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15TH ANNUAL FDA AND THE CHANGING PARADIGM FOR HCT/P REGULATION

FEBRUARY 4 – 5, 2019 | WASHINGTON, DC

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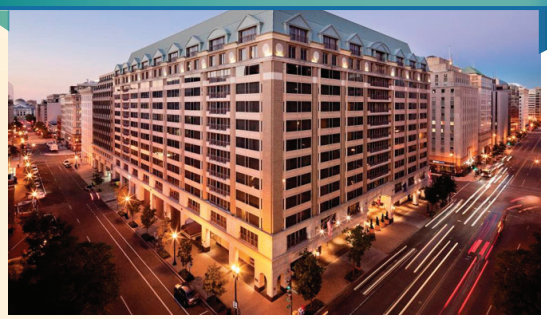

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About the Conference

Please join us in Washington, D.C., for the **15th 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 will include a moving Recipient Story to remind all of us how important our work is to those recipients that receive these tissue and cell based products. There will be updates from the FDA regarding HCT/P Deviation Reporting, Donor Eligibility, Compliance, Manufacturing Arrangements, and Import, as well as industry presentations discussing contracts and agreements, and workshops for HCT/P Deviation Reporting and Implementing Electronic Records. Additionally, FDA presenters will spend time reviewing the final guidance information related to Same Surgical Procedure Exception and Minimal Manipulation/Homologous Use.

We are continuing this year with providing more focused sessions for the reproductive tissue industry by including workshops on Donor Eligibility and Exemption Requests and Inspection Readiness for Reproductive HCT/P Establishments. We are featuring a panel discussion on Gestational Tissues, where industry representatives will discuss types, uses, and testing of those tissue types.

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's conference venue is 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

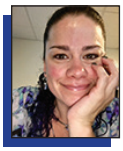
Why Attend?

- These are the most far reaching regulations for the tissue and cell industry
- Learn how to reinforce compliance in specific areas such as Donor Eligibility and HCT/P Deviation reporting
- Learn how other industries comply with Manufacturing Arrangements and Contracts/ Agreements
- Learn how others have implemented electronic records
- Be prepared for a Reproductive HCT/P Establishment Inspection
- Interface with Industry experts and FDA

Register online at www.pharmaconference.com

About the Speakers

Hena Abidi BA, MBA – Ms. Abidi is currently Supervisor of Quality Assurance at MTF Biologics, the largest tissue bank in the world. In her current role, she manages the tissue release process and ensures that all regulatory guidelines, as well as MTF Biologics' stringent quality criteria are met. In her previous role as a Regulatory Affairs Specialist, Ms. Abidi was heavily involved with Market Withdrawals and Compliance.

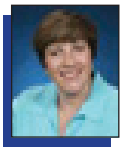


Erica Agy, BS – Ms. Agy has more than 15 years of experience in Quality Assurance in both the pre-clinical and clinical settings. As the Cellular Therapeutics Regulatory Compliance Manager, she is responsible for the regulatory and accreditation continuous readiness program managing inspection preparation, 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.

Scott A. Brubaker, CTBS – 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).



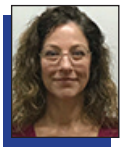
Jennifer DeMatteo, BS, MCM, CIC – Ms. DeMatteo is the Director of Regulations and Standards for the Eye Bank Association of America (EBAA). She oversees the EBAA Accreditation program, Medical Standards process and serves as their regulatory liaison. She was responsible for directing the Infection Prevention 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).

Lawrence A. DiDomenico, DPM, FACFAS, FACFAOM, CWS, FCCWS – Dr. DiDomenico is Section Chief of Podiatry at St. Elizabeth Health Center in Youngstown, Ohio, the Adjunct Professor at Kent State University College of Podiatric Medicine, and the Program Director for the Reconstructive Rearfoot and Ankle Surgical Fellowship program. He is published in the areas of wound care, reconstructive surgery and fixation and has conducted, authored, and published various clinical studies. In 2015, Dr. DiDomenico was the recipient of the American College of Foot and Ankle Surgeon's (ACFAS) Distinguished Service Award, one of the College's highest honors, due to his commitment to patient care, education, and science.

About the Speakers

LT Jessica L. Dunn, PhD – Dr. Dunn is a Senior Regulatory Review Officer within FDA's Center for Biologics Evaluation and Research in the Office of Compliance and Biologics Quality. She joined FDA in 2011 and commissioned as a Lieutenant in the US Public Health Service in 2017. In this capacity, she conducts reviews and analysis of facility inspections for biological drug and 351 HCT/P manufacturers, evaluates Biological Product Deviation Reports, and provides guidance on import and export activities of CBER-regulated products.

Stephanie Frickleton, BS – Ms. Frickleton is the Director of SIMPLIFY Donor Egg Bank/Pacific NW Fertility. She is also the FDA "Most Responsible Person" at Pacific NW Fertility and has enjoyed participating in five successful FDA audits since 2005. In addition, Ms. Frickleton is an Advisory Consultant to RESOLVE: The National Infertility Association and is adjunct faculty at Swedish Medical Center. As a Fertility Counselor since 1999, she has matched over 2,000 patients with an egg donor. Ms. Frickleton is also a certified Parental and Childbirth Educator and a member of both the American Society of Reproductive Medicine and the Canadian Fertility and Andrology Society.



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.

Ellen Heck, BS, MBA, MT(ASCP) – Ms. Heck is the founding director of the Transplant Services Center University of Texas Southwestern Medical Center at Dallas and holds faculty appointments in the departments of Surgery and Ophthalmology. She has served on the boards of the American Association of Tissue Banks, American Burn Association and Eye Bank Association of America where she served as Chairman. Various national activities also include the Blood Products Advisory Committee for the FDA, Chair of Accreditation committee for both AATB and EBAA, and member of the Medical Advisory Board for EBAA. Ms. Heck is currently serving as Editor in chief for the International Journal of Eye Banking.

Safa Karandish, BS, MT(ASCP) – Ms. Karandish is a Consumer Safety Officer with FDA's Office of Tissues and Advanced Therapies in the Division of Human Tissues. She joined FDA in 2010, and her primary focus is related to policy, regulations and review of cellular therapy products. Ms. Karandish has extensive cellular therapy experience in both academic and industry settings.

Victoria (Tory) Lake, RAC, BA, BSc – Ms. Lake is the founder of Sound Regulatory Consulting, LLC where she operates as an independent regulatory affairs consultant. She offers regulatory support and guidance to manufacturing facilities and clinical trial sponsors utilizing novel cell therapy investigational products and hematopoietic progenitor stem cells, subject to FDA's regulations for current Good Manufacturing Practices (CGMP) and current Good Tissue Practices (CGTP). Previously, Ms. Lake served as the Regulatory Affairs Director for Fred Hutchinson Cancer Research Center. Prior to that she served as the Associate Director of Regulatory Affairs for a biologics company focused on immunotherapies.

About the Speakers

Neali H. Lucas, PhD – Dr. Lucas is a regulatory scientist whose professional experience spans various environments including academia, industry, and government. She currently serves as a Supervisory Consumer Safety Officer with the Food and Drug Administration in the Office of Regulatory Affairs, Office of Biological Products Operations. Dr. Lucas manages a team of Investigators that performs inspections and special investigations to ensure that Biologics products are manufactured in a manner that minimizes risks to public health and safety.

Mary Malarkey, BS – Ms. Malarkey is the Director of the Office of Compliance and Biologics Quality (OCBQ) in the Center for Biologics Evaluation and Research at the US Food and Drug Administration. OCBQ is responsible for ensuring the quality of products regulated by CBER over their entire lifecycle through pre-market review and inspection, and post-market review, surveillance, inspection, outreach and compliance. Her previous positions at CBER were Director, Division of Case Management from 2000-2005 and Branch Chief in the Division of Manufacturing and Product Quality (DMPQ) from 1996-2000. She worked in Research and Development in industry prior to joining FDA, and has been with CBER since 1989. She did laboratory work in both the Office of Therapeutics Research and Review and Office of Blood Research and Review prior to becoming a full time reviewer in 1993.

Mark A. Moore, PhD – Dr. Moore is Global Senior Director, Scientific Affairs, LifeNet Health. He has conducted research at the University of Virginia and Harvard Medical School/Children's Hospital, Boston and has 30 years' experience researching and developing implantable materials, the last 15 focused on allografts. He also served as Chair of the AATB Scientific and Technical Affairs Committee, and is a Certified Clinical Research Professional. Dr. Moore has over 100 abstracts, 30 publications, and 10 patents related to transplantable tissues.

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.

Jami Otis, CTBS – Ms. Otis joined AlloSource in May 2007. She brings more than 22 years of experience in the healthcare industry with 15 years focusing on training/education. Ms. Otis received her education from the University of Colorado Boulder in Molecular, Cellular, and Developmental Biology. Prior to joining AlloSource, she spent 13 years in the blood banking industry, has experience in tissue recovery, and was an EMT-Intermediate for a rural ambulance service.

Corrina Patzer, BS – After studying Political Science at Portland State University, Ms. Patzer started her career in ophthalmology at Oregon Health and Sciences University where she was involved in several research studies focused on the genetics of glaucoma. She joined Lions VisionGift in 2002, where she currently holds the position of Chief Strategy Officer. In this capacity she oversees all Tissue Distribution and Processing, Research & Development, and Strategic Relations. She has served on the Eye Bank Association of America (EBAA) Donor Development Taskforce, Chaired the EBAA meetings committee, and is currently serving her second term as Chair of the EBAA Legislative and Regulatory Affairs Committee.

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

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About the Speakers

Catherine V. Quinlan BS – Ms. Quinlan has 30 years of public service with the Food and Drug Administration. During her tenure, she has served as a subject-matter expert for Biologics inspections and as a Compliance Officer handling cases for various commodities. Currently, Ms. Quinlan is the Director of Compliance in the Office of Regulatory Affairs, Office of Biological Products Operations. Her team ensures compliance with the applicable regulations by processing regulatory actions as needed.

Gina Reese, BA, MA – Ms. Reese is a Senior Regional Director at MTF Biologics where she is responsible for recovery partnerships in the Donor Services Division. She has more than 15 years' experience overseeing tissue recovery operations, developing new recovery relationships, enhancing existing partnerships and developing key performance indicators for external and internal clients.

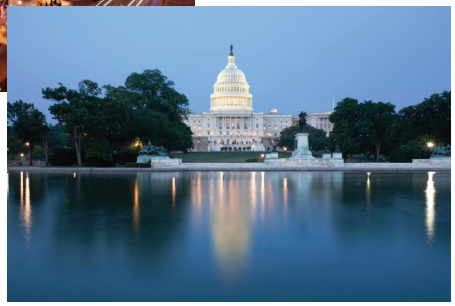
Craig L. Sincaglia, BS – Mr. Sincaglia is the the Director, Quality Assurance at MTF Biologics. He was previously the Manager of Process Engineering at MTF Biologics. He has 19 years of professional experience working on continuous process improvement. In addition to leading the processing engineering and training teams, Mr. Sincaglia trains and leads LEAN and continuous improvement initiatives. 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).

Dan (Kelly) Wang, PhD – Dr. Wang is a biologist in the Division of Human Tissues (DHT), Office of Cellular, Tissue and Gene Therapies (OTAT), Center for Biologics Evaluation & Research (CBER). She joined FDA in 2016, and her primary focus is policy and regulations related to tissue registration. She received her doctoral degree in Molecular and Cellular Pathology from University of Pittsburgh, School of Medicine, followed by a post-doctoral fellowship at UPMC Hillman Cancer Center.

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.

About the Venue



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Agenda

Monday, February 4, 2019
Morning Session: Moderator – Victoria Lake

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome*	
9:10 – 9:40	**FDA Update**	**Scott Brubaker**, FDA, CBER, OTAT, DHT
9:40 – 10:10	**HCT/P Establishment Registration and Listing**	**Dan (Kelly) Wang**, PhD, FDA, CBER, OTAT, DHT, HTRB
10:10 – 10:30	Break*	
10:30 – 11:00	**Final Guidance: SSPE (Same Surgical Procedure Exception)** Clickable Link Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Guidance for Industry	**Safa Karandish**, FDA, CBER, OTAT, DHT, HTRB
11:00 – 11:30	**Final Guidance: MM/HU (Minimal Manipulation/Homologous Use)** Clickable Link Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff	**Scott Brubaker**, FDA CBER, OTAT, DHT
11:30 – 11:45	**HCT/P Deviation Reporting**	**Sharon O'Callaghan**, FDA, CBER, OCBQ
11:45 – 12:05	**Personal Interest Story Related to HCT/Ps**	To Be Introduced
12:05 – 1:20	Lunch*	

Afternoon Session: Moderator – Kip J. Hanks, FDA, ORA

1:20 – 1:50	**Compliance Update**	**Mary Malarkey**, FDA, CBER, OCBQ
1:50 – 2:20	**Compliance Actions – Inspectional Observations**	**Catherine V. Quinlan**, FDA, ORA
2:20 – 3:05	**Donor Eligibility**	**Brychan Clark**, MD, FDA, CBER, OTAT, DHT, HTRB **Simone Porter**, MD, MPH, FDA, CBER, OTAT, DHT, HTRB
3:05 – 3:25	Break*	
3:25 – 4:55	**Workshop 1: Donor Eligibility and Exemption Requests for Reproductive HCT/Ps** This workshop will cover making an appropriate donor eligibility determination for donors of reproductive HCT/Ps. Discussion topics will include the current regulatory requirements for donor screening and testing, when an exception to the 1271 regulations apply, and when an exemption should be requested. Case scenarios will be provided for discussion.	**Brychan Clark**, MD, FDA, CBER, OTAT, DHT, HTRB **Simone Porter**, MD, MPH, FDA, CBER, OTAT, DHT, HTRB **Stephanie Frickleton** **Corey Burke** **Cristi Thompson**

Agenda

Workshop 2: 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.

Cell: **Erica Agy**
Ocular: **Jennifer DeMatteo**
Tissue: **Hena Abidi**
Resource: **Sharon O'Callaghan**, FDA, CBER

Tuesday, February 5, 2019
Morning Session: Moderator – Ellen Heck

9:00 – 9:30	**Manufacturing Arrangements – FDA Overview**	**Neali H. Lucas**, PhD, FDA, ORA
9:30 – 10:30	**Contracts/Agreements – Industry Perspective**	Cell: **Jeffrey Wilson** Ocular: **Corrina Patzer** Tissue: **Gina Reese**
10:30 – 10:50	Break*	
10:50 – 12:20	**Gestational and Viable Allograft Panel**	**Lawrence DiDomenico**, DPM **Jami Otis** **Mark A. Moore, PhD**
12:20 – 1:30	Lunch*	

Afternoon Session: Moderator – Jennifer DeMatteo

1:30 – 3:00	**Workshop 1: Implementing Electronic Records** An Agile EBR Journey – This workshop will include a presentation of how agile methods can work in a historically waterfall world to launch an Electronic Batch Record (EBR). This will be followed by discussion and exercises to demonstrate how Scrum can be used to improve your processes.	**Craig L. Sincaglia**
	Workshop 2: How To Prepare For and What To Expect – Reproductive HCT/P Establishment Inspections This workshop is designed to start with an overview of FDA's regulations and guidances for reproductive HCT/P establishment inspections, followed by an interactive discussion/Q&A covering what to expect and how to prepare for such inspections.	**Tania Y. Hall**, FDA, ORA **Kip J. Hanks**, FDA, ORA
3:00 – 3:20	Break*	
3:20 – 3:50	**Importing HCT/Ps**	**LT Jessica L. Dunn**, PhD, FDA, CBER, OCBQ
3:50 – 4:50	Ask the FDA	**FDA Personnel**

*Denotes non-educational activity

Continuing Education

This conference qualifies for 11.0 hours of continuing education credit.

Register

15th Annual
FDA and the Changing Paradigm for HCT/P Regulation

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