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18TH ANNUAL
FDA AND THE
CHANGING
PARADIGM
FOR HCT/P
REGULATION

APRIL 18 – 19, 2023
ALEXANDRIA, VIRGINIA
HILTON ALEXANDRIA OLD TOWN



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About the Conference

Please join us in Old Town, Alexandria, Virginia, for the **18th Annual FDA and the Changing Paradigm for HCT/P Regulation** conference. We are pleased to have strong representation from FDA and many industry experts crossing the broad spectrum of tissues, cells, and cellular and tissue-based products.

FDA will provide Office and Division updates, an HCT/P Regulatory Framework overview, donor screening, testing, and eligibility presentations, as well as share compliance updates and inspectional observations. Additional topics include an overview of labeling requirements and accompanying documentation and adverse reaction reporting.

Industry will provide insights through presentations that cover submissions for determination of 361 HCT/P status, navigating supply chain issues, and a special presentation regarding the NIST Rapid Microbial Testing Methods Consortium and USP's Evolving Position on the Use of Rapid Microbial Methods. Workshops will address strategies for increasing training effectiveness, HCT/P Deviations, and Practical Applications of Bridging the Gap between 361 and 351 HCT/Ps. Additional workshops include those covering donor screening, testing, and eligibility (including a workshop specifically focused for the reproductive tissue industry.)

This year will include a donor family story, a perspective not yet given at these conferences. It will provide the unique perspective of what a donor's family endures in the loss of a loved one, with the hope of being able to help recipients. Also, an excellent reminder of how important our work is to those recipients that receive tissues, cells, and cellular and tissue-based products.

The conference format again includes smaller workshops each afternoon that will allow participants to interact with 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 two-day conference, we will conclude with the ever popular *Ask the FDA* session. Send your questions early, even right after you register to registration@pharmaconference.com.

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?

- These are the most far-reaching regulations for the tissue and cell industry
- Listen to FDA office and division updates, as well as compliance actions
- Understand the HCT/P Regulatory Framework
- Hear how others have worked with FDA on determination of 361 HCT/Ps
- Learn details about donor screening, testing, and eligibility
- Discuss supply chain issues
- Review requirements for labeling and accompanying documentation
- Learn about the NIST Rapid Microbial Testing Methods Consortium
- Discuss adverse event reporting and HCT/P deviation reporting
- Learn and share best practices for training personnel
- Discuss practical applications of how to bridge the gap between 361 and 351 HCT/Ps
- Discuss Reproductive HCT/P specific issues related to Donor Eligibility and Labeling
- Interface with Industry experts and FDA

Register online at www.pharmaconference.com

About the Speakers



CDR Jason D. Abel, BS, MS, RPS/RPES – CDR Abel has been a Compliance Officer with FDA/Office of Regulatory Affairs (ORA)/Office of Biological Products Operations (OBPO) since 2019. His responsibilities include ensuring compliance of biological establishments/products with FDA enforced laws/regulations. CDR Abel is an officer in the US Public Health Service, Commissioned Corps (PHS). During his career with FDA from 2002–2019, he has served as an Investigator (2002–2015) and District Biologist Specialist (2015–2017) with the New Orleans District and as a Biologics Specialist with OBPO (2017–2019).



Erica Agy, BS – Ms. Agy has more than 20 years of experience in Quality Assurance in both the pre-clinical and clinical settings. As the Senior Manager of Quality Assurance, she is responsible for the regulatory and accreditation continuous readiness program managing inspection preparation, coordination, performance and follow-up for FDA, FACT, CAP, The Joint Commission, and clinical trial monitor visits for both the Cellular Therapy Laboratory and the Apheresis Unit at Fred Hutchinson Cancer Center. Ms. Agy is a practiced auditor to both internal and regulatory standards. She routinely works with multiple internal and external organizations, as well as with corporate sponsors to ensure a seamless, safe and efficient process for delivering life-saving products.



Scott A. Brubaker – Mr. Brubaker was selected in October 2016 as the Director, Division of Human Tissues that resides today in the Office of Cellular Therapy and Human Tissue CMC. Prior to that, he served 12 years as Senior Vice President of Policy at the American Association of Tissue Banks where duties included the development and management of Association policies, professional standards and guidance documents, and oversight of the Accreditation Program. Before joining AATB, Mr. Brubaker acquired 18 years of practical experience involving organ donation and tissue banking while holding various management positions at an OPO/Tissue Bank in Virginia. He has authored or co-authored more than 40 publications and is co-editor of 3 essential guides (books) for tissues and cells that cover donation, processing, and clinical use.



Marla Cassidy, BA – Ms. Cassidy has been with the FDA since 2010, performing domestic and foreign Biologics inspections including testing laboratories, blood banks, source plasma, and HCT/P establishments. Since 2016, she has maintained FDA's Blood Bank and Plasma Center Investigator Certification and became a Biologics Specialist in July 2019. Ms. Cassidy has participated in various internal workgroups including developing an inspectional job aid for reproductive tissue inspections, presented at the FDA Workshop for the Reproductive Tissue Industry in 2020.



Brychan (Brandy) Clark, MD – Dr. Clark is a Medical Officer, board certified in internal medicine and infectious diseases, who works in the Division of Human Tissues, Office of Cell Therapy and Human Tissue CMC, Office of Therapeutic Products, in FDA's Center for Biologic Evaluation and Research. Her work focuses on human cells, tissues and cellular and tissue-based product (HCT/P) regulations, policies and guidances; stakeholder outreach; and review of certain medical devices, test kits, and cellular and tissue therapy products. She also serves as a member of FDA's Tissue Safety Team responsible for reviewing adverse events involving HCT/Ps. She received her medical degree from the University of Miami School of Medicine, completed an internship in Anatomic and Clinical Pathology at the University of Florida College of Medicine and then completed her Internal Medicine residency and Infectious Diseases fellowship at the San Antonio Uniformed Services Health Education Consortium, comprised of Wilford Hall USAF Medical Center, Brooke Army Medical Center, and the University of Texas Health Science Center at San Antonio. She joined FDA in 2015 after retiring from the military.



Stephanie Cottrell, CEBT, CTBS, CQIA, (ASQ) – Ms. Cottrell is the Ocular Quality and Compliance Coordinator at Sierra Donor Services Eye Bank and has been a part of the Quality Assurance Department for the past 22 years. She has filled various quality and compliance roles within her years of service and is involved in various aspects of quality and compliance from implementing policies and procedures to adverse reaction reporting to handling various types or third-party inspections.



Bruce Crise, PhD – Dr. Crise is a Consumer Safety Officer in the Division of Human Tissues within the Office of Cellular Therapy and Human Tissue CMC, in the Office of Therapeutic Products (formerly known as Office of Tissues and Advanced Therapies) in CBER. He joined FDA in 2016, and his primary focus is related to inquiries regarding cell and tissue products, tissue regulations, and policies. He currently serves as the Executive Secretary to the Tissue Reference Group. Additionally, Dr. Crise has extensive background and experience in virology, gene therapy, cell biology, and biological safety.



Jennifer DeMatteo, BS, MCM, CIC – Ms. DeMatteo is the Director of Regulations and Standards for the Eye Bank Association of America (EBAA). She oversees the EBAA Accreditation program, Medical Standards process and serves as their regulatory liaison. 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).



Elizabeth Ellett, BS, MT(ASCP), MSHA, CQA(ASQ) – Ms. Ellett is Senior Vice President of Regulations and Compliance at Advancing Sight Network. In this role, she oversees overall quality and regulatory compliance throughout offices in Alabama, Tennessee and Mississippi. Prior to eye banking, she spent 15 years in quality, regulations and management of a large blood bank within a major university hospital. She served as lead inspector for AABB and CAP for years. She currently sits on the EBAA Quality Committee and Legislative Committee.

About the Speakers



Joshua Farley, BA, CTBS – Mr. Farley has 19 years of experience in the industry. He is the Donor Services Technical Trainer at AlloSource where he provides on-site and remote training to recovery agencies and internal staff while providing BI based metrics to yield data driven process improvement. Mr. Farley currently serves on the Certification Committee for AATB writing and developing the CTBS examination. Previously, he was employed with Infinite Legacy where he specialized in tissue and ocular recovery, compliance and training, donor screening and tissue processing.



Tania Y. Hall, BS – Ms. Hall has been an Investigator with the FDA since 1991 focused in the Biologics Program area, served as the Los Angeles District's Biologics Specialist since 2001 and was selected as a Biologics National Expert in 2018. Since 2007, she has been a member of the training cadre that provides training for new FDA biologics investigators and refresher training for existing biologics investigators in the FDA's Blood Banking and Plasmapheresis Inspection course and the FDA's HCT/P Inspection course. She continues to conduct inspections of Blood, Source Plasma, and HCT/P establishments.



Susan Hurlbert, CEBT – Ms. Hurlbert is a Project Manager with Eversight and has more than 18 years of experience in eye banking. She oversees inspection readiness, the adverse event investigation and reporting process and clinical policy development. Prior to her present role in Quality Improvement and Compliance, Ms. Hurlbert performed ocular tissue recovery, evaluation, processing, and donor eligibility. She has served on a variety of EBAA committees and currently sits on the Medical Review Subcommittee and Accreditation Board.



Scott A. Jackson, PhD – Dr. Jackson joined The National Institute of Standards and Technology (NIST) in May of 2014 and is currently the founding leader of the Complex Microbial Systems Group. In this current role, he is leading international efforts to improve microbial and multi-omic measurements by organizing inter-lab studies, developing reference materials and reference methods, and developing in vitro tools and models systems for complex microbial systems. Prior to joining NIST, Dr. Jackson spent 11 years as a principal investigator with the FDA where he developed genomic tools for investigating the global genomic diversity of enteric pathogens with applications for food safety, bioforensics and public health.



Christopher Jason, MD – Dr. Jason joined the FDA in February 2018 as a medical officer in the Pharmacovigilance Branch. He completed his undergraduate and medical school at The Ohio State University. He completed a residency in internal medicine at the Cleveland Clinic and worked at University of Maryland as a hospitalist prior to the FDA.



Safa Karandish, BS, MT – Ms. Karandish is a Consumer Safety Officer in the Division of Human Tissues within the Office of Cell Therapy and Human Tissue CMC, in the Office of Therapeutic Products (formerly known as Office of Tissues and Advanced Therapies) in CBER. She joined FDA in 2010, and her primary focus is related to tissue regulations, policies, stakeholder outreach, and review of certain cellular and tissue products. Ms. Karandish has extensive cellular therapy experience in both academic and industry settings.



Victoria (Tory) Lake, BA, BSc – 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 and gene 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.



Kathy Loper, MHS, MT(ASCP) – Ms. Loper brings over 25 years of experience in cellular therapy product manufacturing and related disciplines. She is currently the Director of Regulatory Affairs for NMDP Be The Match, a nonprofit that provides life-saving cellular therapies to patients. In this role, Ms. Loper works closely with regulatory agencies, professionals, and other organizations and governmental agencies to provide life-saving cellular therapies to patients. Previously, she served as Senior Director of the AABB Center for Cellular Therapies and the Cell Processing and Gene Therapy Facilities at the Johns Hopkins Medical Institution. These facilities performed all aspects of cellular procurement, processing and release in support of hematopoietic stem cell transplant and innovative immunotherapies in support of phase I/II Oncology clinical trials. Ms. Loper has held numerous volunteer and committee positions and authored numerous publications.

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About the Speakers



Carolyn Morgan, MA – Ms. Morgan is currently a Training and Development Specialist on the QRA team at the NMDP/Be The Match. Previously, she served as Director of Learning and Development (L&D) for a global telecommunications company where she drove innovative, bilingual, hybrid L&D strategy across 20+ international markets. Prior to that, Ms. Morgan was the Senior Instructional Designer at a specialty specific Electronic Health Record systems and solutions company. Her passion is instructional design that enables learners to perform better and faster.



Angela Ondo, BS, MT(ASCP) – Ms. Ondo is the Director of Quality Assurance for the BMT and IEC Program at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in Baltimore, Maryland. She oversees the regulatory and quality of donor screening, collections and processing of 351 and 361 HCT/P products. Ms. Ondo has over 20 years of experience in quality and regulatory for cellular therapies.



Simone Porter MD, MPH – Dr. Porter is a Medical Officer in the Division of Human Tissues within the Office of Cell Therapy and Human Tissue CMC, in the Office of Therapeutic Products (formerly known as Office of Tissues and Advanced Therapies) in CBER. She joined the FDA in 2013, and her primary focus is related to tissue regulations, tissue safety, stakeholder outreach, and review of exemption requests and inquiries related to reproductive cells and tissue. Dr. Porter is a board-certified pediatrician and preventive medicine physician. She received her medical degree from Weill Cornell Medical College and Master of Public Health from Columbia University's Mailman School of Public Health.



Anita Richardson, BS, MAS – Ms. Richardson serves as the Associate Director for Policy in CBER's Office of Compliance and Biologics Quality, where she leads a policy team that is responsible for policy development and review; the program for CBER-regulated product shortages; and informatics and import monitoring. Before leading the OCBQ policy team, Ms. Richardson spent three years as the Director of the Compliance Branch in the FDA's Baltimore District Office, and 10 years as a compliance officer in CBER. Prior to joining FDA, Ms. Richardson worked in the blood banking industry for eight years.



Kevin Rodriguez, BS – Mr. Rodriguez is the Manager of Quality Systems Integration at Biobridge Global. A non-profit organization, Biobridge Global and its subsidiaries South Texas Blood and Tissue, Qualtex Laboratories, and Gencure Biomanufacturing Center support development of medical therapies to save and enhance lives. His career experience for the better part of a decade contains a wide background ranging in multiple quality assurance positions from food manufacturing, blood banking, tissue banking, cellular manufacturing, and electronic quality management system implementation.



Huiping Tu, PhD – Dr. Tu is the senior Principal Scientist managing the Microbiology Expert Committee for United States Pharmacopeia and leads the effort to develop the microbiology related USP general chapters. She has more than 20 years' experience in pharmaceutical industry, academia, and regulatory science with in-depth knowledge of USP-NF and the development of reference standards relevant to pharmaceutical products. Dr. Tu's previous role at USP was the Director of the Biologics Laboratory managing the bioanalytical, bioassay and microbiology teams. Prior to joining USP in 2012, she worked at Merck.

Tuesday, April 18, 2023

Morning Session: Moderator – Victoria Lake

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome*	
9:10 – 9:55	FDA/DHT Update	Scott Brubaker, FDA, CBER, OTP, OCTHT, DHT
9:55 – 10:25	Compliance Update	Anita Richardson, FDA, CBER, OCBQ
10:25 – 10:55	Donor Family Perspective	To Be Introduced
10:55 – 11:15	Break*	
11:15 – 11:45	HCT/P Regulatory Framework	Safa Karandish, FDA, CBER, OTP, OCTHT, DHT
11:45 – 12:15	Compliance Actions – Inspectional Observations	CDR Jason Abel, FDA, ORA, OBPO
12:15 – 1:30	Lunch*	

Afternoon Session: Moderator – Kathy Loper

1:30 – 2:30	Rapid Microbial Testing for HCT/P – The NIST Rapid Microbial Testing Methods (RMTM) Consortium – USP’s Evolving Position on the Use of Rapid Microbial Methods – Session Q&A	Scott Jackson, PhD Huiping Tu, PhD
2:30 – 3:10	Navigating Supply Chain Issues	Angie Ondo
3:10 – 3:30	Break*	
3:30 – 5:00	Workshop 1: Strategies for Increasing Training Effectiveness In this interactive workshop guided by a panel of industry-leading learning and development experts, participants will have the opportunity to discuss, share best practices, and problem-solve common training challenges to support the design and development of more efficient and effective learning events within your organizations.	Moderator: Carolyn Morgan Speakers: Tissue – Joshua Farley Ocular – Stephanie Cottrell Cell – Carolyn Morgan
	Workshop 2: Bridging the Gap: 351/361 Practical Applications (repeats on Day 2)	Moderator: Alyce Jones, PhD Speakers: Cell – To be determined Tissue – To be determined

Wednesday, April 19, 2023

Morning Session: Moderator – Jennifer DeMatteo

8:30 – 9:00	How to Facilitate Review of Submissions to the Tissue Reference Group	Bruce Crise, PhD, FDA, CBER, OTP, DHT
9:00 – 10:00	Donor Screening, Testing and Eligibility Determination	Brychan (Brandy) Clark, MD, FDA, CBER, OTP, DHT Simone Porter, MD, MPH, FDA, CBER, OTP, DHT
10:00 – 10:20	Break*	
10:20 – 10:50	Adverse Reaction Reporting	Chris Jason, MD, FDA, CBER, OBPV, DPV
10:50 – 11:20	Overview of Labeling Requirements and Accompanying Records	Tania Hall, FDA, ORA, OBPO
11:20 – 12:30	Lunch*	

Afternoon Session: Moderator – Jennifer DeMatteo

12:30 – 2:00	WORKSHOPS SESSION ONE: Workshops 1 & 2 Repeat. Workshop 3 held once.	
	Workshop 1: Donor Screening Scenarios, including Emerging Infectious Diseases	Moderator: Jennifer DeMatteo Speakers: Tissue – To be determined Ocular – Susan Hurlbert Cell – Laura Connelly-Smith
	Workshop 2: HCT/P Deviations	Moderator: Erica Agy Speakers: Cell – Erica Agy Ocular – Elizabeth Ellett Tissue – Kevin Rodriguez
	Workshop 3: FDA Requirements for Reproductive Donor Eligibility and Labeling with Case Scenarios This workshop will discuss how the results of donor screening and testing influence the content of accompanying records and applicable labeling for reproductive HCT/Ps under various scenarios.	Moderator: Tania Hall, FDA, ORA, OBPO Speakers: Tania Hall, FDA, ORA, OBPO Marla Cassidy, FDA, ORA, OBPO Industry – Julio Cortes Industry – Corey Burke
2:00 – 2:15	Break*	

Agenda

2:15 – 3:45 **WORKSHOPS SESSION TWO:**

(Repeat) **Workshop 1: Donor Screening Scenarios, including Emerging Infectious Diseases**

Moderator: Jennifer DeMatteo
Speakers:
Tissue – To be determined
Ocular – Susan Hurlbert
Cell – Laura Connelly-Smith

(Repeat) **Workshop 2: HCT/P Deviations**

Moderator: Erica Agy
Speakers:
Cell – Erica Agy
Ocular – Elizabeth Ellett
Tissue – Kevin Rodriguez

(Repeat of Day 1) **Workshop 3: Bridging the Gap: 351/361 Practical Applications**

Moderator: Alyce Jones, PhD
Speakers:
Cell – To be determined
Tissue – To be determined

3:45 – 3:55 Break to reconvene in main conference room*

3:55 – 4:30 **Ask the FDA**

FDA Personnel

*Denotes non-educational activity

Continuing Education This conference qualifies for 12.0 hours of continuing education credit.

About the Venue

The Hilton Alexandria Old Town is located on King Street in Alexandria's vibrant Old Town. King Street Metro Station is across the street, providing easy links to Washington D.C. and Reagan National Airport. The free King Street Trolley stops on the doorstep for exploring in your free time.



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EARLY DISCOUNT: Payment Received By February 17, 2023	<input type="checkbox"/> \$1795	<input type="checkbox"/> \$1595
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Includes conference materials, continental breakfasts, breaks and lunches per agenda

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\$239 single/double

A limited number of rooms have been blocked at the special rate listed per night. Rate is based on single or double occupancy. Rate is available 3 nights either side of the conference dates based upon availability of rooms. **Hotel reservations must be made on or before March 31, 2023, in order to guarantee the special rate.** Individuals are responsible for making their own hotel reservations. **You must mention you are with the group, 18th Annual FDA & Changing Paradigm for HCT/P, when making your reservation in order to obtain these special rates. Please do not use travel agents for reservations.**

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