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19TH ANNUAL

FDA AND THE CHANGING PARADIGM FOR HCT/P REGULATION

MAY 7 – 8, 2024 | ALEXANDRIA, VIRGINIA
HILTON ALEXANDRIA OLD TOWN

PHARMA CONFERENCE INC

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Conference presented in cooperation with EYE BANK ASSOCIATION OF AMERICA

About the Conference

Please join us in Old Town, Alexandria, Virginia, for the **19th Annual FDA and the Changing Paradigm for HCT/P Regulation** conference. We are pleased to have strong representation from FDA, CDC, and many industry experts crossing the broad spectrum of tissues, cells, and cellular and tissue-based products.

FDA will provide Office and Division updates, a donor screening, testing, and eligibility presentation, as well as discuss adverse reaction reporting.

CDC will present a special session discussing the recent mycobacterium outbreak with bone matrix, and this will tie in well with additional topics being presented such as donor screening, testing, and eligibility, tracking and traceability and adverse reaction reporting.

Industry will provide insights through presentations that cover the essential elements of donor authorization and consenting, best practices for tracking and traceability, and a special workshop devoted to the development and implementation of labeling standards. We will have a panel discussion on Environmental Control and Monitoring, where both FDA and industry experts will discuss requirements and examples of implementation. Additionally included is a new workshop format termed "Bootcamp," where several compliance and quality assurance topics will be covered from various industry perspectives. Additional workshops include those covering Adverse Reaction Reporting, HCT/P Deviation Reporting, and a workshop specifically focused for the reproductive tissue industry on donor eligibility, accompanying records, and labeling requirements.

This year will include a speaker who is a bereavement counselor; a perspective not yet given at these conferences. It will provide the unique perspective of how a donor's family is supported through the process of determining donation of their loved one's tissues.

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
- Learn more about the Mycobacterium outbreak associated with bone matrix
- Learn details about donor screening, testing, and eligibility
- Understand essential elements of donor authorization and consenting
- Learn from an industry panel of experts on best practices for tracking and traceability
- Discuss Environmental Control and Monitoring
- Understand the development and implementation of labeling standards
- Get back to basics on compliance and quality assurance topics
- Participate in interactive workshops on adverse event reporting and HCT/P deviation reporting
- Discuss Reproductive HCT/P specific issues related to Donor Eligibility, Accompanying Records and Labeling
- Interface with Industry experts and FDA

About the Speakers

Erica Agy, BS – Ms. Agy has more than 20 years of experience in Quality Assurance. 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, TJC, and clinical trial sponsor audits and 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 and routinely works with multiple organizations to ensure a safe and efficient process for delivering life-saving products.

Vince Amatrudo, JD – Mr. Amatrudo is the new Deputy Director of CBER's Office of Compliance and Biologics Quality. He started in August 2023 and works on the full range of CBER compliance and enforcement issues, including those pertaining to HCT/Ps regulated under section 361 of the Public Health Service Act, as well as HCT/Ps regulated as drugs, devices, and/or biological products. Before joining OCBQ, Mr. Amatrudo worked in FDA's Office of the Chief Counsel for 16 years where he most recently served as Senior Counsel. In that capacity, he advised multiple Centers and senior FDA leadership on drug and device law, combination product regulation and product jurisdiction, as well as legislation, information disclosure, and emergency use authorizations. In 2022, Mr. Amatrudo detailed to the House Committee on Energy and Commerce to work on FDORA and other FDA-related legislation as well as oversight efforts.

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 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.

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.

Kathryn Bushnell, MSHS, MLS(ASCP), CABP(AABB) – Ms. Bushnell is the Manager of the Cell Therapy Laboratory at Children's National Hospital in Washington, DC, and a volunteer Processing Inspector for the Foundation for Accreditation of Cellular Therapy (FACT). She is a certified Medical Laboratory Scientist and Advanced Biotherapies Professional. Ms. Bushnell recently completed a Master of Science in Medical Laboratory Science at the George Washington University. She has over 20 years of experience in Stem Cell Processing and Cellular Therapy and previously worked at Dartmouth Cancer Center and MD Anderson Cancer Center.

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.

About the Speakers

Julio Cortes, Jr, BS – Mr. Cortes is President and owner of Unilab, a laboratory that was established in 1988 as a specialized reproductive lab that is also FDA registered to perform donor testing for sperm and egg donors. With Mr. Cortes at the helm, Unilab has been testing reproductive donors for IVF doctors and clinics across the United States and overseas for over 22 years. Over the years, he has experienced many changes in the donor testing landscape and will share his insight on Donor testing.

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 of third-party inspections.

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.

La' Tasha Gunter, BA, MS – Ms. Gunter was hired as an FDA Consumer Safety Officer in 2009 and became a Biologics Specialist in 2015. She has conducted domestic and international Biologics inspections including blood banks, source plasma centers, testing laboratories, and HCT/P establishments. Ms. Gunter served as a speaker and workshop moderator at the HCT/P Regulation conference in 2018. She received a BA in Religious Studies with a minor in Bioethics from The University of Virginia, and an MS in Health Promotion Management from Marymount University.

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.

Nancy Hegdahl, BS – Ms. Hegdahl is currently a Quality Manager at Be the Match and has held roles in Quality Assurance/Quality Control throughout the majority of her career. She has worked in Quality management roles in regulated industries for over 10 years, overseeing various elements of quality systems governed by both EPA and FDA regulations in the areas of GMP, GLP and GTP. Ms. Hegdahl holds a Bachelor of Science degree in Microbiology from South Dakota State University.

About the Speakers

Cherlita A. Honeycutt, BS – Ms. Honeycutt is the Branch Chief of the Blood and Tissue Compliance Branch within CBER's Office of Compliance and Biologics Quality. She began her civil service career as a Biologist with the National Institutes of Health in Bethesda, Maryland, and joined CBER's Office of Communication, Outreach and Development in 2006 as a Consumer Safety Officer. Ms. Honeycutt was a Compliance Officer in FDA's Baltimore District Office for 11 years prior to rejoining CBER in 2021.

Susan Hurlbert, CEBT – Ms. Hurlbert is a Project Manager with Eversight and has more than 19 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.

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.

Victoria (Tory) Lake, BA, BSc, RAC – 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, 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 a Masters in Health Science Administration from Louisiana State University Medical Center, a B.S. in Applied Science as well as ASCP certification in Medical Technology. She has held numerous volunteer and committee positions and authored numerous publications.

Vivian C. Lopez, BS – Ms. Lopez is the QA Director for the Beauty of Sight Eye Bank, located at the Bascom Palmer Eye Institute in Miami Florida. She has more than 30 years of combined experience in quality control operations, research and development, data analysis, equipment qualifications, process validations and establishing quality management systems. Ms. Lopez has worked in different FDA regulated industries such as Biotechnology, Diagnostics, Medical Device and in Eye Banking for the past 13 years.

Paige McKibbon, BS, MS – Ms. McKibbon brings more than five years of US and International Regulatory experience with backgrounds in Medical Device, Drug, Biologic, and Combination Products Regulations. In addition to her Regulatory experience, she has worked in roles including Quality and Project Management. Ms. McKibbon is an active member of RAPS, ASGCT, and ISCT. In her current role as Senior Regulatory Affairs Associate at the National Marrow Donor Program, she oversees compliance considerations for NMDP's transplant operations. In addition, Ms. McKibbon ensures the compliance of cellular starting material and procurement intended for further manufacturing.

Karen Moniz, MHA, MT(ASCP)SBB – Ms. Moniz is Technical Director at ICCBBA, the international non-profit that maintains, develops, and licenses ISBT 128, the international information standard for terminology, coding, and labeling of medical products of human origin (MPHO). She received a BHS in medical technology from the University of Kentucky, SBB from Johns Hopkins Hospital, and MHA from George Washington University. Ms. Moniz has managed blood centers, transfusion services, and biomedical information technology. She is enthusiastic about evolving the ISBT 128 Standard to continue contributing to global MPHO traceability and biovigilance.

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About the Speakers

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.

Meagan E. Pavek, BS – Ms. Pavek is proud to be associated with BioBridge Global in San Antonio, TX, where she operates as a Senior Quality Control Associate within Global Quality for South Texas Blood and Tissue. She offers QC support and regulatory guidance among the HCT/P operational areas and has been with the organization for six years. Previously, Ms. Pavek was employed for four years with Grifols Biomat located in Laredo, TX, as a Quality Associate.

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.

Jennifer Rabin, MA, BSN, BMTCN – Ms. Rabin is a leader in the Next Generation Therapies practice at Deloitte. She is focused on next generation therapies including cell and gene therapies as curative treatments for patients. Drawing from her background in healthcare, Ms. Rabin provides the patient and clinician perspective to both internal and external facing discussions. In 2019, she founded the Deloitte Next Generation Therapies Industry Working Group consisting of over 40 cell and gene therapy companies, payers and providers, biopharma stakeholders, and regulatory bodies, joining as a consortium tackling some of the industry's biggest challenges, developing standards, and harmonizing to reduce the burden on healthcare providers and breakdown barriers to the delivery of these transformative therapies.

Federico Rodriguez Quezada, SBB, MLS (ASCP) – Mr. Rodriguez Quezada has over 36 years of experience in cellular therapy and immunohematology fields. He earned his Bachelor of Science in Medical Technology from the Autonomous University of Nuevo Leon in Mexico and graduated as Specialist in Blood Banking School at the University of Texas Medical Branch in Galveston, TX. His experience includes all aspects of manufacturing, regulatory requirements and compliance, process design, process improvement and quality management systems in the Cellular Therapy field, including BM, CB and PB as well as other novel therapies.

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.

Susan Smith, BA, MS – Ms. Smith is the Manager of the Grief Support & Life Legacies Program at South Texas Blood & Tissue. Ms. Smith is committed to creating a safe and empathetic space for tissue donor families to navigate the challenging and complex grief journey. She delivers a variety of programs/services including workshops, memorial events, group and individual support - all of which provide opportunities for donor families to connect and honor their loved one's legacy through sharing their donation stories. Ms. Smith is also an active member of the American Association of Tissue Banks Donor Family Services Council.

Amy Van Winkle, MPH, BS – Mrs. Van Winkle is the Director of Quality Assurance at RegenTX Partners in San Antonio, TX. In her role, she oversees and ensures tissue products manufactured and distributed adhere to FDA regulation and AATB standards. Prior to her role at RegenTX Partners, Mrs. Van Winkle was the Quality Manager at a CDMO specializing in cell manufacturing. She has over 10 years of experience in cGMP environments and has commissioned more than three cGMP facilities.

Agenda

Tuesday, May 7, 2024

Morning Session: Moderator – Victoria (Tory) Lake, RAC

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 – 10:40	**Mycobacterium Outbreak with Bone Matrix**	Sridhar Basavaraju MD, CDC
10:40 – 11:00	Break*	
11:00 – 12:30	**Donor Screening, Testing, and Eligibility Determination**	Brychan Clark, MD, FDA, CBER, OTP, DHT Simone Porter, MD, MPH, FDA, CBER, OPT, DHT
12:30 – 1:45	Lunch* (Networking opportunity)	

Afternoon Session: Moderator – Kathy Loper

1:45 – 2:25	**The Essential Elements of Donor Authorization/Consents** (with Q&A)	Cell – Paige McKibbon Tissue – To be determined
2:25 – 3:25	**Tracking and Traceability – Best Practices** (with Q&A)	Cell – Jennifer Rabin Tissue – Jaleia Richey Ocular – Susan Hurlbert, CEBT
3:25 – 3:45	Break*	
3:45 – 5:15	Workshop Session: (held once)	
	Workshop 1: Bridging the Gap – 351/361: The Development and Implementation of Labeling Standards to Ensure Patient Safety	Moderator: Paige McKibbon Jennifer Rabin Cell – Nancy Hegdahl Tissue – Meagan Pavek Karen Moniz
	Workshop 2: FDA Requirements for Reproductive HCT/Ps including Reproductive Donor Eligibility, Accompanying Records and Labeling Requirements with Case Scenarios This workshop will serve as an interactive demonstration of the requirements of donor screening and testing, as well as, how the results of donor screening and testing influence the content and applicability of the accompanying records and labeling for reproductive HCT/Ps, using various scenarios.	Moderator: Tania Hall, FDA, ORA, OBPO Speakers: **FDA Investigators:** Marla Cassidy, FDA, ORA, OBPO La'Tasha Gunter, FDA, ORA, OBPO **Industry:** Julio Cortes Corey Burke

Agenda

Wednesday, May 8, 2024

Morning Session: Moderator – Jennifer DeMatteo

8:30 – 9:00	**Love Lives On…Honoring the Legacies of Tissue Donors**	Susan Smith
9:00 – 9:30	**Compliance Update**	Vince Amatrudo, FDA, CBER, OCBQ Cherlita Honeycutt, FDA, CBER, OCBQ
9:30 – 10:10	**Adverse Reaction Reporting**	Chris Jason, MD, FDA, CBER, OBPV, DPV
10:10 – 10:30	Break*	
10:30 – 11:55	**Environmental Control and Monitoring:** • FDA Overview: Requirements and Expectations • Industry Examples and Panel Discussion	Tania Hall, FDA, ORA, OBPO Cell – Federico Rodriguez Quezada Tissue – Amy Van Winkle Ocular – To be determined
11:55 – 1:10	Lunch* (Networking opportunity)	

Afternoon Session: Moderator – Jennifer DeMatteo

1:10 – 2:40	**WORKSHOPS SESSION ONE:** Workshops Repeat	
	Workshop 1: HCT/P Deviation Reporting	Moderator: Elizabeth Ellett Speakers: Cell – Erica Agy Ocular – Vivian Lopez Tissue – To Be Determined
	Workshop 2: Adverse Reaction Reporting	Moderator: Chris Jason, MD, FDA, CBER, OBPV, DPV Cell – Kathryn Bushnell Ocular – Wayne Dietz, CEBT Tissue – Rebeccah Brown, PhD
	Workshop 3: Bootcamp: Compliance and Quality Assurance **• Risk Management in HCT/Ps** **• Supplier Qualification** **• Designing an Internal Audit Program**	Moderator: Kevin Rodriguez Tissue – Robert Hernandez Ocular – Stephanie Cottrell, CEBT, CTBS Cell – Angela Ondo
2:40 – 3:00	Break*	

Agenda

3:00 – 4:30	**WORKSHOPS SESSION TWO:** The above workshops repeat	
4:30 – 4:40	Break to reconvene in main conference room*	
4:40 – 5:15	**Ask the FDA**	FDA Personnel

*Denotes non-educational activity

Continuing Education

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Register

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Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By February 1, 2024	❑ $1895	❑ $1595
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Includes conference materials, continental breakfasts, breaks, and lunches per agenda

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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 April 22, 2024, in order to guarantee the special rate.** Individuals are responsible for making their own hotel reservations. **You must mention you are with the group, *19th 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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