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14TH ANNUAL FDA AND THE CHANGING PARADIGM FOR HCT/P REGULATION

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About the Conference



Please join us as we return to the Westin Alexandria in Alexandria, Virginia, for the **14th 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.

Two of the three conference days begin with 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. This year we will feature an Emergency Preparedness Panel, where industry representatives will discuss their recent experiences with natural disasters and how these establishments planned and prepared for emergencies. Additionally, there will be updates from the FDA regarding Adverse Reaction Reporting, Donor Eligibility, and Compliance, as well as presentations reviewing Computer Systems & Software Validation and Quality Program requirements related to Training and Personnel.

This year we are featuring more topics of interest to the reproductive tissue industry. In particular, we have included a workshop on Donor Eligibility and Exemption Requests – Reproductive Tissues, where scenarios unique to reproductive tissues will be presented.

The conference format again includes smaller workshops each afternoon that will allow participants to apply the information learned in the morning sessions and allow for interaction between participants, 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 three-day conference, we will conclude with the ever popular “Ask the FDA” session. Be sure to meet and visit with FDA representatives.

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 with your Quality Systems in specific areas
- Learn how other industries have bolstered their emergency preparedness procedures
- Learn how others have developed and implemented their training programs
- Be prepared for an HCT/P Establishment Inspection and learn how best to respond to 483 Observations
- Interface with Industry experts and FDA

Register online at www.pharmaconference.com

About the Speakers



Erica Agy, BS – Ms. Agy started her career in 2000 in the pre-clinical realm primarily working with nonhuman primates in biomedical research. After three years of hands-on animal work, she transitioned to Quality Assurance, where she has since focused her efforts. In 2011, Ms. Agy was introduced to the world of HCT/P products when she was hired by the Seattle Cancer Care Alliance as a Quality Associate. At that time, her primary area of focus was HCT/P product distribution from the Cellular Therapy Laboratory. In 2012, she accepted the role of the Quality Assurance Compliance Specialist. Her responsibilities include providing support to both the Cellular Therapy Laboratory, as well as the Apheresis Unit, which includes donor screening activities, and the collection and processing of 351 and 361 HCT/P products, and the assessment and reporting of HCT/P Deviations and Adverse Reactions.



Ted Bender, RN, CTBS – Mr. Bender started his Tissue Banking career at The Pennsylvania Regional Tissue Bank in 1986 as a tissue bank technician. He was responsible for everything from consent, tissue procurement, processing and distribution. Mr. Bender was in the first class in 1989 to become an AATB certified Tissue Bank Specialist. In 1998, PRTB merged with The Musculoskeletal Transplant Foundation, and Mr. Bender managed the processing section of the Jessup facility. He was promoted to Director of Processing Services in 2007 and presently uses his 31 years experience to help deliver exceptional tissue grafts to the surgical community.



Cindy Blinci, BA, MS, CTBS (AATB), CQA (ASQ) – Ms. Blinci is the Quality Compliance Coordinator for the Colorado Center for Reproductive Medicine. Her current responsibilities include reviewing third party records for FDA compliance, conducting third party supplier audits, employee training, SOP development, and document control. Prior to this, she was a Tissue Specialist with Dohmen Life Science Services (formerly Reglera) and has been serving the HCT/P industry since 2002 in various capacities including recovery, family services and quality assurance.



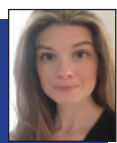
Grace Bolton, BS, MS – Ms. Bolton is the Validation Director at LifeLink Tissue Bank. She has been with LifeLink 11 years and oversees equipment calibration/qualification, processing/packaging/sterilization validation/monitoring and environmental monitoring. She received a B.S. in Microbiology from Florida Atlantic University and a M.S. in Quality Assurance along with a Six Sigma Black Belt certification from Southern Polytechnic University. Ms. Bolton has served on two AATB Task Forces: Microbial Surveillance Program and Container and Packaging Qualification/Validation.



Martin Browning, BS, MS – Mr. Browning is the president and co-founder of EduQuest, Inc. He has over 40 years of FDA and regulatory experience and was one of FDA's first National Computer Systems Experts. He has and demonstrates extensive expertise in management consulting, FDA regulation, regulatory affairs, quality assurance, software and systems engineering, and auditing. Specific experiences include quality systems design, system design assurance, verification and validation of production and manufacturing systems, processes and software. Mr. Browning is a well-known expert in FDA regulations, having written or contributed to writing several during his FDA career.



Scott A. Brubaker, CTBS – Mr. Brubaker was selected in October 2016 as the new Director, Division of Human Tissues (DHT) in the Office of Tissues and 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, he acquired 18 years of practical experience involving organ donation and tissue banking while holding various management positions at LifeNet in Virginia Beach, Virginia.



Katrina Carroll, BS – Ms. Carroll has worked for MTF Biologics for over a decade, moving from a Project Management role into Regulatory. She is responsible for the management of all activities in the Regulatory Affairs Department, including functions related to the FDA and other international bodies, including Medical Device Reporting, device submissions, governmental licensing and managing nonconformances.

About the Speakers



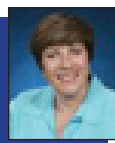
Sejal Chitre, BE, ME – Ms. Chitre is a Regulatory Affairs Manager at MTF Biologics. She has been in the medical device and tissue banking industry for 13 years. Prior to working at MTF, Ms. Chitre was a Process Engineer for a Medical Device company. She holds a Masters of Engineering degree in Systems Engineering, a Bachelors of Engineering Degree in Engineering Management and a Graduate Certificate in Pharmaceutical Manufacturing from Stevens Institute of Technology as well as a Graduate Certificate in Regulatory Affairs – Medical Devices from The University of South Florida.



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 in New York and has 30 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 key committees, including its Medical Advisory Board, Accreditation Board and Certification Board. Additionally, she is an active member of the European Association of Eye Banks. She is also a member of the New York Alliance for Donation, a statewide collaborative organization established to increase awareness for organ, eye and tissue donation, and serves on the New York State Transplant Council.



Jennifer DeMatteo, BS, MCM, CIC – Ms. DeMatteo is the Director of Regulations and Standards for the Eye Bank Association of America. 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).



La' Tasha Gunter, BA, MS – Ms. Gunter was hired as a Consumer Safety Officer with the FDA Baltimore District Office in February 2009. She has conducted domestic HCT/P, blood bank, donor center, testing laboratory, drug, and domestic/foreign food inspections. She is currently the Biologics Specialist under the Office of Biological Products Operations/Division 1.



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.



Susan Hurlbert, CEBT – Ms. Hurlbert has 14 years of experience in eye banking. She joined Eversight in 2004, performing recoveries, tissue evaluations, and donor eligibility. In 2013, she transitioned to a Quality Improvement role. She presently serves as the Clinical Operations Supervisor for the Bloomington, IL office, and is also responsible for all of Eversight's Adverse Reaction investigations and reporting. She currently sits on EBAA's Medical Review Subcommittee and Exam Committee.

About the Speakers



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.



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.



Kristin Mathes, BA, MA – Ms. Mathes began working in eye banking in 1999 in Colorado. She performed recoveries, tissue suitability evaluations, determined donor eligibility, and placed tissue for surgery. In 2007 she left to work for a medical device company in the Regulatory Affairs department. In 2008, she moved to Oregon and began working at Lions VisionGift. In her current role, she is responsible for oversight of LVG's Quality Program and eligibility/tissue release departments.



Stephanie Chea Matias, BS, MS – Ms. Matias is the Manager of Quality Engineering at MTF Biologics. Some of her responsibilities in this role include management of the validation program, risk management program, and external laboratories. Additionally, she has direct interaction with major federal regulatory agencies, both foreign and domestic. Ms. Matias has 10 years of Quality experience in the medical device field and holds a Bachelor's and Master's degree in Biomedical Engineering from NJIT.



Michelle McClure, PhD – Dr. McClure has been a biologist with FDA's Office of Tissue and Advanced Therapies in the Division of Human Tissue since 2014. Her primary focus is policy development and regulatory review as it relates to eligibility of donors of human cells, tissues, and cellular and tissue-based products. Prior to obtaining a Ph.D. in genetics, Dr. McClure worked in a cardiovascular and orthopedic tissue processing laboratory at a biotechnology company.



Ginette Y. Michaud, MD – Dr. Ginette Michaud is a hematologist with 20 years of regulatory experience in biological products and medical devices. Since March of 2016, she has served as the Director of the Biologics Program in the FDA's Office of Regulatory Affairs. Prior to joining ORA, Dr. Michaud was the Deputy Director, Office of Blood Research and Review in the Center for Biologics Evaluation and Research.

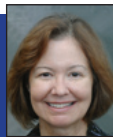


Lindsay Palomino, BSN, RN, HP(ASCP) – Ms. Palomino has been a nurse for over 20 years in the fields of oncology, bone marrow transplant and apheresis. She has over 18 years of adult and pediatric clinical apheresis experience, including four years in the medical device industry providing customer technical support and training for photopheresis. She has built an FDA/FACT compliant apheresis program, implemented a healthy donor cell collection facility, authored two abstracts on apheresis, developed an apheresis nurse Training and Competency program, and implemented a Pediatric Photopheresis Program. Ms. Palomino is currently the Nurse Manager of a 6-bed/16-nurse Apheresis unit at the Seattle Cancer Care Alliance and is a subject matter expert consultant for a biopharmaceutical company.

About the Speakers



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.



Debbie Seem, RN, MPH – Ms. Seem is a Public Health Analyst in the Office of HIV/AIDS and Infectious Disease Policy within the HHS Office of the Assistant Secretary for Health. Her work mainly focuses on issues related to tissue safety identified by the HHS Advisory Committee on Blood and Tissue Safety. Previously, as a Public Health Advisor in the CDC Office of Blood, Organ and other Tissue Safety, she supported investigations, research and public health interventions to improve patient safety related to transplantation.



Craig L. Sincaglia, BS – Mr. Sincaglia is 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, holds a B.S. in Chemical Engineering from NJIT and Advanced Master Certificate in Lean Six Sigma and Lean Six Sigma Master Black Belt certification from Villanova.



Kathleen Swat, BA, BS – Ms. Swat is a Biologics Specialist Investigator with the FDA Office of Regulatory Affairs and is responsible for conducting on-site inspections of biologics firms. She works out of the St Louis, Missouri resident post office and has been with the FDA for over 15 years. Prior to joining FDA, she worked as a dietitian in public health and specialized in nutrition and HIV/AIDS.



Randall J. Thoma, PhD – Dr. Thoma is currently the Principal at VeeSquared Consulting Services. Prior to forming VeeSquared, he was the Associate Director of Quality Assurance for Zimmer Biologics, and he also developed and validated processes for the manufacture of mechanical heart valves. Dr. Thoma served on the AATB Accreditation Committee, is a past-Chair of the committee, and is also currently an inspector for the AATB Accreditation organization.



Wendy Wangsgard, PhD, RM(NRCM) – Dr. Wangsgard has been with Nelson Laboratories for 13 years and is currently a Senior Scientist, providing guidance on testing and regulatory issues. She is a member of the Association for the Advancement of Medical Instrumentation (AAMI) involved in the working groups for Radiation Sterilization, Microbiological Methods, Assurance of Sterility, Sterilization Terminology and the Compatibility of Materials Subject to Sterilization. Dr. Wangsgard is also a member of the American Association of Tissue Banks (AATB).



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.



Craig Zinderman, MD, MPH – Dr. Zinderman is the Associate Director for Product Safety in the Division of Epidemiology (DE), Office of Biostatistics and Epidemiology at FDA's Center for Biologics Evaluation and Research. He has served as a Medical Officer in DE since 2004, initially in the Therapeutics and Blood Safety Branch. Prior to joining FDA, Dr. Zinderman served as a Preventive Medicine Officer in the US Navy. He is Board certified in General Public Health and Preventive Medicine.

Monday, February 5, 2018

Morning Session: Moderator – Victoria Lake

8:00 – 9:00	Registration*
9:00 – 9:10	Welcome*
9:10 – 9:30	Personal Interest Story Related to HCT/Ps
9:30 – 9:50	FDA Update
9:50 – 10:10	FDA Adverse Reaction Reporting
10:10 – 10:55	Donor Eligibility Updates
10:55 – 11:15	Break*
11:15 – 11:45	Compliance Update
11:45 – 12:15	Inspectional Observations
12:15 – 1:30	Lunch*

To Be Introduced
 Scott Brubaker, FDA, CBER, OTAT, DHT
 Craig Zinderman, MD, MPH, FDA,
 CBER, OBE, DE
 Michelle McClure, PhD, FDA, CBER,
 OTAT, DHT, HTRB

Mary Malarkey, FDA, CBER, OCBQ
 Kip Hanks, FDA, ORA

Afternoon Session: Moderator – Victoria Lake

1:30 – 3:00	Emergency Preparedness Panel
3:00 – 3:20	Break*
3:20 – 4:50	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. Workshop 2: Adverse Reaction Reporting This workshop will cover the investigation and current regulatory requirements for reporting adverse reactions, including 1271.350(a). Speakers will present scenarios for different HCT/P types and discuss the reportability of Adverse Reactions.

Debbie Seem, OASH
 Cells: Jeffrey Wilson
 Eye: Patricia Dahl
 Tissue: Ted Bender
 Tissue: Grace Bolton

Moderators:
 Brychan Clark, MD, FDA, CBER, OTAT, DHT, HTRB and Simone Porter, MD, MPH, FDA, CBER, OTAT, DHT, HTRB

Brychan Clark, MD, FDA, CBER
 Simone Porter, MD, MPH, FDA, CBER
 Cindy Blinci

Moderator:
 Jennifer DeMatteo

Erica Agy
 Susan Hurlbert
 Stephanie Matias
 Craig Zinderman, MD, MPH, FDA,
 CBER, OBE, DE

Tuesday, February 6, 2018

Morning Session: Moderator – Jennifer DeMatteo

9:00 – 9:20	Personal Interest Story Related to HCT/Ps	To Be Introduced
9:20 – 9:35	351/361 Regulatory Framework	Scott Brubaker, FDA, CBER, OTAT, DHT
9:35 – 10:05	ANSI/AAMI/ISO/U (American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization/You)	Wendy Wangsgard, PhD
10:05 – 10:25	Break*	
10:25 – 11:30	Computer Systems/Software Validation	Kathleen Swat, FDA, ORA Martin Browning
11:30 – 11:50	Quality Program – Personnel	La' Tasha Gunter, FDA, ORA
11:50 – 12:15	Question and Answer Session	Morning Speakers
12:15 – 1:20	Lunch*	

Afternoon Workshops

1:30 – 3:00	Workshop 1: Training and Personnel: Tailored Programs for Diverse Needs This workshop will cover how HCT/P industries design and implement their training programs. Discussion topics will include how organizations of varying size implement appropriate programs for recovery, processing, and other core cGTP functions. Examples of tools used for training will be presented.	Moderator: La' Tasha Gunter, FDA, ORA Kristin Mathes Lindsay Palomino Craig Sincaglia
	Workshop 2: Responding to 483 Observations This workshop will include "real" 483 observations made during an HCT/P Establishment Inspection, where participants will have the opportunity to design the best response to a 483 observation. Observations will include those related to quality program requirements (1271.160) as well as core cGTPs, including recovery, processing, and donor eligibility.	Moderator: Kip Hanks, FDA, ORA Industry: Randall Thoma, PhD Facilitators: Cells: Erica Agy Eye: Susan Hurlbert Tissue: To Be Determined
3:00 – 3:20	Break*	
3:20 – 4:50	Workshops repeated	

Agenda

Wednesday, February 7, 2018

Morning Session: Moderator – Kip Hanks, FDA, ORA

9:00 – 9:10	Workshop Reports (key discussion and take-aways)	
9:10 – 9:30	FDA/ORAs Program Alignment Reorganization	Ginette Michaud, MD, FDA, ORA, OBPO
9:30 – 10:10	Considerations for International Distribution	Katrina Carroll Sejal Chitre
10:10 – 10:30	Break*	
10:30 – 11:30	Ask the FDA	FDA Personnel

*Denotes non-educational activity

Continuing Education



This conference qualifies for 13.0 hours of continuing education credit.

About the Venue



The Westin Alexandria is conveniently located two Metro stops or a 15-minute taxi ride from Reagan International Airport. From the Metro stop it is a 10-minute walk or the hotel will come pick you up. Seated on the Potomac, Alexandria is a historic community known for its rich history and beautifully preserved 18th and 19th century architecture, not to mention its quaint boutiques and inviting restaurants. Discover Alexandria's historic Old Town, eclectic Del Ray, innovative Carlyle and the diverse West End or visit DC just 25 minutes away. Highlights in the area are Mt. Vernon, the George Washington Masonic National Memorial and George Washington Estate and Gardens.



Register

14th Annual FDA and the Changing Paradigm for HCT/P Regulation

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