REGISTER TODAY!

20th Annual FDA and the Changing Paradigm for HCT/P Regulation

PHARMA CONFERENCE INC

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Conference presented in cooperation with EYE BANK ASSOCIATION OF AMERICA

March 31 - April 2, 2025
Alexandria, Virginia
Hilton Alexandria Old Town

About the Conference

Please join us in Old Town Alexandria, Virginia, for the ***20th Annual FDA and the Changing Paradigm for HCT/P Regulation*** conference. Due to the current situation in the government, FDA is not able to send as many speakers this year, but we are pleased to still have some FDA representation give an overview of the recently published guidances on the first day. We are also pleased to have former FDA regulators and many industry experts crossing the broad spectrum of tissues, cells, and cellular and tissue-based products.

We will open the conference with a Recipient Story to remind all of us how important our work is to those recipients that receive tissues, cells, and cellular and tissue-based products.

James Myers, JD, Associate Director for Policy in CBER, will give a brief overview of the guidances. Then hear from a former FDA, OCC (Office of the Chief Counsel) Biologics Lawyer who will expound on the basics of these guidances. Finally, we will round it out with an industry speaker sharing the *Potential Impact of the New and Proposed Guidance Documents on Our Industry*.

Former FDA will discuss HCT/P Establishment Inspection Processes: Before, During, After and Agency Action - Case Studies; Donor and Product Testing for Cells used in Cell and Gene Therapy Products; as well as lay the foundation for a 351 and 361 HCT/P discussion.

With recent changes to the HCT/P landscape, as well as anticipated future updates for participants to keep on their radar, Politico's AgencyIQ will present on the state of the industry, providing an overview of key updates, developments and trends that are shaping today's HCT/P industry. Then we will delve a little deeper and hear a talk on state licensure requirements from a legal perspective.

Industry will provide insights in two panel discussions: a validation 101 session for process, equipment and software validation and then a panel discussion on sterilization with industry and the National Institute of Standards and Technology (NIST), who will provide an update on development of their rapid sterility program from the 2024 consortium workshop. Also covered will be designing quality systems for compliance to multiple standards where we will discuss how to comply if your organization is involved in all types of products (361, 351) and all of the standards and regulations that need to be considered when designing QS. We have also included a lively Regulatory Jeopardy session!

The conference format again includes smaller workshops each afternoon that will allow participants to interact with industry experts. These include Donor Eligibility Case Scenarios for Sepsis; HCT/P deviation reporting; and bridging the gap where there will be an in-depth comparing and contrasting of cGTPs vs. cGMPs vs. QSR (Quality System Regulation). Additionally included is a workshop format termed "Bootcamp", where investigations, complaints, CAPAs and then change control will be covered. We will again have a workshop specifically focused for the reproductive tissue industry on donor eligibility, accompanying records and labeling requirements led by industry. You can expect to learn as well as provide others with your own experiences and expertise during these sessions.

A new addition to the program: You will have the special opportunity to ask Politico's AgencyIQ any question you have on the political and regulatory landscape. Come ready with your questions!

Though we will not be able to have the *Ask the FDA* session this year, we are having a special question and answer session to close out the conference titled, **Lingering and Open Questions for Former Regulators and Industry Panelists**. Bring your questions and hear from this panel of experts. You can email your questions now to registration@pharmaconference.com, submit written questions during the conference, or ask them live during this session.

Register early to ensure your participation in a great learning opportunity and the chance to network with experts in your field.

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
- Get your questions answered by experts in their field
- Hear recent changes to the HCT/P landscape, as well as anticipated future updates you want to keep on your radar
- Learn about the recently published FDA HCT/P Guidance Documents from FDA and former FDA
- Gain insight from a panel discussion on sterilization with industry and NIST
- Learn from an industry panel of experts on validation 101 for process, equipment and software validation
- Discuss how to comply if your organization is involved in all types of products (361, 351) and all of the standards and regulations that need to be considered when designing quality systems
- Get back to basics on investigations, complaints, CAPAs and change control
- Participate in interactive workshops on HCT/P deviation reporting and donor eligibility case scenarios for sepsis
- Discuss Reproductive HCT/P specific issues related to Donor Eligibility, Accompanying Records and Labeling
- Gain insight with an in-depth comparing and contrasting of cGTPs vs. cGMPs vs. QSR (Quality System Regulation).
- Interface with Former FDA and Industry experts

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.

Website for our room block: **20th FDA & HCT/P**

What attendees say about *FDA and the Changing Paradigm for HCT/P Regulation*

"I enjoyed the workshops!"

"I really liked the panel discussions and the lecture-based presentations."

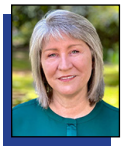
"I enjoyed the meeting and the opportunity to learn a lot and the networking."

"I appreciate the time we have to interact with new people. The collaborative environment is welcome."

To receive emails on our upcoming programs, add reception@pharmaconference.com to your address book.

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.

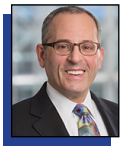


Trabue D. Bryans, BS, M(ASCP) – Ms. Bryans is President of BryKor LLC, a consulting firm specializing in healthcare product microbiology and sterilization. She served on the AAMI Standards Board and Committee on Standards Strategy, as well as co-chair for the SAL, Micro Methods, & Radiation Sterilization Committees. She was convenor and is Expert Member for the ISO Microbiological Methods, Assurance of Sterility and Radiation Sterilization WGs. She has a B.S. from University of Georgia; and M(ASCP) in Microbiology from Medical College of Georgia.

Erin Butler, BS, CTBS – Ms. Butler is a Senior Manager of Quality Systems and Regulatory for HCT/Ps with BioBridge Global and has been with the company for over 15 years working in numerous roles through the organization including donor and biologic testing, Quality Control of collection and manfacturing of cell, tissue, and blood products and regulatory compliance. She is currently responsible for overseeing regulatory and quality systems for HCT/Ps and Advanced Therapies product lines and has been focused on the cell and tissue industry for the last eight years. Ms. Butler holds a BS in Biology from Texas A&M Corpus Christi and is an AATB Certified Tissue Banking Specialist.

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).

Wayne Dietz, CEBT– Mr. Dietz is currently the Quality Assurance Director at the San Diego Eye Bank. He has 38 years of experience in eye banking and currently serves on the Accreditation Board and Quality Assurance Committee for the Eye Bank Association of America.

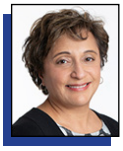


Mike Druckman, JD– Mr. Druckman, a Partner at the global law firm Hogan Lovells, leverages his prior experience at the FDA – and what he has learned since then while extricating companies from regulatory problems – to anticipate and prevent life science clients from getting into trouble in the first place. He chairs the firm's global Cell, Tissue, and Gene Therapies Working Group, a cross-disciplinary team that advises companies in this emerging space on the evolving regulatory and business challenges they face. Mr. Druckman and the team work closely with companies developing HCT/Ps and other regenerative medicines, including placental tissues, stem cells, cord blood, gene therapies, proteins, and wide range of cellular products to help people with serious health problems.

Noelle Edwards, MD – Dr. Edwards is an Associate Medical Director at LifeNet Health and a board-certified Pediatrician. Her passion for tissue donation began when she was first introduced to the field as a tissue recovery technician. Dr. Edwards serves as the Secretary of the AATB Physician's Council and has led numerous discussions on critical topics such as Allograft Cancer Transmission, Adequate Medical Records, Sepsis case reviews, and Tuberculosis. She is also an active contributor to the AATB's Tuberculosis and Sepsis Working Groups.

About the Speakers

Alexander Gaffney, MS, RAC – Mr. Gaffney is a regulatory and media executive responsible for founding and leading the research division of AgencyIQ, the regulatory analysis division of the media company POLITICO. As the Vice President of Regulatory Policy and Intelligence, he directs the division's analysis of regulatory issues affecting pharmaceutical, biotechnology, medical device, and chemical companies. Before joining AgencyIQ, Mr. Gaffney analyzed life sciences regulations as part of PricewaterhouseCoopers's Health Research Institute and was the Manager of Regulatory Intelligence at the Regulatory Affairs Professionals Society (RAPS), where he also served as Managing Editor for the company's flagship publication, Regulatory Focus.



Sangita Jindal, PhD, HCLD – Dr. Jindal earned her PhD in Physiology from the University of Toronto, Canada. For the last 23 years she has been on the faculty at Albert Einstein College of Medicine in New York as Professor and IVF Laboratory Director in the Department of Obstetrics, Gynecology & Women's Health. She is also an off-site lab director of private and academic IVF laboratories across the country. Dr. Jindal serves in leadership roles nationally and internationally within the field of clinical reproductive science.

Amy B. Johnson – Ms. Johnson is a quality and regulatory specialist, with more than 20 years of experience with human tissue requirements. She has an extensive background in regulatory body enforcement responses and remediation activities, Quality Management Systems, auditing, and training. She enjoys working with tissue establishments to help them achieve and maintain compliance with applicable FDA, state, and other regulatory body requirements.

Kristen Klimisch, BS – Ms. Klimisch is an Operations Specialist in Cellular Therapeutics at Fred Hutchinson Cancer Center. She has spent the past decade developing and overseeing the execution of a wide array of validation protocols for cellular therapeutics. Ms. Klimisch's experience includes validating a diverse range of equipment types, spanning general lab equipment to specialized instruments for the collection of HCT/Ps; product labeling software; and flow cytometry test methods.

Beth Kuker, MS – Ms. Kuker is the Regulatory Affairs Manager with NMDP. She is responsible for assessing the organization's compliance with applicable regulations and leading initiatives to develop and improve regulatory processes. She has nine years of experience in regulatory affairs in the field of cell and gene-based immunotherapies.

Areta Kupchyk, Esq, JD – After 20 years in private practice, most recently as partner and co-chair of the FDA practice at Foley Hoag LLP, Ms. Kupchyk established Kupchyk Consulting LLC to provide in-depth, specialized FDA counsel to regulated industries, focusing on drug and biological products, including human cell, tissue and cellular and tissue-based products (HCT/Ps). She brings over 30 years of experience in the field, including 10 years at the U.S. Food and Drug Administration, where she served in the Office of the Chief Counsel as Associate Chief Counsel for Drugs and Biologics and Assistant Chief Counsel for Litigation. While at FDA, Ms. Kupchyk served on CBER's Tissue Reference Group and was a lead attorney on the development and promulgation of the HCT/P Good Tissue Practice regulations. As a partner in private practice, she provided regulatory counsel on pre-approval requirements, post-approval compliance, and responses to enforcement actions. Ms. Kupchyk also assisted clients in communications with various state regulatory authorities and oversaw the development of a 50 State Licensure Survey.

Katie Laney, BS – Ms. Laney began her career as a Quality and Regulatory professional in the Life Sciences industry in 2005, specializing in compliance for Birth Tissue based products, which remains a focused passion for her today. She founded Solaris SRB, an independent FDA compliance consulting firm, in 2013 to facilitate advisement to the Human Tissue, Medical Device and Biological Product industries. Ms. Laney and her team at Solaris are committed to providing customized compliance solutions to clients over a full product lifecycle, from QMS Establishment, Regulatory Pathway determination and submission, to Quality System maintenance and support.

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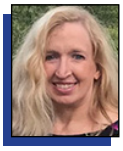
About the Speakers

Nancy J. Lin, PhD – Dr. Lin is the Leader of the Biomaterials Group in the Biosystems and Biomaterials Division at the National Institute of Standards and Technology. Her research focuses on developing measurements and standards to enable detection, characterization, and quantification of microbes and microbial communities, with an emphasis on microbial cell reference materials, microbiome, and biosurveillance. Dr. Lin also co-leads the NIST Rapid Microbial Testing Methods Consortium. She holds a BS in Mechanical Engineering from Valparaiso University and a PhD in Biomedical Engineering from Case Western Reserve University.



Alyce Linthurst Jones, PhD – Over the last 28 years, Dr. Linthurst Jones has cultivated a breadth and depth of scientific, regulatory, clinical and product development knowledge directly applicable to the realization of novel tissue-based products and medical devices. She has developed and brought several novel tissue-based medical devices through the US FDA through numerous on-site presentations and authoring multiple submissions [HDE, IDE (inclusive of clinical trial), pre-RFD, RFDs, Pre-submissions (clinical and pre-clinical), ESRD Innovation Pathway and multiple 510(k)s]. Dr. Linthurst Jones has also supported regulatory submissions to numerous countries where tissue-based products are regulated as drugs. She has various publications and book chapters in the field of cardiovascular tissue engineering and processing and well as multiple patents.

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.

Tiffany Lucas, PhD – Dr. Lucas is Principal Consultant, Eliquent Life Sciences. She leverages over 10 years in biotechnology development and over six years as a product regulatory reviewer at the FDA in cell and gene therapy within the Center for Biologics Evaluation and Research (CBER). Dr. Lucas managed a wide range of products from preIND through license approval and post-licensure changes. Her background as an investment analyst and in technology licensing, patents, and development enhances her understanding of program and product development strategies. She understands that each product is unique, and she provides customized advice tailored to each program.

Iris Marklein, PhD – Dr. Marklein is a Senior Director, Regulatory Affairs at MCRA, providing regulatory support to companies developing cell and gene therapies, combination products, and HCT/Ps. She has over a decade of experience in regulatory affairs, including eight years at the FDA. Prior to joining MCRA, Dr. Marklein was an Associate Director for Policy in the Office of Therapeutic Products in CBER, overseeing the development of guidance documents and policy related to HCT/Ps. Additional former positions at FDA include Team Lead and CMC Reviewer in CBER, along with Lead Reviewer in CDRH.

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.

Roxana Mercado, BS – Ms. Mercado is the Director, Quality Systems, for BioTissue Holdings Inc. She is a Quality Operations leader with extensive expertise in biopharmaceuticals, medical devices, tissue products and pharmaceuticals. She is proficient in Quality Systems management, regulatory compliance, audits and audit readiness, supplier quality, risk management, customer complaints, CAPA, change management, validations and process improvements under FDA, ISO, AATB and global regulations. Ms. Mercado is dedicated to enhancing compliance, efficiency, and operational excellence in regulated healthcare industries.

About the Speakers

Owen Moore, BS – Mr. Moore brings over five years of US and International Quality experience with backgrounds in pharmaceutical excipients and cell therapies. A Senior Quality Liaison with NMDP, he works with the Quality Team, collaborating internally with cross-functional teams to ensure operations are conducted in compliance with all applicable regulations and standards. Mr. Moore also provides Quality support in an internal and external auditing capacity. Before working at NMDP, he worked as a Senior Quality Specialist at Hawkins Pharmaceuticals for manufacturing to ensure compliance for pharmaceutical excipient products.

James Myers, JD – Mr. Myers is the Associate Director for Policy at FDA's Center for Biologics Evaluation and Research (CBER). In this role, he serves as the principal policy advisor to the CBER Center Director and Deputy Director and helps lead CBER's overall policy activities. Mr. Myers previously served in various policy roles in the Center for Drug Evaluation and Research (CDER), including helping to establish the Center's Office of New Drug Policy. Prior to coming to FDA, he worked in private practice at a large international law firm in Washington, D.C.

Jennifer Roe, BS, MBA – Mrs. Roe is a Director of Continuous Improvement who has worked with StimLabs, LLC for four years. She has participated in software system implementations including Citrix, SAP, and Oracle, with her most recent experience leading a full system implementation of Infor CloudSuite Industrial containing Enterprise Resource Planning (ERP) and Electronic Batch Records (EBR) to support HCT/P processing requiring software validation of all current Good Manufacturing Practices (cGMP) and current Good Tissue Practices (cGTP).

Melinda Slason, BS – Ms. Slason is a Quality Systems Management Associate at BioBridge Global. With over 16 years of experience in laboratory testing and quality assurance, she currently assists in managing the Quality System across all subsidiaries, ensuring compliance and continuous improvement across the organization.

Faith Spann, BS, CTBS – Ms. Spann has been part of the DCI Donor Services family for seven years, five of which she spent working directly with donor eligibility. She is passionate about helping others through the gift of donation and loves knowing her work makes a difference every day.

Leslie Wheat, BS, CQA – Ms. Wheat is Manager of Quality & Compliance at BioBridge Global. She has served in several roles over eight years at the organization, including blood-line product manufacturing and QC testing, and Quality Control of Blood and HCT/P products. Ms. Wheat is currently responsible for the Blood and HCT/P Quality Control teams, and Blood Product Compliance team. She holds a BS in Biochemistry from Texas State University San Marcos and is an American Society for Quality Certified Quality Auditor.

Carolyn Yong, PhD – Dr. Yong is a Vice President, Regulatory Affairs at MCRA, providing regulatory and compliance support to companies developing (361, 351) HCT/Ps, regenerative medicine and combination products. She served at FDA for 11 years. Prior to joining MCRA, Dr. Yong was Chief of Special Projects and Policy Staff in the Office of Therapeutic Products and HCT/P regulatory framework expert in CBER. Additional former positions at FDA include Acting Cell Therapies Branch Chief, CMC Reviewer in CBER, and the Tissue Reference Group.

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Agenda

Continuing Education

This conference qualifies for 14.0 hours of continuing education credit.

Monday, March 31, 2025

Morning Session: Moderator – Alyce Linthurst Jones, PhD

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome*	
9:10 – 9:30	**Personal Interest Story Related to HCT/Ps**	To Be Introduced
9:30 – 10:30	**State of the Industry** This plenary session will provide an overview of key updates, developments and trends that are shaping today's HCT/P industry. This will cover recent changes to the HCT/P landscape, as well as anticipated future updates for participants to keep on their radar. **PLUS: AMA "Ask Me Anything" Q&A**	Alexander Gaffney
10:30 – 10:50	Break*	
10:50 – 11:25	**Donor and Product Testing for Cells used in Cell and Gene Therapy Products**	Tiffany Lucas, PhD
11:25 – 12:05	**HCT/P Establishment Inspection Processes: Before, During, After and Agency Action - Case Studies**	Carolyn Yong, PhD
12:05 – 1:20	Lunch* (Networking opportunity)	

Afternoon Session: Moderator – Alyce Linthurst Jones, PhD

1:20 – 1:50	**Recently Published FDA HCT/P Guidance Documents** • Updated HCT/P DE Guidance • Individual HCT/P Guidance Documents for HIV/HBV/HCV • Mtb and Sepsis Guidance Documents	James Myers, JD, FDA, CBER
1:50 – 2:35	**Recently Published FDA HCT/P Guidance Documents – the Basics from a Former OCC (Office of the Chief Counsel) Biologics Lawyer**	Mike Druckman
2:35 – 3:00	**Potential Impact of the New and Proposed Guidance Documents on Our Industry**	Beth Kuker
3:00 – 3:20	Break*	
3:20 – 4:50 *Repeats on Day 2*	**WORKSHOPS SESSION** **Workshop 1: Quality Bootcamp** • **Investigations, Complaints, CAPAs** Presentation will provide an overview of Investigations, Corrective and Preventative actions CAPAs), and Complaint Handling in the context of Human Cell, Tissue, and Cellular and Tissue-Based Products (HCT/Ps) regulation. The presentation aligns with FDA 21 CFR Part 1271 and emphasizes best practices for compliance and risk management. • **Change Control**	Moderator: Alyce Linthurst Jones, PhD Melinda Slason Alyce Linthurst Jones, PhD

Agenda

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Held once	**Workshop 2: FDA Requirements for Reproductive HCT/Ps including Reproductive Donor Eligibility, Accompanying Records and Labeling Requirements with Case Scenarios**	Moderator: Sangita Jindal, PhD
	Industry: They did WHAT? Reproductive HCT/P Challenges 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.	Amy Johnson Sangita Jindal, PhD

Tuesday, April 1, 2025

Morning Session: Moderator – Jennifer DeMatteo

9:00 – 9:50	**Introduction on Regulatory and Quality Differences on HCT/P Products Regulated as Biologics, Devices, and "Tissues" – What Are They?**	
	• Laying Foundation: What Constitutes a Device (820), Biologic (351), or Tissue (361)	Iris Marklein, PhD
	• Talk Product Types - Compare GMPs, GTPs and QSRs	Leslie Wheat, CQA
	• Tissue as a device	
9:50 – 10:20	**State Licensure**	Areta Kupchyk, Esq
10:20 – 10:40	Break*	
10:40 – 11:40	**Designing Quality Systems for Compliance to Multiple Standards** (with Q&A) How to comply if your organization is involved in all types of products (361, 351) and all of the standards and regulations that need to be considered when designing QS	Katie Laney
11:40 – 12:10	**Regulatory Jeopardy**	Owen Moore
12:10 – 1:25	Lunch* (Networking opportunity)	

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Afternoon Session

1:25 – 2:55 **WORKSHOPS: SESSION ONE**

Does not repeat

Workshop 1: Bridging the Gap: Compare and Contrast cGTPs vs. cGMPs vs. QSR (Quality System Regulation) – In-Depth

Moderator: Paige McKibbon
Roxana Mercado

This session focuses on product quality regulations for HCT/Ps regulated under sections 351 and 361 of the Public Health Service Act and as medical devices regulated under the FD&C Act. HCT/Ps regulated under PHS section 361 need to align with 21 CFR 1271. If the HCT/P is regulated under PHS section 351, it needs to align with 21 CFR 1271, 21 CFR 211, and 21 CFR 610. And if the HCT/P is regulated as a medical device, it needs to align with 21 CFR 820. This session will highlight similarities and differences between the three regulations and their intent. It will also cover items to consider when transitioning or supporting products differentially regulated by multiple regulatory paradigms.

Repeats

Workshop 2: HCT/P Deviation Reporting – Case Scenarios

Moderator: Erica Agy
Tissue – Erin Butler
Ocular – Wayne Dietz, CEBT
Cell – Erica Agy

This workshop will look at logic used when determining the reportability of HCT/P deviations through case studies and interactive discussions. Different types of HCT/Ps will be covered, and audience participation is strongly encouraged.

Repeats

Workshop 3: Donor Eligibility Case Scenarios for Sepsis

Tissue – Noelle Edwards, MD
Ocular – Faith Spann

This workshop will include a brief discussion of sepsis syndrome definitions and relevance to donor eligibility, followed by a series of interactive case discussions for both tissue and ocular donors.

2:55 – 3:15 Break*

3:15 – 4:45 **WORKSHOPS: SESSION TWO**

Repeated from Day 1

Workshop 1: Quality Bootcamp

Moderator: Alyce Linthurst Jones, PhD
Melinda Slason

- **Investigations, Complaints, CAPAs**
  Presentation will provide an overview of Investigations, Corrective and Preventative actions CAPAs), and Complaint Handling in the context of Human Cell, Tissue, and Cellular and Tissue-Based Products (HCT/Ps) regulation. The presentation aligns with FDA 21 CFR Part 1271 and emphasizes best practices for compliance and risk management.
- **Change Control**

Alyce Linthurst Jones, PhD

Repeat

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Wednesday, April 2, 2025

Morning Session: Moderator – Kathy Loper

9:00 – 10:10	**Panel: Validation 101** • Process • Equipment • Software validation	Kristen Klimisch Jennifer Roe
10:10 – 10:30	Break*	
10:30 – 11:20	**Sterility Updates for Industry:** • Sterility Assurance and Alternate SALs • Rapid Microbial Testing for Advanced Therapy Products	Trabue Bryans Nancy Lin, PhD, NIST
11:20 – 12:00	**Lingering and Open Questions for Former Regulators and Industry Panelists**	**Former Regulators:** Mike Druckman Tiffany Lucas, PhD Carolyn Yong, PhD **Industry:** Cell - Erica Agy Ocular – Jennifer DeMatteo Tissue - Roxana Mercado

*Denotes non-educational activity

Register

20TH ANNUAL
FDA AND THE CHANGING PARADIGM FOR HCT/P REGULATION

Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By January 31, 2025	❑ $1995	❑ $1795
Payment Received After January 31, 2025	❑ $2195	❑ $1795

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

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Payment

- 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: Conference attendees must be paid in full prior to conference start date.

Hotel

Hilton Alexandria Old Town
1767 King Street, Alexandria, Virginia 22314
(703) 837-0440
$242 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 10, 2025, in order to guarantee the special rate.** Individuals are responsible for making their own hotel reservations. **You must mention you are with the group, *20th Annual FDA & Changing Paradigm for HCT/P Regulation*, when making your reservation in order to obtain these special rates. Please do not use travel agents for reservations.**

Online reservations:
1-800-HILTONS (1-800-445-8667)

Website for our room block:
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