systems.

While GDPR has not yet directly impacted the U.S., it will cause a paradigm shift in the way consumer privacy is viewed and implemented. Many promising futuristic technologies like blockchain and cloud will cause a seismic shift by empowering consumers to be their data owners authorizing organizations like us to use it for limited purposes. Until that happens, we must get used to clicking the "I accept" button to allow organizations to use our private data! 💧

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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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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.

2018 Summer Meeting Registration

[Registration](#) is open for the 2018 Summer Meeting and Medical Directors Workshop in Montreal, Québec hosted by ABC member Héma-Québec July 31st – August 2nd at the Hotel Omni Mont-Royal. Don't miss an exclusive opportunity for blood community leaders to experience peer-to-peer collaboration, while discussing the latest trends impacting community blood centers. The meeting will feature the Medical Directors Workshop, the Scientific, Medical, and Technical Forum, the Business Forum, and ABC Members Meeting. Additionally, Héma-Québec will host a networking event. Please make your hotel reservations by July 9th to ensure best availability at the group [rate](#). Member and government registration rates are below:

- 3-Day Summer \$760: MD Workshop, SMT Forum, Business Forum, Members Meeting
- 2-Day Summer \$655: SMT Forum, Business Forum, Members Meeting
- 2-Day Medical \$655: MD Workshop, SMT Forum, Business Forum
- 1-Day Medical \$435: MD Workshop

You will need a U.S. Passport to enter Canada. Please be sure to check the expiration date.

Hospital, public, and emeritus registration rates are available [here](#). Contact [Leslie Maundy](#) for available sponsorship opportunities. Click [here](#) for additional meeting information.

ABC Participates in Capitol Hill Briefing on 3rd Party Servicing of Medical Devices

ABC's Director of Quality Services, Toni Mattoch, MA, MT(ASCP)SH, SBB, spoke last week at the Advanced Medical Technology Association (AdvaMed) and the Medical Imaging & Technology Alliance (MITA) Capitol Hill briefing held in conjunction with the U.S. House of Representatives' MedTech Caucus. The briefing examined third party servicing of medical devices and the implications for patient care. Additionally, it addressed the need for congressional action from the perspective of medical device manufacturers, third party servicers, and the patients. The other speakers included: Dennis Durmis of Bayer, Vy Tran, JD, of Varian, and Miguel Machuca, of Medical Outfitters.



ABC Executive Compensation Survey Launched

ABC's annual Executive Compensation Survey launched this week. The survey is a benchmarking tool for executive leadership and human resources professionals at ABC member blood centers that features aggregate data on salaries and benefits for C-suite members—including chief executive officers, chief operating

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INSIDE ABC (continued from page 3)

WEBINAR SAVE THE DATE

ABC SMT Journal Club Webinar

August 7, 2018 at 3 PM EDT

Additional details coming soon!

officers, chief financial officers and medical directors—as well as directors and manager-level positions. Blood centers are grouped by center size and budgets.

As with all ABC surveys, data is strictly confidential and anonymized. With this information, ABC can provide a strategic overview of the industry and where blood organizations need to position themselves to compete in the future. All members are encouraged to participate in the survey and should have received the report link via email. If you have not received the link or have any questions, please contact [Sameer Ughade](#). 💧



AMERICA'S BLOOD CENTERS'
56TH SUMMER MEETING
July 30 – August 2, 2018 **Montréal, QC**

2018 SUMMER MEETING SCHEDULE

Monday, July 30	ABC Board Meeting
Tuesday, July 31	Medical Directors Workshop
Wednesday, August 1	SMT Forum Business Forum Host Event by Héma-Québec (off-site)
Thursday, August 2	ABC Members Meeting

Hotel Information

Hotel Omni Mont-Royal
Hotel room rate: \$234 (CAD) + tax

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

For sponsorship opportunities,
please contact Leslie Maundy at
lmaundy@americasblood.org

All of us at Héma-Québec look forward to hosting our ABC colleagues, family and friends at the 2018 ABC Summer Meeting in Montréal. A striking union of European charm and North American attitude, Montréal seduces visitors with a harmonious pairing of the historic and the new, from exquisite architecture to fine dining. We hope you can take the opportunity to see what Montréal has to offer and discover its many colorful and vibrant neighborhoods which overflow with markets, museums, boutiques, restaurants and local cafés—diverse expressions of the inhabitants "joie de vivre."



HÉMA-QUÉBEC

– Luc Vermeersch,
Acting Chief Executive Officer
and Vice-President, Finance
and Strategic Project Management



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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. 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.



RESEARCH IN BRIEF

How to optimize red blood cell (RBC) transfusion? There is fairly robust literature of randomized controlled trials (RCTs) describing clinically accepted, effective transfusion triggers in some key patient groups. The literature describing interventions that translate those results and affect physician behavior is described by authors from Canada. They find the quality of the available studies wanting but their conclusions consistent. From more than 5,000 studies identified in their bibliographic database search, they analyzed 33, only three RCTs, with the rest mainly using a before-and-after design. The body of papers is characterized as low to moderate quality showing evidence for publication bias. Many studies used multiple simultaneous interventions that make isolating the effect of individual components a problem.

The odds of any RBC transfusion, inappropriate transfusion, and the number of units given to transfused patients were decreased by transfusion protocols and multimodal interventions. Hospital length of stay decreased by one day in intervention cohorts. Hospital mortality did not change. Important quality-of-life indicators were not analyzed or described, nor were differential impacts in specific patient groups.

Citations: Soril, L.J., Noseworthy, T.W., Dowsett, L.E. *et al.* [Behaviour modification interventions to optimise red blood cell transfusion practices: a systematic review and meta-analysis](#). *BMJ*. 2018.

Behavior changes noted as preexposure prophylaxis (PrEP) of HIV infection expands. Early evidence in the developed world following substitution of time-limited for lifetime deferral from blood donation by men who have sex with men (MSM) has not demonstrated an increase in the number of HIV infected donations entering the processing and distribution chains of the blood community. Confirmation awaits mature data from the United Kingdom where a 3-month deferral was implemented last year and from the U.S. where the deferral was reduced to 12 months following FDA guidance in late 2015.

PrEP is the continuous use of antiretroviral therapy by at risk populations to prevent HIV infection. It is highly effective (i.e. >90 percent in some RCTs) but not perfect. A study in *Lancet HIV* has correlated condom use and uptake of PrEP among MSM from 2013-17. More than 27,000 MSM in Australia were surveyed to assess their use of condoms, engagement in condomless sex, and receipt of PrEP. During the interval of interest, there was a rapid increase in use of PrEP that was accompanied by an equally rapid decrease in consistent condom use during high-risk sex.

The expansion of PrEP and changes in risk behaviors will be discussed at the 2018 AABB Annual Meeting in Boston, Mass. Questions to be explored will include the potential impact of PrEP use on the performance characteristics of donor HIV tests when PrEP fails, and whether any such changes have the potential to

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RESEARCH IN BRIEF (continued from page 5)

affect the impact of either shorter time-based deferrals or individual risk assessment of high-risk individuals who want to donate blood.

Citation: Holt, M., Lea, T., Mao, L. *et al.* [Community-level changes in condom use and uptake of HIV pre-exposure prophylaxis by gay and bisexual men in Melbourne and Sydney, Australia: results of repeated behavioural surveillance in 2013–17](#). *Lancet HIV*. 2018. 

RECENT REVIEWS

The literature does not exist to determine the relative value of prophylactic vs. therapeutic platelet transfusion in patients with marrow failure. Two prevalent indications for platelet transfusion are prevention of bleeding or its treatment to support patients with bone marrow failure (i.e. myelodysplastic syndromes, aplastic anemia, and the inherited marrow failure syndromes), excluding transfusions in support of myelosuppressive therapies. This review screened studies from the database search, of which 6,957 were excluded from further analysis based on the abstract. Of the remaining 18 undergoing full text review, only one qualified for analysis and it enrolled only nine patients before termination for slow enrollment. The authors understated conclusion is “there is a need for good-quality studies comparing a therapeutic platelet transfusion strategy with a prophylactic platelet transfusion strategy.”

Citation: Malouf, R., Ashraf, A., Hadjinicolaou, A.V. *et al.* Comparison of a therapeutic-only versus prophylactic platelet transfusion policy for people with congenital or acquired bone marrow failure disorders. *Cochrane Database of Systematic Reviews*. 2018. doi: [10.1002/14651858.CD012342.pub2](https://doi.org/10.1002/14651858.CD012342.pub2). 

BRIEFLY NOTED

The World Health Organization (WHO) [announced](#) publication of the new [International Classification of Diseases \(ICD-11\)](#). “The ICD is a product that WHO is truly proud of,” said WHO Director-General Tedros Adhanom Ghebreyesus, PhD, in a WHO news release. “It enables us to understand so much about what makes people get sick and die, and to take action to prevent suffering and save lives.” ICD-11 features 55,000 unique codes, nearly 4-times as many (14,400 codes) as ICD-10, that are used to classify diseases, injuries, and cause of death enabling a standard language for data to be shared globally, including reimbursement by insurers. It will be presented in May 2019 at the World Health Assembly though it is not expected to take effect until January 2022. “ICD is a cornerstone of health information and ICD-11 will deliver an up-to-date view of the patterns of disease, said Lubna Alansari, MBBS, MSc, MRCP, FRCGP, WHO’s assistant director-general for Health Metrics and Measurement.

(Source: WHO News [Release](#), 6/18/18) 

This week, the U.S. Department of Health and Human Services along with several additional agencies, published the final rule that extends the Common Rule Compliance for six more months. The “[Federal Policy for the Protection of Human Subjects](#),” or Common Rule, governs most human-research financed by the federal government and requires compliance by January 21, 2019. Prior to the extension, the Common Rule was scheduled to take effect July 19th after an initial six-month delay from the January 2018 deadline. One exception does exist as “institutions will be permitted (but not required) to implement, for certain research, three burden-reducing provisions of the 2018 Requirements during the delay period (July 19, 2018, through January 20, 2019). Those three provisions are: The revised definition of “research,” which deems certain activities not to be research covered by the Common Rule; the elimination of the

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BRIEFLY NOTED (continued from page 6)

requirement for annual continuing review with respect to certain categories of research; and the elimination of the requirement that institutional review boards (IRBs) review grant applications or other funding proposals related to the research,” according to the final rule.

(Source: *Federal Register* [Final Rule](#), 6/19/18)

The White House has [proposed](#) a plan that would restructure several government agencies including the U.S. Food and Drug Administration (FDA), Department of Health and Human Services (HHS), and the National Institutes of Health (NIH). Under the proposal, HHS would change its name to the Department of Health and Public Welfare (DHPW) with the Department of Agriculture assuming oversight of food from the FDA. Also, the agency (FDA) would become the Federal Drug Administration focusing on “drugs, devices, biologics, tobacco, dietary supplements, and cosmetics,” according to the report. The proposal would “integrate the research” of the Agency for Healthcare Research and Quality (AHRQ), the National Institute for Occupational Safety and Health (NIOSH), and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) into three new NIH institutes: the National Institute for Research on Safety and Quality; the National Institute for Occupational Safety and Health, including the Energy Employees Occupational Illness Compensation Program; and the National Institute on Disability, Independent Living, and Rehabilitation Research in the hopes of “improv[ing] research coordination and outcomes.” According to a report from *Bloomberg*, NIH would need to “eliminate or consolidate three agencies” to comply with a federal regulation that limits the number of institutes and centers at 27, which the agency currently has. Additionally, the Assistant Secretary for Preparedness and Response would gain oversight of the Strategic National Stockpile from the Centers for Disease Control and Prevention. The move would aim “to consolidate strategic decision making around the development and procurement of medical countermeasures, and streamline operational decisions during responses to public health and other emergencies and improve responsiveness. This reorganization is intended to enhance enterprise effectiveness by more fully integrating the Stockpile with HHS’ other preparedness and response capabilities,” according to the proposal.

(Source: [Delivering Government Solutions in the 21st Century — Reform Plan and Reorganization Recommendations](#), 6/21/18) ♦

INFECTIOUS DISEASE UPDATES

WEST NILE VIRUS

The Centers for Disease Control and Prevention (CDC) will investigate the first confirmed human case of West Nile virus (WNV) in the state of Illinois in 2018. It occurred in mid-May, two months earlier than last year’s initial case. Illinois had eight deaths in 2017 out of 90 cases of WNV, which is spread from bites by infected mosquitos. The Illinois Department of Public Health recommends the use of insect repellent when outdoors. More information about West Nile virus is available on the CDC [website](#). As of publication (Friday, June 22nd), four unconfirmed suspected viremic donor infections have been reported to the AABB WNV biovigilance [website](#) since May 23rd.

(Source: Associated Press, [Woman diagnosed with West Nile Virus, Illinois calls in CDC](#), 6/21/18) ♦

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!



WORD IN WASHINGTON

A House panel has recommended allocating \$300 million in discretionary funds to the Centers for Disease Control and Prevention to form an Infectious Disease Rapid Response Reserve Fund in the 2019 budget. The Fund would also be transferable to the National Institutes of Health and would allow other agencies to access this financial resource for outbreaks rather than waiting for Congress to approve requests for funding from the White House as the current system dictates. “If you wanted to protect our country from a threat, you would want to make sure you had reserved resources to address unmet needs and be ready,” said Paul Auwaerter, president of the Infectious Diseases Society of America, to *Bloomberg Law*. “This kind of public health fund is fundamentally important for ensuring readiness and the ability to respond without it being tied up in politics.” The House Appropriation Committee is scheduled to mark up the bill next week. Earlier this month the committee proposed draft legislation to provide billions in additional funding to the U.S. Department of Health and Human Services.

(*Bloomberg Law*, [New CDC Fund could bring faster response to disease outbreaks](#), 6/19/18)

This week, the Senate did not pass rescission legislation out of committee. A similar bill was approved in the House last week with \$15 billion in cuts as part of a White House rescission plan. The proposed cuts would include the Children’s Health Insurance Program (CHIP) and the Center for Medicare and Medicaid Innovation (CMMI). “The American people should be asking their representatives in Washington one simple question: If they cannot pass good-government legislation to recapture unnecessary funds, how can we ever expect them to address Washington’s staggering debt and deficit problem?” said White House Budget Chief Mick Mulvaney according to *The Hill*. The White House Office of Budget and Management recommended cuts of \$7 billion in funding for CHIP and cuts to CMMI totaling \$800 million.

(*The Hill*, [Senate rejects Trump plan to claw back spending](#), 6/20/18) ♦

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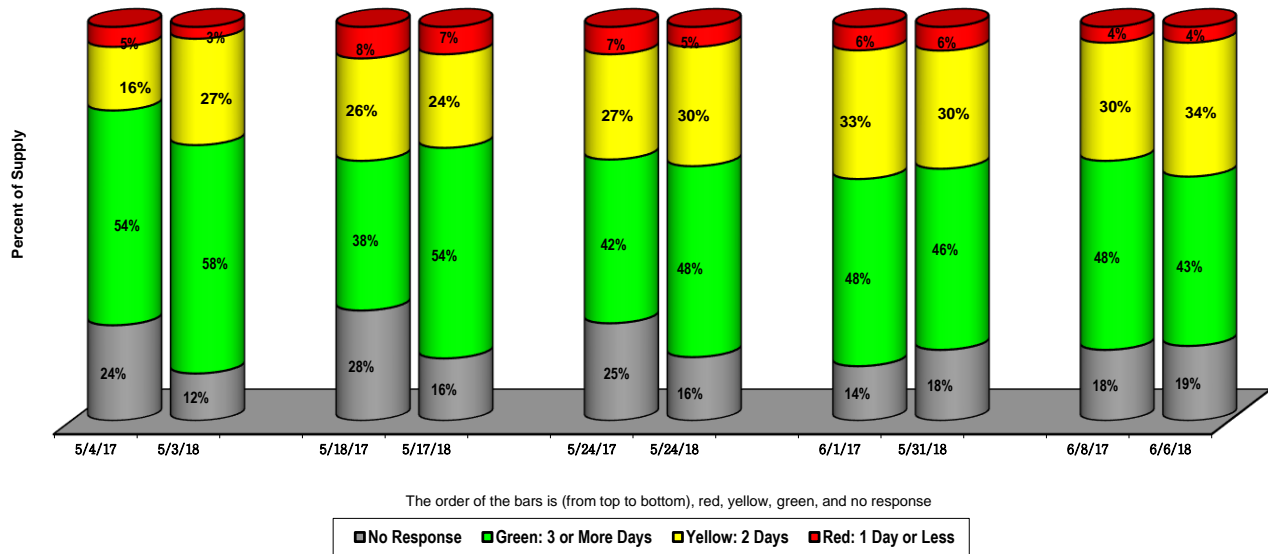
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MEMBER NEWS

A [commentary](#) on the important role diversity plays in health research appeared in the *San Diego Union-Tribune* coauthored by **San Diego Blood Bank** CEO and President David Wellis, PhD and Cinnamon Bloss, PhD, an associate professor of psychiatry, family medicine, and public health at University of California (UC) San Diego Health. Both of their organizations are participating in the National Institutes of Health’s (NIH) “All of Us” program, which aims to bring precision medicine to all in the U.S. by recruiting and examining health data from 1 million individuals to assist with disease prevention and treatment. “We know this is no easy task,” states the commentary. “In some past research studies, many communities were not invited to participate. There have also been some outright abuses in past research, particularly in communities of color, and so some people may understandably have concerns about joining... We believe one way to help All of Us reach out to underrepresented communities is through organizations located within those communities — blood banks, for example, where donor demographics typically reflect the communities in which the banks are located.” The “All of Us” program began in 2016 with \$130 million earmarked. Enrollment officially opened in May. The complete commentary can be found on the San Diego Union-Tribune [website](#).

(Source: *The San Diego Union-Tribune*, [Diversity in health research participants is key to finding cures](#), 6/14/18) ♦

STOPLIGHT®: Status of America's Blood Centers' Blood Supply



Daily updates are available at:

www.AmericasBlood.org

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 Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2018

June 25-26. **FDA 2018 Center for Biologics Evaluation Research Science Symposium, Silver Spring, MD.** More details available [here](#).

July 18-19. **FDA Blood Products Advisory Committee Meeting, Silver Spring, MD.** More details available [here](#).

July 31-Aug. 2. **Summer Meeting & MD Workshop, Montreal, Québec.** Contact: ABC Meetings Dept. Phone: (202) 654-2917; e-mail: meetings@americasblood.org.

Sept. 5-7. **3rd European Conference on Donor Health and Management, Copenhagen, Denmark.** More details available [here](#).

Sept. 11. **37th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD.** More details available [here](#).

Sept. 12. **8th Annual Symposium Red Cell Genotyping 2018: Patient Care, Bethesda, MD.** More details available [here](#).

Oct 15-16. **510(k) Submissions Workshop, Washington, D.C.** More details available [here](#). 💧

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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Division Director. Hoxworth Blood Center seeks a qualified, experienced Division Director to maximize the blood products collected and increase our ability to deliver existing and new products to customers. This Senior Level Director reports directly to the COO. Primary responsibilities: Eliminate inefficient processes, provide meaningful donor satisfaction data, collect new products for our donors, reduce products lost, ensure collection records are completed and issues are resolved within 24 hours, maximize donor operations so Hoxworth has a combination of blood products to resource share \$650,000 in products by end of year one, increase recovered plasma sold and implement the collection of Source Plasma. Requirements: bachelor's degree with nine (9) years of experience; or associate's degree with at least eleven (11) years of experience. Degree must be in a related field and related experience requires at least five (5) years of direct supervision. Apply to <http://www.uc.edu/hr/careers.html>. 💧