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16TH ANNUAL FDA AND THE CHANGING PARADIGM FOR HCT/P REGULATION

APRIL 14 – 15, 2020 | WASHINGTON, DC
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newest information from FDA & industry



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About the Conference



Please join us in Washington, D.C., for the **16th Annual FDA and the Changing Paradigm for HCT/P Regulation** conference. We are pleased we will have strong representation from FDA and many industry experts crossing the broad spectrum of tissues, cells, and cellular and tissue based products.

This year FDA will report on the review process for communicable disease kits, provide Office and Division updates, as well as share compliance updates and inspectional observations. Industry will provide insights through presentations and workshops that cover auditing success, complying with labeling, advertising, and other indications of manufacturers' objective intent, tracking HCT/Ps, risk management, product and process quality as related to patient outcomes, and HCT/P deviation reporting.

We are continuing this year to provide more focused sessions for the reproductive tissue industry by including workshops on Donor Eligibility and Summary of Records, Exemption Requests, and 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.

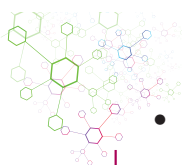
On the last day of the two-day conference, we will conclude with the ever popular "Ask the FDA" session. Send your questions early, even right after you register to registration@pharmaconference.com. Be sure to meet and visit with FDA representatives.

This year, we return to the Grand Hyatt Washington, located in the heart of Washington D.C.'s Penn Quarter neighborhood just steps away from downtown. The hotel is conveniently connected to the Metro Center train station from the lobby, allowing you to travel the red, orange, silver, and blue lines with ease to the city's beloved destinations and neighborhoods. See all of D.C.'s top sights from the hotel's front doors.

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
- Learn how to reinforce compliance in specific areas such as HCT/P Tracking and HCT/P Deviation reporting
- Discuss how product and process quality can lead to better patient outcomes
- Learn how to integrate risk management into your workplace
- Learn how others ensure auditing success
- Learn how other industries comply with labeling, advertising, and other indications of manufacturers' objective intent for 361 HCT/Ps
- Discuss Reproductive HCT/P specific issues related to Donor Eligibility and Summary of Records, Exemption Requests, and Labeling
- Interface with Industry experts and FDA

Register online at www.pharmaconference.com

About the Speakers



Erica Agy, BS – Erica Agy has almost 20 years of experience in Quality Assurance in both the pre-clinical and clinical settings. As the Cellular Therapeutics Regulatory Compliance Manager, 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, DOH and clinical trial monitor visits for both the Cellular Therapy Laboratory and the Apheresis Unit at Seattle Cancer Care Alliance. She is a practiced auditor to both internal and regulatory standards. Ms. Agy 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.



Beth Alden, BA, MT(ASCP) – Ms. Alden has been a Medical Technologist at University of Iowa Hospitals and Clinics since 1985. Initially working in the Microbiology laboratory, she moved to Tissue and Cellular Therapies in 2005, becoming the supervisor in 2008. During this time, she has overseen the transition of human tissue management from the ORs to the Blood Bank, the implementation of an electronic tissue tracking system and coordination of offsite clinical use of tissue.



Elsa Arteaga Torres, MA – Ms. Arteaga Torres has more than 14 years' experience in eye banking. As a Senior Quality Improvement and Compliance Specialist for Eversight, she is responsible for inspection preparation across Eversight's multiple locations, ensuring compliance with FDA, Eye Bank Association of America (EBAA) and Standard Operating Procedures regulations. Ms. Arteaga Torres creates and implements quality improvement initiatives such as behavior based quality analysis, PDSA projects, root cause analysis and LEAN system application.



J. Wade Atkins, MS, MT(ASCP) SBB, CQA(ASQ) – Mr. Atkins is a Quality Assurance Specialist for the Department of Transfusion Medicine (DTM) for the National Institutes of Health in Bethesda, Maryland. The DTM is a full service blood bank with a licensed collection facility and a full transfusion service. He has been in this position for the past 14 years. The DTM also has an active HCT/P manufacturing facility that supports roughly 80 protocols, and 30 of those are under IND at the FDA. He was a lead author for the WHO Annex for GMP in Blood Establishments. Prior to his current responsibilities at NIH, he worked as a Quality Assurance Specialist for Virginia Blood Services (VBS) in Richmond, Virginia. He also served VBS as the Technical Director prior to changing to QA. He also had positions in hospital transfusion services. He often speaks at local, national and international meetings on quality related topics. He is currently a volunteer assessor for AABB and an Inspector for CAP.



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.

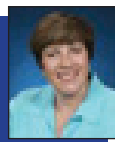


Brychan Clark, MD – Dr. Clark received her M.D. from the University of Miami School of Medicine in 1999 and then completed her Internal Medicine residency followed by a fellowship in Infectious Diseases at the San Antonio Uniformed Services Health Education Consortium. Dr. Clark retired from the United 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).



Patricia Dahl, BS – Ms. Dahl is the Executive Director/CEO of The Eye-Bank for Sight Restoration, which serves New York City, Long Island, and the Lower Hudson Valley, and has more than 35 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 the association's key committees. She is also a member of the European Eye Bank Association, Donate Life New York State (a statewide collaborative organization established to increase awareness for organ, eye and tissue donation) and has served on the New York State Transplant Council since 2002.

About the Speakers



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).



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 37 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.



Arlyn Garcia – Ms. Garcia is the IVF Third Party Clinical Coordinator for The Fertility Center of Las Vegas. She began her career with FCLV in 2004, initially working as an IVF coordinator before moving into her current position. In addition to handling clinical coordination for the center's third party IVF patients, Ms. Garcia ensures that FCLV meets FDA standards for third party reproduction, works with the lab director to ensure compliance, and is responsible for reporting the center's IVF outcomes to the Society for Assisted Reproductive Technology.



Tania Y. Hall, BS – Ms. Hall has been an Investigator with the FDA since 1991, focused in the Biologics Program area. She conducts inspections of Blood, Source Plasma, and HCT/P (Human Cellular and Tissue Based Products) establishments. Ms. Hall was involved in consent decree working committees that reviewed firm responses and corrective actions for adequacy and compliance with the consent decree. Since 2007, she has been a member of the FDA training group for the FDA's Blood Banking and Plasmapheresis Inspection training course and the FDA's HCT/P Inspection training course that is given to new FDA investigators.



Kip J. Hanks, BS – Mr. Hanks is a Biologics National Expert for FDA's Office of Regulatory Affairs. He began employment with the Agency in 1997 as a generalist investigator in New Orleans, LA. Over the years, his work focused on biologics and bioresearch monitoring. He served as the district biologics specialist for New Orleans and Atlanta Districts and was selected as the ORA biologics national expert in 2011 upon returning to post-Hurricane Katrina New Orleans. In this position, Investigator Hanks serves as a liaison between ORA and CBER, trains and mentors biologics investigators, participates on policy workgroups and continues to perform international inspections.



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.



Natalie Holland, BS – Ms. Holland has more than eight years of GxP experience with nearly four of those in Cellular Therapeutics Quality Assurance at Seattle Cancer Care Alliance. As a Quality Specialist, she is responsible for product release for administration and assisting with the regulatory and accreditation continuous readiness program, which includes FDA, FACT, CAP, The Joint Commission, Washington State Department of Health, and clinical trial sponsors for the Cellular Therapy Laboratory. She works with multiple departments to qualify internal documents per FDA regulations, standards set by accrediting bodies, and sponsor product manuals.

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About the Speakers



Cherlita A. Honeycutt, BS – Ms. Honeycutt began her civil service career in 2002 as a Biologist with the National Institutes of Health in Bethesda, Maryland. In 2006, she joined the FDA as a Consumer Safety Officer in CBER's Office of Communication, Outreach and Development. In 2010, Ms. Honeycutt joined the BLT-DO where she reviews and evaluates evidence to support the implementation of enforcement actions.



Deb Kleinfeld, MBA, BSN, RN – Ms. Kleinfeld is the founder of Kleinfeld Consulting, LLC, which she started in 2009. She is a retired FDA Investigator with over 16 years of investigative experience, with 14 years served as the Human Tissue Specialist. She has a broad and extensive understanding of all aspects of the regulatory process. Her regulatory expertise, coupled with her clinical experience as a Registered Nurse provides her with a unique perspective.



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.



James H. Lewis, MD, FACP, FACG – Dr. Lewis has spent more than 30 years treating all forms of chronic and acute liver disease as a sub-specialty in the Washington, DC, area. Dr. Lewis is Professor of Medicine at Georgetown University School of Medicine, and Director of Hepatology in the Division of Gastroenterology. He currently serves as Associate Director of the Gastroenterology Fellowship training program of the combined MedStar Georgetown University Hospital, MedStar Washington Hospital Center and the DC Veteran's Affairs Medical Center. In addition to direct patient care, Dr. Lewis has extensive consulting experience with the FDA and pharmaceutical manufacturers on a variety of liver-related conditions. A recognized local and national expert on the management of hepatitis B, hepatitis C and drug induced liver disease, Dr. Lewis is widely published in the profession's most prestigious clinical journals. His special research interests include viral hepatitis and drug induced liver injury.



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 Senior Director of the AABB Center for Cellular Therapies, a not-for-profit international organization specializing in education, standards setting and voluntary accreditation of cellular therapy and transfusion medicine facilities. In this role, Ms. Loper works closely with professionals in the field and other professional organizations and governmental agencies. Before joining AABB, she managed 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 bone marrow and peripheral blood transplant and innovative immunotherapies including cancer vaccines. These services supported phase I and phase I/II Oncology clinical trials at the Sidney Kimmell Cancer Center.



Larry Macal, BS, MBA, AATB – Mr. Macal is the Director of Operations at Amnio Technology, LLC. He has been in the medical products industry for over 25 years, serving in leadership roles related to new product development, operations, supply chain, supplier management, and continuous improvement. Mr. Macal has held other senior leadership roles within medical device companies in Minneapolis, MN, Flagstaff, AZ, and Switzerland.



James Marchese, BS – Mr. Marchese is the Manager of Audit and CAPA Systems at MTF Biologics, the largest tissue bank in the world. He has over 14 years of professional experience working in various Quality and Regulatory roles within the Biological, Tissue and Medical Device industries. Currently he manages both the internal and supplier auditing processes, ensuring standard and regulatory compliance within the company while confirming external processes remain compliant.

About the Speakers



Linda Martin, BA – Ms. Martin is Vice-President, Tissue and Support Services, Mid-America Transplant. She is an accomplished leader with over 25 years of experience in the transplant industry. Ms. Martin has been with Mid-America Transplant for 29 years, rising through the ranks to oversee Tissue Clinical Services before becoming Vice President of Tissue and Support Services in 2014. Among her key accomplishments is serving as the project lead for the organization's 2015 Malcolm Baldrige National Quality Award application, resulting in Mid-America Transplant being named the first Organ Procurement Organization in the country recognized as a Baldrige recipient. Ms. Martin has also served on the Board of Examiners for the Baldrige Program for the past six years. In addition, she has been actively involved in industry organizations including the Eye Bank Association of America, the Association of Organ Procurement Organizations, and the American Association of Tissue Banks. Her passion for donation, combined with her collaborative style, builds consensus and fosters organizational growth and sustainability.



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, and she was instrumental in developing the regulation on Biological Product Deviation Reporting, which was published in 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.



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 policy team, she 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.



Craig L. Sincaglia, BS – Mr. Sincaglia is the Director, Quality Assurance at MTF Biologics. He joined MTF in 2011, holding positions in operations and process engineering before moving into his current role. He has over 20 years of professional experience working on continuous process improvement. He is an ASQ Certified Six Sigma Black Belt and holds an Advanced Master Certificate in Lean Six Sigma and Lean Six Sigma Master Black Belt certification from Villanova.



Cristi Thompson, BS, MT (ASCP) – Ms. Thompson joined Colorado Center for Reproductive Medicine (CCRM) in 1992 and was instrumental in establishing the clinical laboratory as part of the reproductive center. In her current role as assistant manager of the clinical laboratory, she oversees 21 employees, which include medical technologists and phlebotomists. She also has served as Secretary on the Board of Colorado Association of Reproductive Technologists (CART).



Jeffrey Wilson, BS – Mr. Wilson is the Assistant Director of the MD Anderson Cord Blood Bank. He has 20 years of experience working in the stem cell field, specializing in cGMP compliant manufacturing. In his current position he is responsible for oversight of the day-to-day operations of the cord blood bank program and cGMP/ISO 7 manufacturing facility. Previously, Mr. Wilson managed the cGMP manufacturing laboratory at Baylor College of Medicine's Center for Cell and Gene Therapy.



Trevor Wright, BA, RAC – Mr. Wright is the Director of Regulatory Affairs at one of the nation's largest non-profit tissue banks, AlloSource, located in Centennial, Colorado. His current responsibilities include oversight of domestic and international regulatory strategy, compliance, and registration including: product categorization and development compliance; pre- and post-market quality and regulatory submissions; labeling and marketing material content; and audit system management. Mr. Wright has 18 years of experience in Quality and Regulatory Affairs in the Blood, Medical Device, and HCT/P spaces. 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.

Tuesday, April 14, 2020

Morning Session: Moderator – Victoria Lake

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome*	
9:10 – 9:50	Hepatitis C and the Changes in Patient Outcomes and Transmission Risk with Newer Antiviral Therapy	James Lewis, MD, FACP, FACG
9:50 – 10:20	Review Process for Communicable Disease Test Kits	Brychan Clark, MD, FDA, CBER, OTAT, DHT, HTRB
10:20 – 10:40	Break*	
10:40 – 11:05	FDA/DHT Update	Scott Brubaker, FDA, CBER, OTAT, DHT
11:05 – 11:35	Compliance Update	Anita Richardson, FDA, CBER, OCBQ
11:35 – 12:05	Compliance Actions – Inspectional Observations	Cherlita Honeycutt, FDA, ORA
12:05 – 1:20	Lunch*	

Afternoon Session

1:20 – 1:50	Workshop 1: Better Mousetrap for Tracking An interactive review and discussion focused on current and potential future methods of tracking tissue implantation records. The workshop will explore industry best practices for cells, ocular, and tissue, as they relate to Title 21, CFR Part 1271.290 along with potential future methods.	Moderator: Larry Macal Cell – J. Wade Atkins, NIH Ocular – Patricia Dahl Tissue – Larry Macal
	Workshop 2: Integrating Risk Management – How to Increase Compliance and Decrease Cost This workshop will cover how Risk is integrated in the Quality Management System, from design control to post-market surveillance. Discussions will include when to initiate a risk management file, how to ensure risk drives the validation/verification process, and how to utilize risk planning to assess process deviations and post-market feedback.	Moderator: Craig Sincaglia Ocular – Elsa Arteaga Torres Tissue – To be determined

Workshop 3: Reproductive HCT/Ps – Donor Eligibility

This workshop will review and discuss the requirements that need to be met to perform an appropriate donor eligibility determination. Topics covered will include review of testing records as well as review of relevant medical records including the donor medical history interview and physical examination.

Moderator: Kip Hanks, FDA, ORA

Industry – Corey Burke
Industry – Benjamin R. Emery
FDA – Tania Hall, ORA &
Wendy Hively, CBER, OCBQ

2:50 – 3:10

Break*

3:10 – 4:40

Workshops 1 and 2 Repeated (Workshop 3 will not repeat)

Wednesday, April 15, 2020

Morning Session: Moderator – Kip Hanks, FDA, ORA

8:30 – 9:45

Panel: Auditing Success – Quality Audits for Suppliers, Contractors, and Internal Auditors

Contract Auditor – Deb Kleinfeld
Tissue – James Marchese
Cell – Erica Agy

9:45 – 10:00

Break*

10:00 – 10:10

FDA Perspective: Labeling, Advertising and Other Indications of Manufacturers' Objective Intent for 361 HCT/Ps

Kip Hanks, FDA, ORA

10:10 – 11:00

Industry Perspective: Compliance with Labeling, Advertising and Other Indications of Manufacturers' Objective Intent for 361 HCT/Ps

Beth Alden
Kathy Loper, AABB

11:00 – 12:15

Lunch*

Afternoon Session

12:15 – 1:45

Workshop 1: 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 – Natalie Holland
Ocular – Jennifer DeMatteo
Tissue – Trevor Wright

Agenda

Workshop 2: The Quality Chain for Patient Outcomes

This workshop will cover quality concepts and tools used through recovery, processing, and distribution. It will provide ideas on how introducing these quality concepts can drive down variability and costs, provide quality products, and ultimately affect patient outcomes.

Moderator: Jeffrey Wilson

Cell – Jeffrey Wilson

Ocular – Linda Martin

Tissue – Craig Sincaglia

Workshop 3: Reproductive HCT/Ps – Summary of Records (SORs), Exemption Requests, Labeling

This workshop will identify and discuss when a request for an exemption from or alternative to any requirement in subpart C or D must be made. In addition, for situations when an exemption request is no longer required, the discussion will include how to apply the regulations for labeling covered in 21 CFR 1271.90(b).

Moderator: Kip Hanks,
FDA, ORA

Industry – Arlyn Garcia

Industry – Cristi Thompson

FDA – Tania Hall, ORA &

Wendy Hively, CBER, OCBQ

1:45 – 2:00 Break*

2:00 – 3:30 **Workshops 1 and 2 Repeated** (Workshop 3 will not repeat)

3:30 – 4:10 **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



The Grand Hyatt Washington is located in the heart of Washington D.C.'s Penn Quarter neighborhood, just steps away from downtown. The hotel is conveniently connected to the Metro Center train station from the lobby, allowing you to travel the red, orange, silver, and blue lines with ease to the city's beloved destinations and neighborhoods. See all of D.C.'s top sights from the hotel's front doors.



16th Annual FDA and the Changing Paradigm for HCT/P Regulation



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Includes conference materials, continental breakfasts, breaks, and lunches per agenda

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Phone: 1-800-233-1234

Link to make reservations: <https://www.hyatt.com/en-US/group-booking/WASGH/G-PHCO>

Group Code: G-PHCO

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For additional information, contact Pharma Conference Inc:
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