12th Annual 
FDA and the Changing Paradigm for 
HCT/P Regulation

San Antonio, Texas | February 24 – 26, 2016
Grand Hyatt San Antonio

REGISTER EARLY!
Special discounts available
Please join us in San Antonio Texas for the **12th Annual FDA and the Changing Paradigm for HCT/P Regulation** conference. San Antonio is one of the top tourist destinations in the U.S., and for good reason. The world-famous Alamo, the gorgeous River Walk, its old Spanish missions (which were recently designated as World Heritage Sites), and its ever-present Texas hospitality make any visitor feel welcome. (And don’t forget – it’s the capital of Tex-Mex food!) Once again we are thrilled to announce we will have strong representation from many FDA, CBER and HRSA staff members. You won’t want to miss out on the opportunity to hear the FDA representatives present a summary of compliance issues, and updates on guidance pertaining to the HCT/P regulations.

Back by popular demand, the conference format will include provocative and informative topics presented daily and smaller workshops one afternoon. The understanding and interpretation of the FDA HCT/P regulations and guidance documents continue to expand each year and will be discussed. There will be engaging topics presented by both FDA representatives and members of the cell and tissue industry on donor eligibility, manufacturing arrangement, HCT/P deviations and reporting, adverse reactions, process validation and surveillance.

**New this year** will be a presentation from an HRSA representative about how HRSA regulations are relevant to HCT/Ps. In addition, the well known standard-setting organizations in the tissue industry, such as EBAA, AATB, FACT and AABB, will present major guidance and standards changes in each of their accrediting agencies standards as they pertain to the FDA HCT/P regulations.

The afternoon workshops will include valuable information on reviewing relevant medical records, record retention, HCT/P Deviation reporting, adverse reactions, process validation, terminal sterilization and other facility validations.

On the last of the three-day conference, you won’t want to miss out on a presentation from a facility about learning how to survive an FDA Warning Letter as well as the ever-popular Ask the FDA session at the conclusion of the conference.

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

Because these are the most far-reaching regulations to affect your employment arena in recent history. In all probability, your industry and your local operations will be coming under closer FDA scrutiny in the near future. How are you and your organization adapting?

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The University of Maryland School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This knowledge-based activity meets the ACPE criteria for continuing education credit. Statements of credit will be mailed within 60 days to those participants who successfully complete the activity. Successful completion requires participation at the entire activity and completion of a activity evaluation form. No partial credit will be awarded.
About the Speakers

Brenda Alder, MS, MT(ASCP)SBB – Ms. Alder has worked for 18 years in the field of cell therapy transplant, tissue and cord blood banking, transfusion and donor services. She works at Northside Hospital in Atlanta, GA as the Quality Assurance, Standards and Regulatory Specialist for the Blood and Marrow Transplant Program at Northside Hospital. Ms. Alder currently serves on the AABB Cell Therapy Standards Program Committee and the AABB Cell Therapy Accreditation Program Committee. She is also the past committee chair for the AABB Interorganizational Donor History Questionnaire – Cellular Therapies Task Force from its inception until early 2012 and continues to serve as a consultant to this committee and is knowledgeable on donor eligibility determination. She has lectured for several organizations including AABB, Johns Hopkins Somatic Cell Therapy Symposium and the International Society for Cellular Therapy (ISCT).

Julie Allickson, PhD – Dr. Allickson focuses on the translation of regenerative medicine products including cell therapy, tissue engineering, biomaterials and devices. This process begins at Proof-of-Concept where early discussion with regulators and clinicians are critical in moving the technology from the bench to the bedside. The Translational Team includes Quality Assurance, Quality Control, Regulatory Affairs, Process Development and the GMP-compliant Manufacturing Facility. Prior to joining the institute, she was an Executive Officer of the company and Vice President of Laboratory Operations and R & D at Cryo-Cell International, Inc., an AABB accredited Cord Blood Bank.

Jennifer DeMatteo, MCM, CAC – 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).

Kip Hanks, BS – Mr. Hanks is an Investigator with the FDA. He began employment with the FDA as a generalist in the New Orleans District Office in 1998. As years passed, his work focused in bio-research monitoring (BIMO), drugs, medical devices and biologics. Investigator Hanks spent a few years in Atlanta District's Charleston, SC resident post as the District's biologics specialist. Upon returning to post-Katrina New Orleans, he served as the New Orleans District's biologics specialist. Investigator Hanks was selected as the Office of Regulatory Affair's biologics national expert in January 2011. His experience includes inspections and investigations, as well as providing training to FDA and industry, for all types of biologics establishments, including blood, source plasma and human tissue. Mr. Hanks is an active member of FDA's foreign inspection cadre for the biologics and BIMO program areas.

Ellen Heck, BS, MBA, MT(ASCP) – Ms. Heck is the 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.

Erica Lang, BS – Ms. Lang 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. Lang 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.

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About the Speakers

Jennifer Li, MD – Dr. Li is an Associate Professor of Ophthalmology at the UC Davis Eye Center. She received her medical degree and residency at the Baylor College of Medicine in Houston, Texas, and subsequently completed a fellowship in cornea, external disease and refractive surgery at UC Davis. Dr. Li is an active member of the Eye Bank Association of America (EBAA). She was selected to participate in the EBAA Young Physician Leadership Program in 2011 and currently serves on the EBAA Accreditation Board and the Scientific Programs Committee. She is the current Vice Chair of the EBAA Medical Advisory Board. She is also the co-medical director of Sierra Donor Services along with Dr. Mark Mannis, and is a member of the Sierra Donor Services Advisory Board.

Mary Malarkey, BS – Ms. Malarkey is the Director, Office of Compliance and Biologics Quality (OCBQ), at FDA’s Center for Biologics Evaluation and Research (CBER). From 2000 through 2004, she was the Director, Division of Case Management (DCM), OCBQ, CBER. Prior to that, Ms. Malarkey was a Branch Chief in the Division of Manufacturing and Product Quality (DMPQ), CBER. She worked in Research and Development in industry prior to joining FDA, and has been with CBER since 1989.

Tim Maye, BS, MT – Mr. Maye is the Vice President of Quality Systems for LifeNet Health, where he is responsible for ensuring the overall effectiveness of the quality system and corporate-wide compliance with FDA, ISO 13485, AATB, State and international requirements. During his 17 years there, Mr. Maye served in roles within Laboratory and Cardiovascular operations, Medical Examiner relations, and Quality Systems. He currently serves as the Vice-Chair of AATB’s Standards Committee, and previously served on AATB’s Program Committee.

Michelle McClure, PhD – Dr. McClure is a biologist at the FDA. In 2003, she began working at a tissue establishment as a processor of cardiovascular and orthopedic tissues. After five years of working as a technician and a team leader, Dr. McClure decided to leave the field to attend graduate school at the University of Alabama at Birmingham. Her research focused on investigating novel molecular pathways that serve as potential therapeutic targets for the treatment of Cystic Fibrosis. In 2013, she was awarded a Ph.D. in Biomedical Sciences through the Department of Genetics. She now works at the FDA in the Office of Cellular, Tissue, and Gene Therapies in the Division of Human Tissues and serves as the FDA liaison to several organizations and working groups.

Sharon O’Callaghan, BS – 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.

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About the Speakers

Laura M. St. Martin, MD, MPH – Dr. St. Martin is a Medical Officer with FDA/CBER in the Division of Human Tissues and a Captain in the U.S. Public Health Service Commissioned Corps. She joined FDA in May of 2006 and her primary responsibilities are related to tissue safety. Dr. St. Martin is Chair of FDA’s Tissue Safety Team, which investigates reports of adverse reactions in tissue recipients. Prior to joining FDA, she served over seven years as Chief Medical Officer for the Division of Transplantation in the Health Resources and Services Administration, which oversees solid organ transplantation.

Chris Stoeger, MBA, CEBT, CTBS – Mr. Stoeger is the Director of Operations at Lions VisionGift in Portland, OR. He has over 20 years of experience in the eye and tissue banking field. He has served on numerous committees at the EBAA as well as on the EBAA Board of Directors. Mr. Stoeger currently serves on the Accreditation Board and the Medical Advisory Board. He is the co-author of numerous peer reviewed scientific articles and currently serves on the Editorial Board of the International Journal of Eye Banking. Mr. Stoeger has presented at many industry and scientific meetings with a special expertise in ocular tissue processing.

Jonna Turner, MS, CQA, CTBS – Ms. Turner is the Manager of Quality Systems at LifeNet Health, a full-service tissue bank and trusted provider of transplant solutions headquartered in Virginia Beach, Virginia. Ms. Turner joined the organization in 2008 and is currently responsible for ensuring regulatory compliance and effective implementation of quality systems within the west coast locations of LifeNet Health based in Renton, Washington. She provides leadership and oversight for activities of the Quality Systems department, including: audits, investigations, complaints, validations and lean implementation.

Phyllis Warkentin, MD – Dr. Warkentin, Professor of Pathology/Microbiology and Pediatrics, University of Nebraska Medical Center, is the Chief Medical Officer and a founding member of the Board of Directors of the Foundation for the Accreditation of Cellular Therapy (FACT), headquartered at and affiliated with the University of Nebraska Medical Center, Omaha, NE. She is board-certified in Pediatric Hematology/Oncology and Transfusion Medicine. She is also the Medical Director of the Biologics Production Facility at the University of Nebraska.

Martha A. Wells, MPH, RAC – Ms. Wells joined Dohmen Life Science Services (formerly Reglera) in 2010. Her responsibilities include development and implementation of strategic regulatory approaches for complex human tissue and cellular therapies. As VP of Regulatory Affairs for Tissue and Biologics she is involved with assisting clients with route to market assessments, regulatory submissions, as well as responses to FDA compliance actions. Prior to joining Dohmen Life Science Services, Ms. Wells held a number of different positions at FDA for over 30 years. At the time she retired from FDA, she was the Chief of the Human Tissue and Reproduction Branch of the Division of Human Tissues, in the Office of Cellular, Tissue, and Gene Therapies, CBER, FDA.

Venue

San Antonio
San Antonio captures the spirit of Texas. Now the seventh largest city in the United States, the city has retained its sense of history and tradition, while carefully blending in cosmopolitan progress. The city has always been a crossroads and a meeting place. Sounds and flavors of Native Americans, Old Mexico, Germans, the Wild West, African-Americans and the Deep South mingle and merge. Close to 20 million visitors a year delight in the discovery of San Antonio’s charms, which include The Alamo, the world-famous Paseo Del Rio or River Walk, and the World Heritage Site Spanish missions.
February 24, 2016
Morning Session Moderator – Brenda Alder, Conference Chairman

8:00 – 9:00  Registration
9:00 – 9:10  Welcome
9:10 – 9:50  FDA Regulatory and Guidance Update  
             OCTGT, CBER, FDA Invited
9:50 – 10:10 AATB Major Guidance and Standards Changes  
              Tim Maye
10:10 – 10:30 EBAA Major Guidance and Standards Changes  
              Jennifer Li, MD
10:30 – 10:50 AABB Major Guidance and Standards  
              Julie Allickson, PhD
10:50 – 11:10 Break*
11:10 – 11:30 FACT Major Guidance and Standards  
             Phyllis Warkentin, MD
11:30 – 12:00 FDA Compliance Update  
             Mary Malarkey, OCBQ, CBER, FDA Invited
12:00 – 12:30 Question and Answer Session  
             Morning Speakers
12:30 – 1:45 Lunch*

Afternoon Session Moderator – Ellen Heck
1:45 – 2:45  HRSA as relevant to HCT/Ps  
             Melissa Greenwald, HRSA Invited
2:45 – 3:15  Manufacturing Arrangements – FDA Overview  
             Kip Hanks, ORA, FDA Invited
3:15 – 3:35  Break*
3:35 – 4:35  Manufacturing Arrangements – Maintaining Compliance with FDA Regulations -Industry  
             Victoria Lake and Martha Wells
4:35 – 5:00  Question and Answer Session  
             Afternoon Session

February 25, 2016
Morning Session Moderator – Martha Wells

9:00 – 9:45  HCT/P Deviation Coding  
             Sharon O’Callaghan, OCBQ, CBER, FDA Invited
9:45 – 10:15  Adverse Reactions  
             Laura St. Martin, MD, OCTGT, CBER, FDA Invited
10:15 – 10:35  Break*
10:35 – 11:05  Donor Eligibility  
             Michelle McClure, PhD, OCTGT, CBER, FDA Invited
11:05 – 12:05  Process Validation and Surveillance  
             Speaker TBA
12:05 – 12:45  Question and Answer Session  
             Morning Speakers
12:45 – 2:00  Lunch*
Afternoon Workshops

2:00 – 3:30  **Workshop 1: Relevant Medical Records**  
Summary of Records  
Record Retention  
Sources of Records  
Ellen Heck  
Jennifer Li, MD  
Angela Ondo  
FDA Representative: OCBQ, CBER, FDA Invited

**Workshop 2: HCT/P Deviation Reporting**  
Adverse Reactions  
Erica Lang  
Jonna Turner  
FDA Representative:  
Laura St. Martin, MD, OCBQ, CBER, FDA Invited

**Workshop 3: Process Validation**  
Micro  
Terminal Sterilization  
Verification of Other Facilities Validation  
Joel Osborne  
Chris Stoeger  
Speaker TBA  
FDA Representative: OCBQ Staff  
OCBQ, CBER, FDA Invited

3:30 – 3:50  Break*

3:50 – 5:20  **Workshops Repeated**

February 26, 2016  
**Morning Session Moderator – Jennifer DeMatteo**

9:00 – 10:00  **Surviving an FDA Warning Letter**  
Joel Osborne

10:00 – 10:15  **Question and Answer Session**

10:15 – 10:35  Break*

10:35 – 11:50  **Ask the FDA**

*Denotes non-educational activity
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Fees

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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.

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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.

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$229 single/double

A limited number of rooms have been blocked at the special rates listed per night. Hotel reservations must be made on or before February 2, 2016, 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.

Link to make reservations:

For additional information, contact Pharma Conference Inc:
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