11th Annual
FDA and the Changing Paradigm for HCT/P Regulation

A Cellular/Tissue Conference

THE conference for the newest information from FDA & Industry!

Washington D.C. Area/Bethesda, Maryland
March 23 – 25, 2015
Hyatt Regency Bethesda
Please join us in Bethesda, Maryland, for the 11th Annual FDA and Changing Paradigm for HCT/P Regulation conference. The conference is held practically in the backyard of the FDA headquarters, and once again will are thrilled to announce we will have strong representation from many FDA staff members. You won’t want to miss out on the opportunity to hear the FDA representatives present a summary of compliance issues from the past year and to be able to interact personally with FDA staff and ask questions.

Back by popular demand, the conference format will include provocative and informative topics presented each morning and smaller break out groups each afternoon. Although the FDA HCT/P regulations haven’t changed much since their inception in 2005, the understanding and interpretation of the regulations and guidance documents continue to expand each year. There will be engaging topics presented by both the FDA and members of the cell and tissue industry on donor suitability/eligibility, FDA inspection readiness and reporting, compliance, recalls, deviations and adverse reactions. We will dissect the FDA Tissue Registration rule and learn more about labeling HCT/P products.

On the last day of the three-day conference, you won’t want to miss the ever-popular Ask the FDA session and to hear more details about FDA Guidance documents that are due to be released to the public by the end of 2014.

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.

### ABOUT THE VENUE

Bethesda, Maryland, is a thriving urban district that is part of the Washington, DC Metro Area. Access to the national monuments is less than 30 minutes away on the Metro Red Line. Bethesda is also the home of the Bethesda Naval Hospital (Bethesda Naval Medical Center) and the National Institutes of Health (NIH).

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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).

Paul Ashford, MSc – Mr. Ashford is Executive Director of ICCBBA, the international standards organization that is responsible for the ISBT 128 Information Standard for Medical Products of Human Origin. ICCBBA is a nongovernmental organization in official relations with the World Health Organization. From a background as a Clinical Scientist in transfusion medicine, Mr. Ashford moved into the IT field in the early 1980’s. He obtained a Masters Degree in Computer Science and now has over 30 years experience working at the interface between the scientific, clinical and informatics interests in the field of transfusion and transplantation medicine.

Michael Bauer, MD – Dr. Bauer is board certified in Clinical Pathology and Transfusion Medicine. He served in Grand Rapids, Michigan, East Orange, New Jersey and Denver, Colorado as a blood bank physician. Since beginning a private consulting practice in September of 2000, Dr. Bauer has become a nationally recognized medical expert in tissue banking, infectious disease consulting, and laboratory testing. He is a Certified Tissue Bank Specialist, and has been involved in eye and tissue banking for over 18 years. Since surviving cancer in 1999, Dr. Bauer has become involved in the field of personalized medicine, serving as Physician of Record for direct-to-consumer testing laboratories.

Sherri Cyrus, MT (ASCP) SBB – Ms. Cyrus is currently Director of Operations for the Specialty Laboratories at Creative Testing Solutions (CTS). CTS (formerly Blood Systems Laboratories) is an FDA registered, CLIA licensed donor testing laboratory serving many different blood and tissue center customers. Ms. Cyrus has spent more than 35 years in various clinical laboratory settings and has devoted the past 30 years to blood, organ, eye and tissue donor testing. For the past 20 years, she has been directly involved in providing leadership and operational management for donor screening, confirmatory and supplemental donor testing, component quality control and research support at CTS. Throughout her career she has participated in several clinical trials, many infectious disease reagent studies and has collaborated on several publications.

Patricia Dahl, BS – Ms. Dahl is the Executive Director/CEO of The Eye-Bank for Sight Restoration in New York and has 30 years of experience in eye banking. She is a past Chair of the Eye Bank Association of America and has served on a variety of key committees, including its Medical Advisory Board, Accreditation Board and Certification Board. Additionally, she is an active member of the European Association of Eye Banks. She is also a member of the New York Alliance for Donation, a statewide collaborative organization established to increase awareness for organ, eye and tissue donation, and serves on the New York State Transplant Council.

Janice Davis-Sproul, MAS, MT(ASCP)SBB – Ms. Davis-Sproul is the Manager of the Cell Therapy Laboratory at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in Baltimore, Maryland. She is responsible for the operation of the Cell Therapy Laboratory as well as the process development teams that support the Cell Therapy and the cGMP Cell Processing and Gene Therapy Facility. These laboratories manufacture clinical cell and gene therapy products for use within Johns Hopkins. Prior to this, Ms. Davis-Sproul was the Director of Cell Processing Development and Operations for Osiris Therapeutics, Inc. She has worked in the field of cell processing for more than 20 years.

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).

David Glasser, MD – Dr. Glasser is in private practice in Columbia, Maryland. He is Chairman of the Board of Directors of the Eye Bank Association of America, President of the Maryland Society of Eye Physicians and Surgeons, Past President of the Cornea Society, and serves on the Editorial Board of the journal Cornea. Dr. Glasser lectures nationally and internationally. In addition, he is Assistant Professor of Ophthalmology at the Johns Hopkins University School of Medicine and Clinical Associate Professor of Ophthalmology at the University of Maryland School of Medicine, and is Associate Medical Director of the Medical Eye Bank of Baltimore and Washington, DC.
THE SPEAKERS

Kip J. Hanks, BS – Mr. Hanks began employment with the FDA as a generalist in the New Orleans District Office in 1998. As years passed, his work focused in bioresearch monitoring (BIMO), drugs, medical devices and biologics. Mr. 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 New Orleans District's biologics specialist. Mr. Hanks was selected as DDFI's biologics national expert in January 2010 and continues to work out of New Orleans District's Metairie, LA resident post. His experience includes inspections and investigations, as well as providing training to FDA and industry, for all types of biologics establishments, including blood, plasma, biological drugs and human tissue. Mr. Hanks is an active member of DDFI'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.

Richard Jordan, BBA, CEBT, CTBS – Mr. Jordan has worked in tissue and eye banking for more than 30 years and is the Associate Director for the Transplant Services Center (TSC) at UT Southwestern Medical Center in Dallas, Texas. TSC is a full service tissue and eye bank serving primarily the Dallas/Fort Worth Metroplex, North Central and North East Texas. Mr. Jordan oversees Clinical Review and the Quality Assurance program and has served on a variety of committees and Board positions for both AATB and EBAA.

Safa Karandish, BS, MT(ASCP) – Ms. Karandish is a Consumer Safety Officer with FDA's Office of Cell, 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. She is a member of the Tissue Safety Team. Ms. Karandish has extensive cellular therapy experience in both academic and industry settings.

Victoria Lake, 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. Her relevant work experience includes managing the FDA regulatory submission process; including writing and reviewing numerous IND/IDE applications and amendments, contributions to chemistry, manufacturing, and controls development for cell therapy products, regulatory strategy from preclinical development through clinical trials, FDA interactions, FDA Inspection support, CGMP compliance, CGTP compliance, Good Clinical Practices compliance, and contributions to clinical protocol design, case report form design, and integration of clinical data into regulatory submissions.

Ellen Lazarus, MD – Capt. Lazarus is the Director of the Division of Human Tissues in the Office of Cellular, Tissue, and Gene Therapies, Center for Biologics Evaluation and Research. While at FDA she has been involved in regulatory review and policy development for human cells and tissues, and blood products. Prior to joining FDA, she served as a pathologist and blood bank medical director in the US Army.

Mary Malarkey, BS – Ms. Malarkey is the Director, Office of Compliance and Biologics Quality (OCBO), 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.

Kristin Mathes, BA, MA – Ms. Mathes started working in eye banking in 1999 in Colorado for Rocky Mountain Lions Eye Bank. She performed recoveries, tissue suitability evaluations, determined donor eligibility, and placed tissue for surgery. She was a Certified Eye Bank Technician (CEBT) until 2007 when she left RMLEB to work for a medical device company in the Regulatory Affairs department. In 2008, she moved to Oregon and began working at Lions VisionGift in the Quality Assurance department.

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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.

Simone Porter, MD, MPH – Dr. Porter is a medical officer in the Division of Human Tissues (DHT) at FDA's Center for Biologics Evaluation and Research (CBER). She joined DHT in 2013 where she reviews exemption requests, investigates reports of adverse reactions in tissue recipients, and develops regulatory policy for human cells, tissues and cells and tissue-based products (HCT/Ps).

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.

Olive Sturtevant, MHP, MT (ASCP) SBB, SLS – Ms. Sturtevant is the Director for the Quality Assurance department for Cellular Therapies at Dana Farber Cancer Institute and affiliated institutions. She oversees quality initiatives and provides regulatory support for cell therapy based programs and clinical trials covering the areas of bone marrow transplantation, immunotherapy and regenerative medicine. In this role her responsibilities range from managing the quality improvement program to providing regulatory support for cell therapy based INDs and overseeing implementation of new assays, instruments and information systems to meet the rapidly changing technical requirements in this novel field. Ms. Sturtevant has over 30 years of experience and has held a variety of management positions.

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.

Diane Wilson, RN, BSN, MSN/MHA, CTBS – Ms. Wilson is the Chief Operating Officer of Tissue Services for Community Blood Center/Community Tissue Services based in Dayton, Ohio. She earned her Associate Degree in Nursing from Everett Community College in Everett, Washington. She received her Bachelors of Science Degree in Nursing from the University of Phoenix, and her Master's of Science in Nursing and Health Administration from the University of Phoenix. Ms. Wilson is an active AATB Member and has served on all AATB Committees and was past President of AATB.

Trevor Wright, BA, RAC – Mr. Wright is the Regulatory Affairs Manager at one of the nation’s largest non-profit tissue banks, AlloSource, located in Centennial, Colorado. His current responsibilities include domestic and international regulatory compliance and registration, including evaluation of donor eligibility criteria, product labeling, and regulatory submissions. He has 12 years of experience in Quality and Regulatory Affairs in the Blood, Medical Device, and HCT/P industries. Prior to his QA/RA roles, he spent two years in the Peace Corps in Honduras and three years working as a field biologist, supporting ecosystem modeling projects for the EPA in Corvallis, Oregon.

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Monday, March 23, 2015 Morning Session
Moderator – Brenda Alder, Conference Chair

8:00 – 9:00  Registration
9:00 – 9:10  Welcome
9:10 – 9:35  FDA HCT/P Regulatory Update  Ellen Lazarus, MD, FDA
9:35 – 10:05  FDA Registration Form 3356  Safa Karandish, FDA

• What is manufacturing?
• Requirements for registration
• More than one site
• Management

10:05 – 10:35  FDA Compliance Update  Mary Malarkey, FDA

• Inspection findings
• Compliance actions
• Recalls
• Legal actions
• New initiatives – compliance related

10:35 – 10:55  Break*
10:55 – 11:35  Reporting Biologic Product Deviations and Adverse Reactions  Laura St. Martin, MD, FDA

• Regulations and numbers of reports  Sharon O'Callaghan, FDA
• Statistics

11:35 – 12:00  Question and Answer Session  Morning Speakers
12:00 – 1:15  Lunch*

Afternoon Workshop Sessions: Attendees may attend two of three sessions

1:15 – 2:45  Workshop 1:  Saifa Karandish, FDA
FDA Registration  Brenda Alder

Workshop 2:
Inspection Readiness  Kip Hanks, FDA
Focus on Cell Therapy  Victoria Lake

Workshop 3:
Reporting  Richard Jordan, Olive Sturtevant
Laura St. Martin, MD, FDA  Sharon O’Callaghan, FDA

2:45 – 3:05  Break*
3:05 – 4:35  Above workshops are repeated, please attend the second workshop of your choice
5:00 – 6:00  Reception*

Tuesday March 24, 2015 Morning Session
Moderator – Martha Wells

9:00 – 9:30  FDA Eligibility  Michelle McClure, PhD, FDA
9:30 – 10:00  Donor Suitability/Eligibility  Michael Bauer, MD
10:00 – 10:30  Communicable Disease Testing  Sherri Cyrus

• Sample reaction
• Time frames
• Approved test kits

10:30 – 10:50  Break*
10:50 – 11:20  Labeling and Accompanying Records  
Kip Hanks, FDA

11:20 – 12:00  Question and Answer Session  
Morning Speakers

12:00 – 1:15  Lunch*

Afternoon Workshop Sessions: Attendees may attend two of three sessions

1:15 – 2:45  Workshop 1:  
Labeling  
Pre-Distribution, Eligibility and Package Inserts  
Accompanying Records and Summary  
Approved Kits  

Brenda Alder  
Trevor Wright  
Kristen Mathes  
Kip Hanks, FDA

1:15 – 2:45  Workshop 2:  
Testing  
Dilution – False Positive  
Sample Integrity  

Sherri Cyrus  
Ellen Heck  
FDA OCBQ Invited

1:15 – 2:45  Workshop 3:  
Eligibility/Suitability  
Case Studies  
Cord  
Cells  
Tissues  

David Glasser, MD  
Angela Ondo  
Michelle McClure, PhD, FDA

2:45 – 3:05  Break*

3:05 – 4:35  Workshops repeated

Wednesday March 25, 2015
Morning Session – Moderator: Jennifer DeMatteo

8:30 – 10:30  ISBT (Information Standard for Blood and Transplant) Panel  
Paul Ashford  
Diane Wilson, RN  
Patricia Dahl  
Olive Sturtevant

10:30-10:50  Break*

10:50 – 11:10  FDA Update (for new guidance documents)  
Simone Porter, MD, FDA  
Ellen Lazarus, MD, FDA

11:10 – 12:00  Ask the FDA

12:00  Meeting Adjourns

*Denotes non-educational activity

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