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17th ANNUAL

FDA AND THE CHANGING PARADIGM FOR HCT/P REGULATION

APRIL 12 – 13, 2022 | CAMBRIDGE, MD

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About the Conference

Please join us in Cambridge, Maryland, for the **17th 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.

We will open the conference with an interesting presentation about the transmission of disease through bone grafts to remind us about opportunities for improving donor eligibility processes.

FDA will provide Office and Division updates, adverse reaction reporting and donor screening, testing, and eligibility presentations, as well as share compliance updates and inspectional observations. Additionally, an overview of the HCT/P Regulatory Framework and refreshers on core cGTP will be reviewed. Industry will provide insights through presentations and workshops that cover specific core GTP functions, specifically outsourced cGTP functions, best practices for suppliers and contracted vendors, discussion of bridging the gap between 361 and 351 HCT/Ps, donor eligibility workshops, and HCT/P deviation reporting.

This year will include Recipient Stories to remind all of us how important our work is to those recipients who receive tissues, cells, and cellular and tissue-based products.

We are continuing this year to provide focused sessions for the reproductive tissue industry by including topics such as outsourced donor testing, as well as a workshop covering Donor Eligibility Scenarios, and specifically, Labeling for Reproductive HCT/Ps.

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 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
- Listen to FDA office and division updates, as well as compliance actions
- Review Core cGTP requirements
- Learn details about donor screening, testing, and eligibility
- Understand the HCT/P Regulatory Framework
- Discuss adverse event reporting and HCT/P deviation reporting
- Learn how to reinforce compliance in specific areas such as suppliers and contracted vendors
- Discuss 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

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 Seattle Cancer Care Alliance. 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.

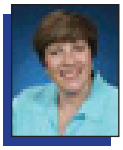
Sridhar Basavaraju, MD – Dr. Basavaraju is the Director of the CDC Office of Blood, Organ, and Other Tissue Safety. His office is tasked with coordinating investigations of infectious disease transmission through blood transfusion, tissue implantation, and solid organ transplantation.

Scott A. Brubaker – Mr. Brubaker was selected in October 2016 as the Director, Division of Human Tissues (DHT) in the Office of Tissues & 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, 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.

Corey Burke, BS, CLS – Mr. Burke is the Tissue Bank Director for Cryos International. As the world's largest sperm bank and first free-standing, independent egg bank in the US, Cryos International is an industry leader. As Tissue Bank Director, Mr. Burke is responsible for the safety and quality of donors and donor products as well as the scientific direction of the Cryos Egg Banks in the US and Europe.

Erin Butler, BS, CTBS – Ms. Butler is a Senior Manager in Quality & Compliance with BioBridge Global and has been with the company since 2010. She is responsible for overseeing the quality & compliance for HCT/Ps and Blood product lines and ensuring compliance with GMP processes and documentation for quality control activities. Ms. Butler holds a BS in Biology from Texas A&M Corpus Christi and is an AATB Certified Tissue Banking Specialist.

Brychan Clark, MD – Dr. Clark received her M.D. from the University of Miami School of Medicine in 1999 and then completed her Internal Medicine residency followed by a fellowship in Infectious Diseases at the San Antonio Uniformed Services Health Education Consortium. Dr. Clark retired from the United States Air Force as a Lieutenant Colonel in 2015 and then joined the FDA as a Medical Officer in the Division of Human Tissues, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research (CBER).



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).

Tracy T. Douglas, DNP, RN, NEA-BC, BMT-CN – Dr. Douglas is one of two quality managers for the Transplant and Cellular Therapy Program at the University of Maryland Greenebaum Comprehensive Cancer Center. She has 31 years' experience in the stem cell transplant field at two of the large academic centers in Maryland. Over the last three years her focus has been a quality, regulatory, and managing collection and processing HCT/Ps.

Elizabeth Ellett, BS, MT(ASCP), MSHA – 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

Benjamin R. Emery, MPhil, TS – Mr. Emery completed his M.Phil. at The University of Utah School of Medicine in 2009, where he evaluated sperm nuclear proteins and their impact on human fertility. Following his graduate training, he continued at the Andrology & IVF Laboratories at the University of Utah as a laboratory manager and embryologist. He presently is the Director of Healthcare and serves on the Utah Center for Reproductive Medicine operations board. His research focuses on sperm function testing and identifying genetic and epigenetic factors associated with male infertility. He has been an invited speaker at ASRM Assisted Reproductive Managers meeting on the topic of laboratory and clinic integration addressing topics that help to coordinate a seamless connection of lab and clinic. Mr. Emery has authored 42 scientific articles on male infertility and clinic management, has sat on the organization committee of the International Genetics of Male Infertility Symposium, and is an ad hoc reviewer for many scientific journals.

Tiana Golding, MS, CTBS – Ms. Golding supports regulatory compliance and strategic early product development initiatives; she brings over 10 years of compliance, clinical laboratory science, and assay development experience to her current role. Ms. Golding holds an MS in Molecular & Cellular Biology from Arizona State University; a Certificate in Medical Writing from the University of California, San Diego; and is an AATB Certified Tissue Banking Specialist.

Heather Hatcher, PhD – Dr. Hatcher is a Regulatory Scientist with Womble Bond Dickinson (US) LLP. She has an extensive background as a basic and clinical research scientist, as well as Regulatory Affairs. She advises clients with respect to early regulatory strategy and product development and has worked with clients on many types of FDA-regulated products, including biologics, drugs, regenerative medicine (cell and gene therapies and biomaterials), medical devices, foods, and combination products.

Wendy P. 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.

Susan Hurlbert, CEBT – Ms. Hurlbert is a Project Manager with Eversight and has 17 years 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, she 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.

Christopher Jason, MD – Dr. Jason is a Medical Officer in the Division of Epidemiology in the Center for Biologics Evaluation and Research at the FDA. He is a member of the Tissue Safety Team responsible for reviewing adverse events involving Human Tissues, Cells and Tissue Based Products at the FDA. He received his medical degree from The Ohio State School of Medicine and completed his Internal Medicine residency at the Cleveland Clinic.

Safa Karandish, BS, MT – Ms. Karandish is a Consumer Safety Officer in the Division of Human Tissues within the 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.

Bethanie Kuker, BS, MS – Ms. Kuker is the Regulatory Affairs Manager with the National Marrow Donor Program/Be The Match. She is responsible for assessing the organization's compliance with applicable laws and regulations and leading initiatives to develop and improve regulatory processes. She has seven years of experience in regulatory affairs in the field of cell and gene-based immunotherapies.

Victoria (Tory) Lake, RAC, 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 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.

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 and Biologics Quality, Center for Biologics Evaluation and Research. Prior to joining FDA, she worked at a community hospital as a bench tech and supervisor in all areas of the laboratory. She joined the FDA in 1988 as a medical technologist. Ms. O'Callaghan has managed the Biological Product Deviation Reporting since 1990. She was instrumental in developing the regulation on Biological Product Deviation Reporting, which was published September 7, 2001. She also developed two guidance documents to accompany this rule. Ms. O'Callaghan also developed the deviation reporting system for the Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) and was instrumental in developing the guidance for HCT/P deviation reporting. She has participated in many outreach efforts to the blood and plasma industry, the traditional biological product industry, as well as the HCT/P industry.

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. 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

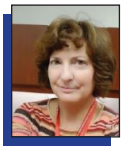
Jami Otis, BA, CTBS – Ms. Otis joined AlloSource in May 2007 and started the AlloSource Placenta Donation Program in 2017. She brings more than 25 years of experience in the healthcare industry with 15 years focusing on training/education. Ms. Otis received her education from the University of Colorado Boulder in Molecular, Cellular, and Developmental Biology. Prior to joining AlloSource, she spent 13 years in the blood banking/cord blood banking industry, has experience in tissue recovery, and was an EMT-Intermediate for a rural ambulance service.

Karthika Perumal, PhD, JD – Dr. Perumal is a life sciences patent and transactional attorney in the Houston office of Womble Bond Dickinson (US) LLP. She advises clients in the healthcare sector across a wide range of technologies, such as vaccines, small molecule pharmaceuticals, medical devices, biologics, and research tools. Prior to her legal career, Dr. Perumal was the Associate Director for Technology Development at the University of Texas Medical Branch (UTMB). In that role, she led numerous successful IP monetization deals, including helping to structure six life sciences start-up companies. She has a Ph.D. in Pharmacology from the Baylor College of Medicine and a JD from the University of Houston Law Center.

Simone Porter MD, MPH – Dr. Porter received her medical degree from Weill Cornell Medical College and Master of Public Health from Columbia University's Mailman School of Public Health. She is trained as a pediatrician from Duke University Medical Center and as a preventive medicine physician from Maryland's Department of Health and Mental Hygiene. She joined the Division of Human Tissues within the Office of Tissues and Advanced Therapies, CBER, FDA, as a Medical Officer in 2013.

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, CTBS – 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.



Clarissa Saba, BS, MT – Ms. Saba is the Program Manager, Quality/Compliance for the UMSOM Cell Therapeutics GMP Facility. She is also one of two quality managers for the Transplant & Cellular Therapy Program at the University of Maryland Greenebaum Comprehensive Cancer Center, which is where her career started, and she returned to three years ago. She was part of a team that started a stem cell company, Head of Quality for a molecular diagnostics company, and Quality/Regulatory for a CRO.

Jennifer Sheehan, BS, MPH – Ms. Sheehan has been an Investigator with the FDA since 2010, focused in the Biologics Program area, and has served as Biologics Specialist since 2019. She continues to conduct inspections of Blood, Source Plasma, and HCT/P (Human Cellular and Tissue Based Products) establishments.

Agenda

Tuesday, April 12, 2022
Morning Session: Moderator – Victoria Lake

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome*	
9:10 – 9:45	**Transmission of Mycobacterium Tuberculosis through Bone Grafts: Opportunities to Enhance Donor Testing and Improve Traceability**	Sridhar Basavaraju MD, CDC
9:45 – 10:15	**FDA/DHT Update**	Scott Brubaker, FDA, CBER, OTAT, DHT
10:15 – 10:35	Break*	
10:35 – 11:05	**Compliance Update**	Anita Richardson, FDA, CBER, OCBQ
11:05 – 11:35	**Compliance Actions – Inspectional Observations**	CDR Jason Abel, FDA, ORA, OBPO
11:35 – 12:05	**HCT/P Regulatory Framework**	Safa Karandish, FDA, CBER, OTAT, DHT, HTRB
12:05 – 1:20	Lunch*	

Afternoon Session: Moderator – Victoria Lake

1:20 – 1:50	**Core cGTP Requirements**	Wendy Hively, FDA, CBER, OCBQ
1:50 – 2:20	**Industry Considerations Core cGTP Principles: Supplies/Reagents**	Erin Butler
2:20 – 2:50	**Industry Considerations Core cGTP Principles: Outsourced Core cGTP Functions (e.g., related to donor testing and screening, recovery, testing for microorganisms, or other manufacturing arrangements)**	Angie Ondo
2:50 – 3:10	Break*	
3:10 – 4:40	**Workshop 1: Ensuring Compliance: Best Practices for Supplier, Contracted Vendors, Quality Agreements and Oversight** Industry speakers in this workshop will share their best practices for handling external suppliers and vendors,	Tracy T. Douglas, DNP, RN, NEA-BC, BMT-CN Clarissa Saba, MT

Agenda

such as testing laboratories, materials suppliers, donor testing facilities, and other external entities contracted for responsibilities related to core GTPs. Topics covered may include audits, quality agreements, and other mechanisms for ensuring compliance.

Workshop 2: Bridging the Gap between 361 HCT/Ps and HCT/Ps Regulated as Drugs, Devices and/or Biological Products
This workshop will provide an overview of FDA guidance documents and available resources for firms on or interested in the Investigational New Drug (IND) pathway. Presentations will be followed by an opportunity for discussion with industry representatives regarding their experience Bridging the Gap between 361 HCT/Ps and HCT/Ps Regulated as Drugs, Devices and/or Biological Products.

Moderator: Tiana Golding, MS
Tiana Golding, MS
Heather Hatcher, PhD
Karthika Perumal, PhD, JD

Wednesday, April 13, 2022
Morning Session: Moderator – Jennifer DeMatteo

8:30 – 9:10	**Road to a Cure: An HCT/P Patient and Physician Perspective**	To Be Introduced
9:10 – 9:40	**Adverse Reaction Reporting**	Chris Jason, MD, FDA, CBER, OBE
9:40 – 9:55	Break*	
9:55 – 11:25	**Donor Screening, Testing, Eligibility Determination**	Simone Porter, MD, MPH, FDA, CBER, OTAT, DHT, HTRB Brychan Clark, MD, FDA, CBER, OTAT, DHT, HTRB
11:25 – 12:30	Lunch*	

Afternoon Session: Workshops & Moderator – Jennifer DeMatteo

12:30 – 2:00	**Workshop 1: Reproductive HCT/Ps: Donor Scenario-Based, Labeling** This workshop will discuss accompanying records and/or labeling requirements for reproductive HCT/Ps under various scenarios.	Moderator: Wendy Hively, FDA, CBER, OCBQ Industry – Corey Burke and Benjamin R. Emery Wendy Hively, FDA, CBER, OCBQ Jennifer Sheehan, FDA, ORA, OBPO

Agenda

	Workshop 2: Donor Eligibility Scenario-Based, Other HCT/Ps This session will review donor eligibility information and focus on donor eligibility scenarios from the ocular, cell, and tissue spaces. Attendees will discuss the scenarios and recommend eligibility determinations based on the information available.	Moderator: Beth Kuker Tissue – Jami Otis Cells – Beth Kuker Ocular – Elizabeth Ellett
	Workshop 3: HCT/P Deviation Reporting This workshop will cover how to determine the reportability of HCT/P Deviations for different HCT/P types through case scenarios and interactive discussion.	Moderator: Sharon O'Callaghan, FDA, CBER, OCBQ Cell – Erica Agy Ocular – Susan Hurlbert Tissue – Kevin Rodriguez
2:00 – 2:15	Break*	
2:15 – 3:45	**Workshops 2 and 3 Repeated (Workshop 1 will not repeat)**	
3:45 – 3:50	Break to reconvene in main conference room*	
3:50 – 4:30	**Ask the FDA**	FDA Personnel

*Denotes non-educational activity

Continuing Education

This conference qualifies for 11.0 hours of continuing education credit.

About the Venue

Located on the scenic Eastern Shore of Maryland, the Hyatt Regency Chesapeake Bay Golf Resort, Spa and Marina is the area's finest full-service, year-round resort. Built on over 342 acres, the 400 room resort features an 18-acre nature preserve with guided hikes and wildlife observation, an 18,000 square foot European Health Spa, a glass-enclosed pool and lounge area, an 18-hole Keith Foster designed championship golf course, and a 150-slip marina.

Cambridge, Maryland is 79 miles southeast of BWI Airport, 90 miles southeast of Ronald Reagan Washington National Airport, and 117 miles southeast of Dulles. For exact directions to the hotel, please log on to https://chesapeakebay.regency.hyatt.com/en/hotel/our-hotel/map-and-directions.html

Register

17th Annual
FDA and the Changing Paradigm for HCT/P Regulation

Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By January 31, 2022	❑ $1795	❑ $1595
Payment Received After January 31, 2022	❑ $1995	❑ $1595

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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- All credit card transactions are processed in US Dollars (your bank will convert to your local exchange rate when billing)
- You will receive a confirmation via email as soon as the registration is processed. In order to receive any early registration discounts, payment must be made by the deadline specified in the brochure. (Taxpayer ID #27-1438344)
- Registrations must be accompanied by full payment.

Payment Terms: Attendees must be paid in full prior to conference start date.

Hotel

Hyatt Regency Chesapeake Bay Hotel
100 Heron Blvd
Cambridge, MD 21613
(410) 901-1234
$240 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 and is available 3 nights either side of the conference dates based upon availability of rooms. **Hotel reservations must be made on or before March 14, 2022, in order to guarantee the special rate.** Individuals are responsible for making their own hotel reservations. **You must mention *17th Annual HCT/P* AND *Pharma Conference* when making your reservation in order to obtain these special rates. Please do not use travel agents for reservations.**

Online: **https://www.hyatt.com/en-US/group-booking/CHESA/G-PARC**
Copy and paste the URL in your browser to make hotel reservations online or call (410) 901-1234.

The conference area in the hotel is large enough to allow for proper social distancing, and the hotel has agreed to disinfect everything in the meeting rooms and dining areas daily. Visit Hyatt.com for more details on the hotel.

For additional information, contact Pharma Conference Inc:
(830) 315-0055 • e-mail: contactus@pharmaconference.com

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