

2009 CONFERENCE SERIES



Las Vegas, Nevada

12th Annual FDA and the Changing Paradigm for Blood Regulation

January 14 - 16, 2009

The Westin Casuarina Hotel, Casino & Spa

Conference sponsored by



UNIVERSITY OF
RHODE ISLAND
COLLEGE OF
PHARMACY

Conference produced by



Conference presented in cooperation with



Advancing Transfusion and
Cellular Therapies Worldwide

ABOUT THE CONFERENCE

Pharma Conference's premiere blood program is back in Las Vegas this year, and it promises to be one of the best yet with opportunities to hear from industry leaders and a number of Food and Drug Administration experts. The agenda is packed full of informative talks and back again, by popular demand, are our workshops and new "mini sessions", designed to allow participants to attend areas in which they have a special interest. Participants will hear about the latest in using data in continuous process improvement, new approaches to meeting FDA recall requirements, issues related to workforce shortages and much, much more.

The grand finale for the meeting is a discussion with input from the FDA, collections facilities, transfusion services and vendors that answers the following five questions:

1. Describe your view of where the industry is regarding quality and compliance?
2. What is the biggest challenge and obstacle facing the industry?
3. Where should we go?
4. How are you getting there?
5. Is what we are doing working towards improving Public Health?

In addition to the opportunity to learn and network, Las Vegas also provides attendees a chance to have fun during free time. There is a host of entertainment opportunities that are sure to please. Of course, we'll have our annual attendee reception (included in your registration price) which is always a good time. You won't want to miss that.

Sign up today and encourage your colleagues to join you. This meeting is a sure bet!

WHO SHOULD ATTEND?

- FDA Responsible Heads
- Blood Bank Chief Executive Officers and Chief Operating Officers
- Medical Directors
- Supervisors and Staff with responsibility for regulatory compliance
- Blood Center and Hospital Quality Personnel
- Managers and Supervisors, Quality Assurance Personnel
- Managers and Supervisors in charge of operational activities in blood centers
- Senior Management
- Plasma and Fractionation Personnel
- Directors of Collection and Education
- Establishment and Licensing Personnel

WHY ATTEND?

- For current regulatory information affecting blood
- To enhance your insight of GMP and other regulatory matters
- For the opportunity to visit with industry experts and FDA on a one to one basis
- To gain continuing education credit in your field of employment
- To network and discuss industry problems and solutions with your peers
- To maintain a cutting edge awareness of where FDA stands in its enforcement programs

CONTINUING
EDUCATION



Participants will receive 1.9 CEUs (19.00 contact hours) for **12th Annual FDA and the Changing Paradigm for Blood Regulation** conference attendance. The University of Rhode Island College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Attendance and completion of evaluation forms and self-assessment tools at the conclusion of the program are required for issuance of a statement of credit. Statements will be mailed within six to eight weeks of program completion. ACPE universal program number 060-999-08-057-L04-P.

Register online at www.pharmaconference.com

ABOUT THE PRESENTERS



Mary Beth Bassett, BS, MT(ASCP) – Ms. Bassett has been the Vice President Quality Management/Regulatory Affairs for Blood Systems, Inc. in Scottsdale, Arizona since 1996. She has over 25 years in blood banking and began her career in quality as the Director of Quality Assurance/Compliance Officer in 1988 at the American Red Cross. Previous positions at the American Red Cross include CEO of National Testing Laboratory and Acting National Director of Quality Assurance.



Cathy L. Burgess, BSFS, JD – Ms. Burgess is Counsel in the Washington DC office of Crowell & Moring. Before joining Crowell & Moring, Ms. Burgess was Associate General Counsel for Regulatory Law at the American Red Cross where she provided advice and counsel concerning the Red Cross Amended Consent Decree, assisted the organization on compliance matters, provided guidance on inspection management, responses to Form FDA 483s, recalls and operating procedures. Ms. Burgess also provided advice and counsel on a variety of state law issues related to blood banking. Before joining the Red Cross in 2003, Ms. Burgess was in private practice for 15 years.



Judy Ellen Ciaraldi, BS, MT(ASCP)SBB, COA (ASQ) – Ms. Ciaraldi is a Consumer Safety Officer in the Division of Blood Applications, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA. She worked as a blood bank medical technologist, blood bank education coordinator and assistant supervisor in the Washington Hospital Center (Washington, DC) for 25 years before joining the FDA in 1995. In addition to her blood and plasma reviewer duties, she performs pre-license inspections of Blood Banks and Source Plasma facilities and trains FDA field investigators on the technical aspects of blood banking and plasma center practices.



William M. Coenen – Mr. Coenen is the Chief Operating Officer for America's Blood Centers (ABC). He has more than 30 years experience in blood banking, 25 of which with the Community Blood Center (Kansas City, MO), where he retired as Chief Operating Officer. Mr. Coenen is a past president of America's Blood Centers, Foundation for America's Blood Centers, Heart of America Association of Blood Banks and past chair and founding director of the Community Blood Centers' Exchange, a captive insurance company providing professional liability insurance to over 40 blood centers.



Gilliam B. Conley, MS – Mr. Conley is the Director, Division of Inspections & Surveillance, FDA/CBER Office of Compliance and Biologics Quality. He joined the FDA in 1995 after a 23-year career in hospital clinical laboratories. His division is responsible for a wide variety of activities related to the manufacture of biological products including inspections, bioresearch monitoring, and compliance programs.



Danielle Drummond, BBA – Ms. Drummond is an Associate at Booz Allen Hamilton, a consulting firm specializing in providing business and IT solutions to government agencies. She has worked in the Office of Information Technology at the Center for Devices and Radiological Health (CDRH) since 2004, and recently expanded her experience to include the Center for Biologics Evaluation and Research (CBER) and the Center for Veterinary Medicine (CVM), serving various roles on the eSubmitter Electronic Submissions program. Currently, Ms. Drummond is serving as the deputy project manager of the CeSub project at CDRH and is leading the eSubmitter efforts at CBER.



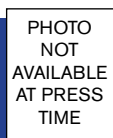
Paul Epner, MBA, MEd – Mr. Epner is the Director of Healthcare Improvement Initiatives for the Diagnostics Division of Abbott Laboratories where he has spent more than 30 years working in the U.S., in Japan and in China. During these years, his responsibilities have included operations, strategic planning, marketing, R&D, and general management. In his current position, Mr. Epner represents Abbott in working with laboratorians to solve problems facing the clinical laboratory profession. His focus includes the laboratory workforce shortage and redefining the laboratorian's scope of practice to drive improved patient clinical and economic outcomes.



Lore Fields, BS, MT(ASCP)SBB – Ms. Fields is a Consumer Safety Officer in the Division of Blood Applications, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA. Prior to joining FDA, she worked as a blood bank medical technologist at Beth Israel Hospital in Boston, MA, a Donor Testing Lab Manager, Manager of Manufacturing and Distribution, and a Blood Bank Manager for 10 years. In addition to her blood and plasma reviewer duties, she performs pre-license inspections of Source Plasma facilities and has also chaired a committee and participated on committees responsible for preparing FDA guidance documents to industry.



Beth Hartwell, MD – Dr. Hartwell is the Medical Director at Gulf Coast Regional Blood Center. Prior to joining The Blood Center in 2005, Dr. Hartwell served as Medical Director of Pathology and Laboratory Services and Director of the Transfusion Service at Memorial Hermann Hospital and Children's Memorial Hermann Hospital in the Texas Medical Center. She has extensive experience in the transfusion management of a variety of medical, surgical, and trauma patients, both adult and pediatric, and has an active role in the education of blood donors, medical students, residents, and physicians.



Laura D. Hieronymus, MS, MT(ASCP)SBB – Ms. Hieronymus is the Senior Recall Coordinator for the Center for Biologics Evaluation and Research (CBER). She joined FDA in 2001 as a Consumer Safety Officer with the Division of Case Management/Blood and Tissue Compliance Branch. Ms. Hieronymus manages the most complex, controversial and precedent-setting recall issues involving biological products. She is responsible for reviewing recall recommendations to determine the significance of deviations from the statutes and regulations, to assure completeness of evidence to support the deviation, and to designate the agency's final classification of the firm's action as either a recall or a market withdrawal. Ms. Hieronymus also functions as a liaison among the agency's local Recall Coordinators and is CBER's expert in recall matters.

PHOTO
NOT
AVAILABLE
AT PRESS
TIME

Register online at www.pharmaconference.com

ABOUT THE PRESENTERS



Faye Kugele, BS, MS, MT(ASCP), CQA (ASQ) – Ms. Kugele is a Principal Associate with Biomedical Headquarters with the American Red Cross and is responsible for developing standardized procedures for product quality control, hematology analyzers and irradiation. Her experience includes supervisory and management responsibilities in the hospital laboratory, transfusion services, advanced level immunohematology reference laboratory, and blood center quality assurance. She has been with the Red Cross for the past 18 years.



Robert Marriott, BS – Mr. Marriott is employed by BloodCenter of Wisconsin as the Quality Systems Analyst, Quality Support Services. His primary responsibility is to maintain, streamline, and simplify the electronic systems and processes that are used to support BloodCenter's quality system including CAPA, Audit, Risk Management, and Change Control. Prior to joining BloodCenter, Mr. Marriott spent 15 years serving in various roles focused on global quality systems improvement, quality/compliance management, product development, sales, and R&D at a number of global medical device manufacturers and academic institutions.



Patrick Ooley, BS, MS, MT(ASCP), CQA (ASQ) – As the Corporate Director Quality Operations at Blood Systems, Mr. Ooley is responsible for oversight and direction for the field operations for Quality Management staff including the QA staff at the corporate office, at each United Blood Services center, at Blood Systems Laboratories and at Blood Centers of the Pacific. He oversees staff responsible for QA functions, auditing, quality monitoring, deviation management and management of external inspections. Mr. Ooley also oversees Quality Source, Blood System's quality consulting group that provides consulting services to Blood Systems customers. Prior to joining Blood Systems, he was a member of the executive management team at the Indiana Blood Center in Indianapolis, Indiana.



David Perez, BS – Mr. Perez is president and chief executive officer of CaridianBCT, formerly known as Gambro BCT, the leading global provider of products and services in automated blood collections, therapeutic systems, whole blood processes and pathogen reduction technologies. He has over two decades of leadership, management, commercial development, finance and operations experience in complex medical device and healthcare service businesses. In this role, he guides the strategic direction, growth and execution of the company and its mission to improve lives through innovation, quality and services delivered by the company's people, products and processes.



Eva Quinley, MS, MT(ASCP)SBB – Ms. Quinley is the Senior Vice President of Quality Systems and Compliance for the American Red Cross and has over 28 years of experience in the blood banking industry. For the past 15 years, her career focus has been in the areas of regulatory compliance, quality, and training. She has developed and presented numerous training programs and seminars nationally and internationally and has become recognized as a resource for such information.



Kathleen Sazama, MD, JD – Dr. Sazama is Professor of Laboratory Medicine and Medical Director for Donor Operations at the University of Texas MD Anderson Cancer Center in Houston, where she also served as the Vice President of Faculty Academic Affairs until 2003. She is board certified in anatomic and clinical pathology, as well as in blood banking/transfusion medicine. She has practiced pathology and laboratory medicine in various venues, including solo and group community practice, faculty at academic medical centers with multisite responsibilities and as Branch Chief, CBER, FDA.



Graham Sher, MD, PhD – Dr. Sher is the Chief Executive Officer of Canadian Blood Services, the agency charged with managing Canada's national blood, plasma and bone marrow programs in all provinces and territories across Canada, excluding Quebec. He has been with Canadian Blood Services since it began operations in September 1998, when he joined as its first Vice President for medical and scientific affairs. Dr. Sher is a hematologist by training and is a recognized expert in transfusion medicine and science. He was formerly a physician and scientist on staff at the Toronto Hospital and on faculty in the Department of Medicine at the University of Toronto.



Michael Simeone, RPh, MBA – Mr. Simeone is the Director of Continuing Education, College of Pharmacy, University of Rhode Island. He has an extensive background in developing and implementing continuing pharmaceutical education programs. Prior to joining the College of Pharmacy, he practiced hospital pharmacy for over twenty years. Mr. Simeone is also a Certified Diabetes Outpatient Educator in the state of Rhode Island.



Mary Wartick, BS, MQM – Ms. Wartick is the Senior Director Quality Metrics for the American Red Cross. In this role she provides the majority of compliance and quality data analysis for blood services. She has over 30 years of blood banking experience, 26 of which were at the regional level.

AGENDA

Wednesday, January 14, 2009

Morning Session: Moderator – Eva Quinley, Conference Chair

7:30 – 8:30	Registration
8:30 – 8:40	Welcome/Moderator Comments
8:40 – 9:40	Blood Safety Decision Making: Changing the Paradigm
9:40 – 10:20	Hazard Analysis of Critical Control Point
10:20 – 10:40	Break
10:40 – 11:40	Legal Risks for Blood Establishment
11:40 – 12:15	Question and Answer Session
12:15 – 1:30	Lunch

Michael Simeone, URI College of Pharmacy
Graham Sher, MD, PhD
To Be Determined

Cathy Burgess

Afternoon Session

1:30 – 3:00	Breakout Sessions (Choose one to attend) <ol style="list-style-type: none">1. Turbosubmission - Demonstration2. CPI Application3. Deviations
3:00 – 3:20	Break
3:20 – 4:50	Breakout Sessions Repeated (Choose one to attend)
5:30 – 7:00	Evening event

Danielle Drummond
Rob Marriott, Mary Wartick
Pat Ooley

Thursday, January 15, 2009

Morning Session: Mary Beth Bassett, Associate Chair

Oops! Now What? (Product Management in These Situations)

8:30 – 9:15	FDA Perspective on In-House Products: When Would a Variance Apply?
9:15 – 10:00	FDA Perspective on Distributed Products: When Would a Recall Apply?
10:00 – 10:20	Break
10:20 – 11:00	Blood Establishment Perspective
11:00 – 11:40	Transfusion Service Perspective
11:40 – 12:15	Question and Answer Session
12:15 – 1:30	Lunch

Judy Ciaraldi, FDA

Laura Hieronymus, FDA

Pat Ooley
Beth Hartwell, MD

Afternoon Session

1:30 – 3:00	Breakout Sessions (Choose one to attend) <ol style="list-style-type: none">1. Product QC2. Case Studies Recall/Nonconforming Product3. Workforce Issues
3:00 – 3:20	Break
3:20 – 4:50	Breakout Sessions Repeated

Lore Fields, FDA and Faye Kugele
Eva Quinley
Paul Epner

Friday, January 16, 2009

Morning Session: Moderator – Pat Ooley

Where Are We? Where Can We Go?

8:30 – 9:15	FDA Perspective
9:15 – 10:00	Blood Establishment Perspective
10:00 – 10:20	Break
10:20 – 11:05	Transfusion Service Perspective
11:05 – 11:50	Vendor Perspective
11:50 – 12:15	Question and Answer Session

Gilliam Conley, FDA
William Coenen

Kathleen Sazama, MD
David Perez

REGISTRATION

12th Annual FDA and the Changing Paradigm for Blood Regulation

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FEES

Payment Received By October 30, 2008

\$1095

Payment Received After October 30, 2008

\$1195

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

Cancellation Policy: 30 days or more for a full refund less \$150 cancellation fee; under 30 days, no refund, but attendee substitutions may be made at any time. Cancellations and substitutions must be made in writing to Pharma Conference (email registration@pharmaconference.com). In the event of any civil disorder, extremely adverse weather conditions, or other Acts of God, Pharma Conference reserves the right to reschedule the meeting dates in the interest of attendee safety.

PAYMENT

Full payment may be made by credit card or company check

- Checks must be received within 15 days of receipt of registration form.
- Checks should be made payable to Pharma Conference, in U.S. dollars and drawn on a U.S. bank.
- Registrations will be confirmed when full payment has been received. Taxpayer ID #20-3497383.
- **Registrations made within 15 days of conference start date must be accompanied by full payment.**

Checks should be sent to Pharma Conference at the following addresses (see check instructions above):

Airmail to: P.O. Box 690588, San Antonio, Texas 78269 USA

Express to: 8122 Datapoint, Suite 804, San Antonio, Texas 78229 USA

HOTEL

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Direct Phone: (702) 836-5900

Toll free: 1-866-837-4215

\$169/night single or double*

A limited number of rooms have been blocked at the special rates listed per night. Hotel reservations must be made on or before **Friday, December 19, 2008** in order to guarantee the special rate. The Group Rate is offered prior/post conference dates based on hotel availability and is not guaranteed by Pharma Conference. Individuals are responsible for making their own hotel reservations. **You must mention the title of the program when making your reservation in order to obtain these special rates. Please do not use travel agents for reservations.**

*Rate includes the hotel's mandatory \$10.00 resort fee per day/per room which provides daily newspaper, workout facility, sauna and steam rooms, swimming pool access, bottled water in guest room, incoming faxes, notary public, unlimited local calls, and boarding pass printing.

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For additional information, contact Pharma Conference (210) 341-5300 Fax: (210) 341-9777 or e-mail: contactus@pharmaconference.com.

Our office hours are 8:00 a.m. to 4:00 p.m. Monday through Thursday and 8:00 a.m. to 1:00 p.m. Friday central USA time.

Register online at www.pharmaconference.com