THE conference with the newest information from FDA & Industry!

13th Annual
FDA AND THE CHANGING PARADIGM FOR HCT/P REGULATION

Alexandria, Virginia | February 13 – 15, 2017
The Westin Alexandria

REGISTER EARLY!
Special discounts available

Conference produced by

Conference sponsored by
Please join us in a new location and venue in Alexandria, Virginia, for the 13th Annual FDA and the Changing Paradigm for HCT/P Regulation conference. We are pleased that we will have strong representation from FDA and many industry experts crossing the broad spectrum of tissues, cells, and cellular and tissue based products.

The conference opens with a moving Recipient Story to remind all of us how important our work is to those recipients that receive these tissue and cell based products. Additionally, there will be updates from the FDA regarding Donor Eligibility, Guidance documents, and Compliance as well as presentations reviewing Quality Program requirements related to Corrective Actions and Audits and HCT/P Establishment Inspections.

The conference format again includes smaller workshops each afternoon that will allow participants to apply the information learned in the morning sessions and allow for interaction between participants, industry experts, and FDA. You can expect to learn as well as provide others with your own experiences and expertise during these sessions.

On the last day of the three-day conference, we will conclude with the ever popular “Ask the FDA” session. Be sure to meet and visit with FDA representatives.

Our venue this year is the Westin Alexandria, conveniently located two Metro stops or a 15-minute taxi ride from Reagan International Airport. From the Metro stop it is a 10-minute walk or the hotel will come pick you up. Seated on the Potomac, Alexandria is a historic community known for its rich history and beautifully preserved 18th and 19th century architecture, not to mention its quaint boutiques and inviting restaurants. Discover Alexandria’s historic Old Town, eclectic Del Ray, innovative Carlyle and the diverse West End or visit DC just 25 minutes away. Highlights in the area are Mt. Vernon, the George Washington Masonic National Memorial and George Washington Estate and Gardens.

Register early to ensure your participation in a great learning opportunity and the chance to network with experts in your field both from industry and the FDA.

Who Should Attend?

- CEOs & COOs
- MDs and Medical Directors
- Donor Screeners
- Regulatory Managers and Personnel
- Recovery Personnel
- Quality Assurance Managers and Personnel
- Laboratory Supervisors and Personnel
- Processing Managers
- Compliance Professionals
- Legal Representation

Why Attend?

- These are the most far reaching regulations for the tissue and cell industry
- Learn how to reinforce compliance with your Quality Systems in specific areas
- Be prepared for an HCT/P Establishment Inspection and learn how best to respond to 483 Observations
- Interface with Industry experts and FDA

Continuing Education

The University of Tennessee College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Successful completion of this knowledge-based program will provide a statement for fourteen (14.0) live contact hours credit (1.4 CEUs) and will be mailed within 3 weeks following the program. Successful completion includes attending the session, signing the attendance sheet, and completion of the program evaluation form. CE credit will also be submitted to the NABP CE Monitor. Universal Activity Number (UAN): 0064-9999-17-009-L04-P

Register online at www.pharmaconference.com
About the Speakers

**Erica Agy, BS** – Ms. Agy started her career in 2000 in the pre-clinical realm primarily working with nonhuman primates in biomedical research. After three years of hands-on animal work, she transitioned to Quality Assurance, where she has since focused her efforts. In 2011, Ms. Agy was introduced to the world of HCT/P products when she was hired by the Seattle Cancer Care Alliance as a Quality Associate. At that time, her primary areas of focus were chart review and HCT/P product release from the Cellular Therapy Laboratory. In 2012, she accepted the role of the Quality Assurance Compliance Specialist. Her responsibilities include providing support to both the Cellular Therapy Laboratory, as well as the Apheresis Unit, which includes donor screening activities, and the collection and processing of 351 and 361 HCT/P products, and the assessment and reporting of HCT/P Deviations and Adverse Reactions.

**J. Wade Atkins, MS, MT(ASCP)SBB** – Mr. Atkins is a Quality Assurance Specialist for the Department of Transfusion Medicine (DTM) for the National Institutes of Health in Bethesda, Maryland. The DTM is a full service blood bank with a licensed collection facility and a full transfusion service. He has been in this position for the past 14 years. The DTM also has an active HCT/P manufacturing facility that supports roughly 80 protocols, and 30 of those are under IND at the FDA. He was a lead author for the WHO Annex for GMP in Blood Establishments. Prior to his current responsibilities at NIH, he worked as a Quality Assurance Specialist for Virginia Blood Services (VBS) in Richmond, Virginia. He also served VBS as the Technical Director prior to changing to QA. He also had positions in hospital transfusion services. He often speaks at local, national and international meetings on quality related topics. He is currently a volunteer assessor for AABB and an Inspector for CAP.

**Ashley Bilbo, BS, CTBS** – Ms. Bilbo has 10 years of experience in Tissue Banking. She joined LifeNet Health, a Virginia Beach based Tissue Bank in 2007. As the Manager of Quality Systems, her team is responsible for Tissue Supplier Audits, Internal Audits, Complaint Investigations, Nonconformance Investigations, and hosting second/third party audits of LifeNet Health. She started her work in tissue processing (2007-2010) and then transitioned to quality (2010-current).

**Scott Brubaker, CTBS** – Mr. Brubaker was selected in October 2016 as the new Director, Division of Human Tissues (DHT) in the Office of Tissues and Advanced Therapies (OTAT) within the Center for Biologics Evaluation & Research (CBER) at the Food & Drug Administration (FDA). Prior to that he served 12 years as Senior Vice President of Policy at the American Association of Tissue Banks (AATB) where duties included oversight of the Accreditation Program and the development and management of the Association’s policies, professional standards and guidance documents. Before joining AATB, he acquired 18 years of practical experience involving organ donation and tissue banking while holding various management positions at LifeNet in Virginia Beach, Virginia.

**Jennifer DeMatteo, MCM, CIC** – Ms. DeMatteo is the Director of Regulations and Standards for the Eye Bank Association of America. She oversees the EBAA Accreditation program, Medical Standards process and serves as the liaison with regulatory bodies, such as the FDA. She was responsible for directing the Infection Prevention and Control (IPC) and Employee Health programs and personnel at major tertiary hospital and ambulatory care settings. Ms. DeMatteo has been a Healthcare Epidemiologist for over 20 years and is certified in Infection Control & Epidemiology (CBIC).

**Michelle Haider, CQM/OE** – Ms. Haider is the Quality Improvement Manager for Saving Sight. She has 20 years quality experience in Medical Device, Pharmaceuticals and Eye Banking. She served with 2 start-up medical device companies, creating quality systems that brought products to market and was selected for a quality re-start initiative to rebuild the quality culture in the organization for a large pharmaceutical company. Ms. Haider has been an ASQ Certified Manager of Quality/Organizational Excellence since 2003 and holds a Medical Administration diploma from Minnesota School of Business. She is also pursuing a double-major in Quality Management and Manufacturing Management with a Minor in International Business through the University of Minnesota. She currently sits on the EBAA’s Quality Assurance Committee.

**Kip Hanks, BS** – Mr. Hanks is a Biologics National Expert for FDA’s Office of Regulatory Affairs. He began employment with the Agency in 1997 as a generalist investigator in New Orleans, LA. Over the years, his work focused on biologics and bioresearch monitoring. He served as the district biologics specialist for New Orleans and Atlanta Districts and was selected as the ORA biologics national expert in 2011 upon returning to post-Hurricane Katrina New Orleans. In this position, Investigator Hanks serves as a liaison between ORA and CBER, trains and mentors biologics investigators, participates on policy workgroups and continues to perform international inspections.

**Ellen Heck, BS, MBA, MT(ASCP)** – Ms. Heck is the founding director of the Transplant Services Center University of Texas Southwestern Medical Center at Dallas and holds faculty appointments in the departments of Surgery and Ophthalmology. She has served on the boards of the American Association of Tissue Banks, American Burn Association and Eye Bank Association of America where she served as Chairman. Various national activities also include the Blood Products Advisory Committee for the FDA, Chair of Accreditation committee for both AATB and EBAA, and member of the Medical Advisory Board for EBAA. Ms. Heck is currently serving as Editor in chief for the International Journal of Eye Banking.

To receive emails on our upcoming programs, add reception@pharmaconference.com to your address book.
About the Speakers

Wendy Hively, BS – Ms. Hively is a Consumer Safety Officer in the Division of Case Management, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research (CBER) and has been with the FDA since 2004. She is responsible for evaluating enforcement actions for blood and tissue products regulated by CBER and provides training on regulatory requirements for blood and tissue products within FDA. Ms. Hively also serves as a committee member for regulatory oversight and policy communication in the blood and tissue industries. From 2000 to 2003, she managed the Environmental Compliance Program for Kadena Air Base in Okinawa, Japan. Prior to her compliance work, Ms. Hively studied the role of oncogenes and tumor suppressor genes in the development of breast cancer and brain cancer in the Varmus Lab at the National Institutes of Health.

Safa Karandish, BS, MT(ASCP) – Ms. Karandish is a Consumer Safety Officer with FDAs Office of Cellular, Tissue and Gene Therapies in the Division of Human Tissues. She joined FDA in 2010, and her primary focus is related to policy, regulations and review of cellular therapy products. Ms. Karandish has extensive cellular therapy experience in both academic and industry settings.

Victoria (Tory) Lake, RAC, BA, BS – Ms. Lake is the founder of Sound Regulatory Consulting, LLC where she operates as an independent regulatory affairs consultant. She offers regulatory support and guidance to manufacturing facilities and clinical trial sponsors utilizing novel cell therapy investigational products and hematopoietic progenitor stem cells, subject to FDA’s regulations for current Good Manufacturing Practices (CGMP) and current Good Tissue Practices (CGTP). Previously, Ms. Lake served as the Regulatory Affairs Director for Fred Hutchinson Cancer Research Center. Prior to that she served as the Associate Director of Regulatory Affairs for a biologics company focused on immunotherapies.

Mary Malarkey, BS – Ms. Malarkey is the Director of the Office of Compliance and Biologics Quality (OCBQ) in the Center for Biologics Evaluation and Research at the US Food and Drug Administration. OCBQ is responsible for ensuring the quality of products regulated by CBER over their entire lifecycle through pre-market review and inspection, and post-market review, surveillance, inspection, outreach and compliance. Her previous positions at CBER were Director, Division of Case Management from 2000-2005 and Branch Chief in the Division of Manufacturing and Product Quality (DMPO) from 1996-2000. She worked in Research and Development in industry prior to joining FDA, and has been with CBER since 1989. She did laboratory work in both the Office of Therapeutics Research and Review and Office of Blood Research and Review prior to becoming a full time reviewer in 1993.

Linda Martin, BA – Ms. Martin is the Vice-President, Tissue and Support Services for Mid-America Transplant. She is an accomplished leader with over 25 years of experience in the transplant industry. She has been with Mid-America Transplant for 26 years, rising through the ranks from Tissue Services Coordinator to oversee Tissue Clinical Services before becoming Vice President of Tissue and Support Services in 2014. Among Ms. Martin’s key accomplishments is serving as the project manager for the organization’s 2015 Malcolm Baldrige National Quality Award application, resulting in Mid-America Transplant being named the first Organ Procurement Organization in the country recognized as a Baldrige recipient. She has also served on the Board of Examiners for the Baldrige Program for the past four years. In addition, Ms. Martin has been actively involved in industry organizations including the Eye Bank Association of America, the Association of Organ Procurement Organizations, and the American Association of Tissue Banks. Her passion for donation, combined with her collaborative style, builds consensus and fosters organizational growth and sustainability.

Kristin Mathes, BA, MA – Ms. Mathes began working in eye banking in 1999 in Colorado. She performed recoveries, tissue suitability evaluations, determined donor eligibility, and placed tissue for surgery. In 2007 she left to work for a medical device company in the Regulatory Affairs department. In 2008, she moved to Oregon and began working at Lions VisionGift. She has a Bachelor's and Master's degree in Political Science from the University of Colorado – Denver and is currently seeking a Master's in Science with a focus on Regulatory Science from Johns Hopkins University.

Michelle McClure, PhD – Dr. McClure has been a biologist with FDA’s Office of Cellular, Tissue, and Gene Therapies in the Division of Human Tissue since 2014. Her primary focus is policy development and regulatory review as it relates to eligibility of donors of human tissue. Prior to obtaining a Ph.D. in genetics, Dr. McClure worked in a cardiovascular and orthopedic tissue processing laboratory at a biotechnology company.

Audra McConnell, CTBS – Ms. McConnell joined RTI Surgical, Inc. in 2003 and is currently the Senior Manager of Regulatory Compliance. She has been working in tissue banking for over 20 years with experience in donor recovery and eligibility, quality management systems and compliance for HCT/Ps and medical devices. Her expertise is primarily in complaint handling, CAPA, auditing and regulatory reporting.

Register online at www.pharmaconference.com
About the Speakers

Sharon O’Callaghan, BS, MT(ASCP) – Ms. O’Callaghan is a Consumer Safety Officer with the Division of Inspections and Surveillance, Office of Compliance, Center for Biologics Evaluation and Research (CBER). She joined FDA in 1988 as a medical technologist and has managed the Biological Product Deviation (formerly Error and Accident) Reporting System since 1990. Ms. O’Callaghan was instrumental in developing the final rule on reporting Biological Product Deviations, published November 7, 2000.

Angela Ondo, BS, MT(ASCP) – Ms. Ondo is the Quality Assurance Manager for the BMT Program and Cell Therapy Laboratory at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in Baltimore, Maryland. Her responsibilities include overseeing regulatory and quality of donor screening, collections and processing of 351 and 361 HCT/P products. Prior to this, Ms. Ondo was a Quality Assurance Officer in the Blood Donor Center at the Johns Hopkins Hospital.

Joel Osborne, BA, MT(ASCP), CTBS – Mr. Osborne is currently the Vice President of Affairs with the Musculoskeletal Transplant Foundation, where he is responsible for maintaining worldwide regulatory compliance. He has been with MTF since 1990. Mr. Osborne started his career with the American Red Cross and has worked in the field of tissue banking and blood banking for more than 35 years. He is a member of the American Association of Tissue Banks, American Society for Quality, American Society of Testing and Materials, and the Regulatory Affairs Professional Society.

Lindsay Palomino, BSN, RN, HP – Ms. Palomino has been a nurse for over 20 years in the field of oncology and bone marrow transplant. She has over 15 years of adult and pediatric clinical apheresis experience in two states, including three and a half years in the medical device industry providing customer technical support and training. She has been with the Seattle Cancer Care Alliance Apheresis Unit for over five years, providing patient care, managing the Training and Competency program, developing the Pediatric Photopheresis Program, publishing two abstracts to ASFA in the past three years, and recently succeeding to the Apheresis Manager position.

Kelly Patrick, BFA, CTBS – Ms. Patrick works for Community Tissue Services (CTS), where she has been employed since April 2006. At CTS, she approves new and revised procedures for Recovery and Microbiology operations, including those that involve Recovery’s environmental monitoring program. She also drives continuous improvement and CAPA opportunities, performs dozens of internal and external audits, and works to maintain both internal and regulatory compliance. Ms. Patrick is currently revising CTS’s Recovery Environmental Monitoring procedures to meet recent AATB updates to this Standard. She began her career with U.S. Tissue and Cell in Cincinnati, Ohio in 2003 as a Tissue Processing Technician. She became a Processing Supervisor in 2005 and continued in this position until U.S. Tissue and Cell was restructured in 2006.

Kristen Pereira, BS, CEBT, CTBS, CQIA, CQA (ASQ) – Ms. Pereira, Quality Compliance Coordinator, has been a part of the Sierra Donor Services Quality Assurance Department for the past eight years. She is involved in all aspects of Quality, from implementing policies and procedures, to adverse reaction reporting, to handling various types of third party inspections.

James Ravitz, BA, JD – Mr. Ravitz is practice group leader for Arent Fox LLP’s FDA Practice (Food & Drug). He also is a member in the life sciences and advertising groups, with a well-rounded practice focused on food and drug law, healthcare, consumer product safety, and advertising. Mr. Ravitz serves as vice chair of the firm’s consumer product safety committee. His FDA practice assists clients in navigating regulatory requirements impacting medical device combination products and medical technologies. He also helps clients through all regulatory phases of the approval, manufacture, marketing and retail process.

William “Drew” Timmons, RN, CTBS – In his 22 years as a Recovery Coordinator, Mr. Timmons has been involved in all aspects of organ, tissue, and eye donation. He began his career in donation at the Louisiana Organ Procurement Agency. There he was an organ recovery coordinator covering the entire state, then later became the regional manager for the north. At Transplant Services Center UT Southwestern Medical Center, Mr. Timmons covers a number of roles to include family services, hospital development, electronic donor record guru, graphic design, and wizard of cleaning printer jams. He maintains TSC’s facebook page and coordinates the donor and recipient stories portion of the website. He is also an award-winning photographer.

To receive emails on our upcoming programs, add reception@pharmaconference.com to your address book.
# Agenda

**Monday, February 13, 2017**

**Morning Session: Moderator – Victoria Lake**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 – 9:00</td>
<td>Registration</td>
</tr>
<tr>
<td>9:00 – 9:10</td>
<td>Welcome</td>
</tr>
<tr>
<td>9:10 – 9:30</td>
<td>Personal Interest Story Related to HCT/Ps To Be Introduced</td>
</tr>
<tr>
<td>9:30 – 9:45</td>
<td>FDA Update Scott Brubaker, OTAT, CBER, FDA</td>
</tr>
<tr>
<td>9:45 – 10:15</td>
<td>Establishment Registration and Listing Safa Karandish, OCTGT, CBER, FDA</td>
</tr>
<tr>
<td>10:15 – 10:50</td>
<td>Donor Eligibility and Guidance Updates Michelle McClure, PhD, OCTGT, CBER, FDA</td>
</tr>
<tr>
<td>10:50 – 11:10</td>
<td>Break*</td>
</tr>
<tr>
<td>11:10 – 11:40</td>
<td>Compliance Update Mary Malarkey, OCBQ, CBER, FDA</td>
</tr>
<tr>
<td>11:40 – 12:10</td>
<td>Question and Answer Session Morning Speakers</td>
</tr>
<tr>
<td>12:10 – 1:15</td>
<td>Lunch*</td>
</tr>
</tbody>
</table>

### Afternoon Workshops

**Workshop 1:**

**HCT/P Deviations and Reporting**
- **Eye**
- **Cells**
- **Tissue**

**Moderator:** Jennifer DeMatteo
- Kristin Mathes
- Erica Agy
- Ashley Bilbo
- Sharon O’Callaghan, OCBQ, CBER, FDA

**Workshop 2:**

**Donor Eligibility**
- **Eye**
- **Cells**
- **Tissue**

**Moderator:** Victoria Lake
- William Timmons
- Lindsay Palomino
- William Timmons
- Michelle McClure, PhD, OCTGT, CBER, FDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:55 – 3:15</td>
<td>Break*</td>
</tr>
<tr>
<td>3:15 – 4:45</td>
<td>Workshops Repeated</td>
</tr>
<tr>
<td>5:00 – 6:00</td>
<td>Networking Reception</td>
</tr>
</tbody>
</table>

**Tuesday, February 14, 2017**

**Morning Session: Moderator – Ellen Heck**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00 – 9:20</td>
<td>Establishment and Maintenance of a Quality Program Wendy Hively, OCBQ, CBER, FDA</td>
</tr>
<tr>
<td>10:05 – 10:50</td>
<td>Quality Audits – Industry Linda Martin</td>
</tr>
<tr>
<td>10:50 – 11:10</td>
<td>Break*</td>
</tr>
<tr>
<td>11:10 – 12:10</td>
<td>FDA Inspections of HCT/P Establishments Kip Hanks, ORA, FDA</td>
</tr>
<tr>
<td>12:10 – 12:30</td>
<td>Question and Answer Session Morning Speakers</td>
</tr>
<tr>
<td>12:30 – 1:35</td>
<td>Lunch*</td>
</tr>
</tbody>
</table>

Register online at [www.pharmaconference.com](http://www.pharmaconference.com)
Afternoon Workshops

1:45 – 3:15

**Workshop 1:**
**Responding to 483 Observations**
- FDA
- Industry

*Moderator: Kip Hanks, ORA, FDA*

Joel Osborne

**Facilitators:**
Cells - Erica Agy
Eye - Kristin Mathes
Tissue - Ashley Bilbo

**Workshop 2:**
**Quality Program**
- Supplies and Reagents
- Environmental Controls and Monitoring

*Moderator: Angela Ondo*

Eye - Kristen Pereira
Cells - J. Wade Atkins, NIH – invited
Tissue - Kelly Patrick
Cells - Angela Ondo
Wendy Hively, OCBQ, CBER, FDA

3:15 – 3:35 Break*

3:35 – 5:05

**Workshops Repeated**

Wednesday, February 15, 2017

Morning Session Moderator – Jennifer DeMatteo

9:00 – 9:40 **HCT/P 351 vs. 361 Products**
James Ravitz

9:40 – 10:00 **Tracking: Eyes/Tissues**
Michelle Haider

10:00 – 10:20 **Tracking: Cells**
J. Wade Atkins, NIH – invited

10:20 – 10:40 Break*

10:40 – 11:00 **Question and Answer Session**
Morning Speakers

11:00 – 12:00 **Ask the FDA**
FDA Personnel

*Denotes non-educational activity
13th Annual
FDA and the Changing Paradigm for HCT/P Regulation

Fees

<table>
<thead>
<tr>
<th></th>
<th>Industry</th>
<th>U.S. Gov't &amp; Press</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXTRA EARLY DISCOUNT: Payment Received Before November 1, 2016</td>
<td>$1495</td>
<td>$995</td>
</tr>
<tr>
<td>EARLY DISCOUNT: Payment Received By December 20, 2016</td>
<td>$1595</td>
<td>$995</td>
</tr>
<tr>
<td>NO DISCOUNT: Payment Received After December 20, 2016</td>
<td>$1695</td>
<td>$995</td>
</tr>
</tbody>
</table>

Includes conference materials, continental breakfasts, coffee breaks, lunches and reception per agenda

Cancellation Policy: 30 days or more for a full refund less $250 USD cancellation fee; under 30 days, no refund, but attendee substitutions may be made at any time. Cancellations and substitutions must be made in writing to Pharma Conference (email registration@pharmaconference.com). In the event of any civil disorder, extremely adverse weather conditions, or other Acts of God, Pharma Conference reserves the right to reschedule the meeting dates in the interest of attendee safety.

CLICK HERE TO REGISTER ON OUR SECURE SERVER

Payment

Full payment may be made by credit card or company check

- Checks must be received within 15 days of receipt of registration form.
- Checks should be made payable to Pharma Conference Inc, in U.S. dollars and drawn on a U.S. bank.
- Registrations will be confirmed when full payment has been received. Taxpayer ID #27-1438344.
- Registrations made within 30 days of conference start date must be accompanied by full payment.

Checks should be sent to Pharma Conference Inc at the following addresses (see check instructions above):
   Airmail to: P.O. Box 291386, Kerrville, Texas 78029 USA
   Express to: 819 Water Street, Suite 350, Kerrville, Texas 78028 USA

Hotel

The Westin Alexandria
400 Courthouse Square
Alexandria, Virginia 22314
1 (703) 253-8600
$189 single/double

A limited number of rooms have been blocked at the special rate listed per night. Rate is available 3 nights either side of the conferences dates. Hotel reservations must be made on or before January 13, 2017, in order to guarantee the special rate. Individuals are responsible for making their own hotel reservations. You must mention the title of the program AND Pharma Conference when making your reservation in order to obtain these special rates. Please do not use travel agents for reservations.

Reservations via Stargroups website for conference room block:
https://www.starwoodmeeting.com/events/start.action?id=1609222521&key=12BDF626
or call (866) 837-4210

For additional information, contact Pharma Conference Inc:
(830) 896-0027 • Fax: (830) 896-0029 • e-mail: contactus@pharmaconference.com

CLICK HERE TO REGISTER ON OUR SECURE SERVER