21ST ANNUAL

FDA AND THE CHANGING PARADIGM FOR HCT/P REGULATION

April 13 – 15, 2026
Tysons Corner, Virginia
Hyatt Regency Tysons Corner Center

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Conference presented by

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EYE BANK ASSOCIATION OF AMERICA

About the Conference

Please join us in Tysons Corner, Virginia, for the **21st Annual FDA and the Changing Paradigm for HCT/P Regulation** conference. We are pleased to have representation from FDA and many industry experts crossing the broad spectrum of tissues, including ocular and reproductive, 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.

FDA CBER has been confirmed to share the most current information with the Division of Human Tissues (DHT) update, while FDA CBER's Office of Compliance and Biologics Quality (OCBQ) has been invited to share their most current information. Laurissa Flowers, Biologics National Expert from FDA's Office of Inspections and Investigations, is confirmed to give a presentation on the Inspectional Process and Most Frequently Cited Observations.

As the HCT/P landscape evolves and churns at FDA, coupled with anticipated changes 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 into artificial intelligence and machine learning with a plenary talk on its use in donor screening and an interactive workshop on integrating AI into your Quality Systems to increase efficiencies, prevent hallucinations and maintain compliance. And you do not want to miss the interesting discussions that occur during the Regulatory Jeopardy session!

Industry will provide insights on determining your product classification and finding the fastest route to FDA approval, plus a session on screening. Also,we will delve into the confounding process of screening for sepsis and associated 483s in a post-Mtb transmissions environment. In that same vein, we will cover microbiological testing for Mtb (Mycobacterium) addressing challenges and considerations for test method validation and limitations of rRNA testing for Mtb in recipients using laboratory developed tests. We will consider warning letters and what they are telling us about how FDA's current thinking is evolving and where enforcement is going.

The conference format again includes smaller workshops each afternoon that will allow participants to participate in an interactive format with industry experts. These include strengthening practices, preventing errors, and preparing for FDA audits in regard to donor eligibility and screening; HCT/P deviation reporting; looking at individual donor assessment and moving toward risk-based screening; and looking at lessons learned and considerations for implementation and execution of electronic batch production records, including demonstrations from an electronic system currently in use. Additionally included is a session on identifying a standard process for implementing commercially available HCT/Ps within an organization, specifically cell therapy products (e.g., CAR-T, genetically modified, etc.) that have been approved for commercial use by the FDA. We will again have a workshop specifically focused for the reproductive tissue industry on donor eligibility, accompanying records and labeling requirements led by industry (and closely organized with 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-and-a-half-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 (due by March 27, 2026). Be sure to meet and visit with FDA representatives at the meeting.

Register early to save hundreds of $$ and ensure your participation in a great learning opportunity and the chance to network with experts in your field both from industry and the FDA.

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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?

- Listen to FDA office and division updates
- Hear recent changes to the HCT/P landscape, as well as anticipated future updates you want to keep on your radar
- Screening for sepsis and associated 483s
- Learn details about donor screening, testing, and eligibility
- Gain insight from OII on the Inspectional Process and Most Frequently Cited Observations
- Learn about the applications for artificial intelligence and machine learning in the HCT/P industry during a plenary session and interactive workshop
- Consider warning letters and what they are telling us about how FDA's current thinking is evolving and where enforcement actions are trending
- Discuss microbiological testing for Mtb (Mycobacterium) and the pitfalls and challenges of rRNA testing for Mtb in surgical site infections using laboratory developed tests
- Get training in strengthening practices, preventing errors, and preparing for FDA audits in regard to donor eligibility and screening
- Participate in interactive workshops on HCT/P deviation reporting and looking at individual donor assessments and moving toward risk-based screening
- Discuss Reproductive HCT/P specific issues related to Donor Eligibility, Accompanying Records and Labeling
- Look at FDA's evolving approach to donor screening, shifting from blanket deferrals to individualized, risk-based assessments
- Gain insight on determining your product classification and finding the fastest route to FDA approval
- And you do not want to miss the interesting discussions that occur during the Regulatory Jeopardy session!
- Interface with Industry experts and FDA

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

"Great topics discussed!"

"Overall, great conference in this very volatile regulatory time."

"The Jeopardy game was great – it opened the floor for great conversation."

"I enjoyed the workshop sessions on HCT/Ps."

"First time coming and really appreciated the content and the people. I've definitely taken more information and tools away!"

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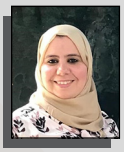
About the Speakers

Erica Agy, BS – Ms. Agy has worked at Fred Hutchinson Cancer Center for the past 15 years and currently serves as the Interim Director of Quality Assurance. She is responsible for the regulatory and accreditation continuous readiness programs, managing inspection preparation, coordination, performance, and follow-up for FDA, FACT, CAP, TJC, as well as clinical trial sponsor audits and monitor visits for the Cellular Therapy Laboratory and the Apheresis Unit. Ms. Agy also oversees the QA/QC groups who support the GMP Cellular Processing Facility, the Clinical Labs Quality Assurance team, and the FACT Clinical Quality team at Fred Hutch.



Fatima Amchich, BS, MPh – Ms. Amchich is a Senior Regulatory Compliance Specialist at NMDP, specializing in the reviewing domestic and international donor and cord blood unit eligibility in accordance with regulatory and accreditation requirements. Her work focuses on ensuring accurate and consistent donor eligibility documentation that supports patient safety, regulatory compliance, and audit readiness. Ms. Amchich actively contributes to continuous improvement initiatives by identifying trends, gaps in eligibility review processes and collaborating on corrective and preventive actions that strengthen quality systems and reduce recurrence.

Jonathan Boyd, MS – Mr. Boyd's career in donation started in 2009 at an organ and tissue procurement organization, where he worked in surgical recovery and leadership roles. In 2017, he joined the Association for Advancing Tissue and Biologics and served as Director of Education until he moved to Lonza in 2023, where he is now the Director of Tissue Acquisition, leading a team supporting initiatives involving donated tissues and cells. Additionally, Mr. Boyd is the CEO of AlloEd, which offers technical training and education to donation and transplant professionals.

Rebeccah Brown, MS, PhD – Dr. Brown is the founder of CGC, and her three decades of global experience encompass strategic leadership, regulatory expertise, quality oversight, and product innovation in biotechnology. She holds numerous patents, was named a Top 25 Women Leader in Medical Devices (2021), and collaborates with industry, regulatory bodies, and other organizations worldwide. Dr. Brown serves on Georgia Tech's College of Engineering Advisory Board and previously chaired its Mechanical Engineering Advisory Board and the Women of Woodruff program. She earned her SB from MIT and MS/PhD from Georgia Tech in Mechanical Engineering.

Chris Dayton, BS – Mr. Dayton is the Co-Founder and CEO of QualityAssured.ai, a company delivering closed-system, on-premise AI purpose-built for pharmaceutical and HCT/P quality operations. He specializes in applying AI to QMS, QRM, and regulated workflows while aligning with FDA, EMA, and MHRA expectations. Mr. Dayton advises life-science organizations on integrating inspection-ready AI, supports federal R&D initiatives, and speaks nationally on safe, compliant AI adoption in highly regulated manufacturing environments.

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 the former Quality Assurance Director at the San Diego Eye Bank (SDEB). He recently transitioned to the position of Director of Community Outreach after celebrating his 40th anniversary at SDEB.

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.

Laurissa Flowers, BS – Ms. Flowers has served with the FDA for more than 14 years as a biologic's investigator, Biologics Specialist, and Supervisory Investigator, and now serves as a Biologics National Expert within the Office of Biologics Inspectorate (OBI). She has conducted hundreds of inspections and investigations in biologics, human tissue, biological drugs. Prior to joining the FDA Ms. Flowers served in the US Army as a Preventive Medicine Specialist, after which she attended and graduated from the University of Maryland, College Park with a degree in Kinesiology.

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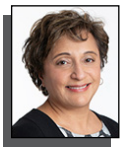
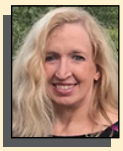
About the Speakers



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 the Associate Director of Tissue Services at Eversana. As 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.

Charles "Cheyne" Levermore, BASc, MIB, MDA – Mr. Levermore has over 20 years of leadership experience across healthcare and medical device organizations. He specializes in analytics driven strategy, organizational transformation, and workflow optimization. As Vice President of Global Quality Assurance at LifeNet Health, Mr. Levermore leads the chart review process, performance improvement, postproduction releases, and strategic AI initiatives. Known for driving impactful change, he has delivered major efficiency gains, multimillion dollar savings, and award winning advancements in quality, innovation, and data visualization. In conjunction with LifeNet Health, Mr. Levermore provides sponsorship for data analytic practicums for multiple universities.



Alyce Linthurst Jones, PhD – Dr. Linthurst Jones is the Scientific Liaison and Quality Vice President at LifeNet Health. Over the last 30 years, she has cultivated a breadth and depth of scientific, regulatory, clinical, research, and product development knowledge directly applicable to the realization of novel tissue-based products and medical devices for cardiac, vascular, orthopedic, and trauma applications. Dr. Linthurst Jones has developed and brought several novel tissue-based medical devices through the US FDA through numerous on-site presentations and authoring multiple submissions [IDE (inclusive of clinical trial), pre-RFD, RFDs, Qsubs, (clinical and pre-clinical), ESRD Innovation Pathway and multiple 510(k)s] and 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, tissue disinfection, and processing as well as multiple patents. Dr. Linthurst Jones is active in ASTM F04.44 for Tissue Engineered Medical Products (TEMPs) and AATB Scientific and Technical Affairs and Standards Committees.

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 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 16 years.

Anna Greene McDonald, MD – Dr. McDonald has been the Medical Director at Birth Tissue Recovery since 2016. Her work is focused on determining donor eligibility to ensure tissue safety using her expertise in Perinatal and Forensic Pathology. Dr. McDonald is active in the AATB as Vice Chair of the Physician's Council, active in numerous working groups, and has authored numerous presentations regarding clinical relevance and tissue safety. She completed her medical degree at Duke University School of Medicine, Anatomic and Clinical Pathology residency at Massachusetts General Hospital, Pediatric Pathology fellowship at Boston Children's Hospital, and Forensic Pathology fellowship at the Boston OCME.

Owen Moore, BS – Mr. Moore brings more than five years of US and International Quality experience with a background 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.

Federico Rodriguez Quezada, BS, SBB, MLS (ASCP) – Mr. Quezada has over 36 years of experience in cellular therapy and immunohematology fields. He is currently the Client Services Manager with FACT CS. He earned his Bachelor of Science in Medical Technology from the Autonomous University of Nuevo Leon in Mexico; he graduated as Specialist in Blood Banking School at the University of Texas Medical Branch in Galveston, TX. Mr. Quezada's 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.

Jan Zajdowicz, BS, MS, CTBS – Mr. Zajdowicz is Vice President, Product Safety & Laboratory Services at AlloSource. He has worked 25+ years in various tissue banking functions, including microbiology, laboratory, quality, and research roles. Mr. Zajdowicz currently leads the product safety and quality laboratory teams at AlloSource, Centennial, CO. He volunteers for the American Association for Tissue Banks, serving as the committee chair for the Scientific and Technical Affairs Committee and leading subcommittees for emerging infectious diseases and Mycobacterium testing. Mr. Zajdowicz is a Certified Tissue Banking Specialist through AATB (2007-present).

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Agenda

Continuing Education

This conference qualifies for 16.0 hours of continuing education credit.

Monday, April 13, 2026

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 – 10:15	**FDA/DHT Update**	FDA, CBER, OTP, OCTHT, DHT **CONFIRMED** – Speaker To Be Determined
10:15 – 10:45	**Compliance Update**	To Be Determined
10:45 – 11:05	Break*	
11:05 – 11:50	**Designing Machine Learning to Do Initial Donor Screening**	Charles "Cheyne" Levermore
11:50 – 12:35	**Regulatory GPS: Determining Your Product Classification and the Fastest Route to FDA Approval**	Rebeccah Brown, PhD
12:35 – 1:50	Lunch*	

Afternoon Session: Workshops

1:50 – 3:20	**Workshop 1: Donor Eligibility & Screening Excellence: Strengthening Practices, Preventing Errors, and Preparing for FDA Audits** This session offers practical guidance for strengthening donor eligibility workflows to meet FDA expectations and reduce compliance risks. Learn the most common documentation errors and proven strategies to prevent them, along with clear dos and don'ts, process improvements, and tools to enhance accuracy, consistency and audit readiness.	Moderator: Wayne Dietz, CEBT Speakers: Wayne Dietz, CEBT Fatima Amchich Amy Johnson

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	Workshop 2: HCT/P Deviation Reporting 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.	Moderator: Erica Agy Speakers: Cell - Erica Agy Ocular – Vivian Lopez Tissue - Jonathan Boyd
3:20 – 3:40	Break*	
3:40 – 5:10	**Workshops – above workshops repeat**	

Tuesday, April 14, 2026

Morning Session: Moderator – Jennifer DeMatteo

9:00 – 9:05	Housekeeping Announcements*	
9:05 – 10:05	**Microbiological Testing for Mtb (Mycobacterium) and rRNA Laboratory Developed Testing for Mtb in Surgical Site Infections Post-Allograft Implantation**	Jan Zajdowicz Anna McDonald, MD
10:05 – 10:25	Break*	
10:25 – 11:25	**Screening for Sepsis and Associated 483s in a Post-Mtb Transmissions Environment**	To Be Determined
11:25 – 12:25	**State of the Industry (including 15 minutes Q&A)**	Alexander Gaffney
12:25 – 1:40	Lunch*	

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Afternoon Session: Workshops

1:40 – 3:10	**WORKSHOPS SESSION 1**	
Repeats	**Workshop 1: Lessons Learned and Considerations for Implementation and Execution of Electronic Batch Production Records, Including Demonstrations from an Electronic System** This workshop will look at case examples, practical guidance for implementation, and common/expected pitfalls.	Moderator: Joseph Higdon Speakers: Joseph Higdon Chris Dayton
Repeats	**Workshop 2: Individual Donor Assessment – Moving Toward Risk-Based Screening** • **Policy Implications** • **Implementation Strategies, and Sample Screening Questions** This session will look at the FDA's evolving approach to donor screening, shifting from blanket deferrals to individualized, risk-based assessments. Learn how this impacts eligibility decisions for HIV, HBV, HCV, Mtb, Sepsis and other communicable diseases. This paradigm shift promotes more inclusive and precise donor evaluations.	To Be Determined
One time	**Workshop 3: Identifying a Standard Process for Implementing Commercially Available HCT/Ps within an Organization** This session outlines the end-to-end onboarding process for introducing novel cell therapies – e.g., CAR-T, genetically modified, etc. – into healthcare institutions, examines common operational, regulatory, and organizational challenges encountered before and during implementation, and identifies key stakeholders and their roles in ensuring a coordinated, efficient, and successful integration. Objectives: • Describe the general onboarding process to bring novel cell therapies into healthcare institutions. • Discuss different challenges and roadblocks that institutions could face before and during the onboarding process. • Identify key stakeholders and their roles that will make the process go seamlessly.	Federico Rodriguez Quezada To Be Determined

Agenda

Continuing Education

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3:10 – 3:30	Break*	
3:30 – 5:00	**WORKSHOPS SESSION 2**	
Repeat	**Workshop 1: Lessons Learned and Considerations for Implementation and Execution of Electronic Batch Production Records, Including Demonstrations from an Electronic System** This workshop will look at case examples, practical guidance for implementation, and common/expected pitfalls.	Moderator: Joseph Higdon Speakers: Joseph Higdon Chris Dayton
Repeat	**Workshop 2: Individual Donor Assessment – Moving Toward Risk-Based Screening** • **Policy Implications** • **Implementation Strategies, and Sample Screening Questions** This session will look at the FDA's evolving approach to donor screening, shifting from blanket deferrals to individualized, risk-based assessments. Learn how this impacts eligibility decisions for HIV, HBV, HCV, Mtb, Sepsis and other communicable diseases. This paradigm shift promotes more inclusive and precise donor evaluations.	To Be Determined
One time	**Workshop 3: 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: Sangita Jindal, PhD Speakers: Sangita Jindal, PhD Amy Johnson

Agenda

Continuing Education

This conference qualifies for 16.0 hours of continuing education credit.

Wednesday, April 15, 2026

Morning Session: Moderator – Erica Agy

8:30 – 9:30	**Warning Letters – Homologous Use in Advertising, Minimal Manipulation, and Sepsis: What Are These Telling Us About FDA's Current Thinking and Where is it Going?**	To Be Determined
9:30 – 10:30	**Donor Screening, Testing and Eligibility Determination**	To Be Determined
10:30 – 10:50	Break*	
10:50 – 11:25	**Regulatory Jeopardy**	Owen Moore
11:25 – 12:25	**FDA OII Inspectional Process and Most Frequently Cited Observations**	Laurissa Flowers, FDA, OII **CONFIRMED**
12:25 – 1:00	**Ask the FDA**	All FDA Speakers – invited

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Fees

	Industry	U.S. Gov't & Press
SUPER EARLY 20% DISCOUNT: Payment Received By December 19, 2025	❑ $1756	❑ $1436
EARLY DISCOUNT: Payment Received December 20, 2025 – February 6, 2026	❑ $2195	❑ $1795
Payment Received After February 6, 2026	❑ $2395	❑ $1795

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

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- 5 to 9 registrants from the same company: 10% off the registration price*
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** To receive the group discount, attendees must register on the group registration form and pay concurrently.*

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- All credit card transactions are processed in US Dollars (your bank will convert to your local exchange rate when billing)
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- Registrations must be accompanied by full payment.

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

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$299 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 23, 2026, in order to guarantee the special rate.** Individuals are responsible for making their own hotel reservations. **If calling, you must mention you are with the group, *21st 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.**

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(703) 893-1234 or (877) 803-7534

Online reservations:
21st Annual HCT/P

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