

Hotel Rooms:

A limited number of hotel rooms have been reserved at the DoubleTree Guest Suites in Downtown Charleston. Please make reservations directly with the hotel by calling 843-577-2644 or 800-222-TREE. The EBAA room rate is \$129 single/double. Please make your reservations as soon as possible. The DoubleTree is located 12 miles from the Charleston International Airport.. Shuttles, taxis, and rental cars are readily available for your transport to and from the airport.

Travel:

Airline reservations should be made for arrival on the morning of Tuesday, February 15th, with a departure after 5pm on Thursday, February 17th.

Dress Attire: Business Casual

The Eye Bank Association of America,
in conjunction with LifePoint
presents

**THE ABCs OF
QUALITY ASSURANCE
(QA)**



LifePoint



**EYE BANK
ASSOCIATION
of AMERICA**

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February 15-17, 2005
DoubleTree Guest Suites
Charleston, SC

The Current Good Tissue Practices (cGTP) regulations go into effect May 25, 2005. To prepare your eye bank for the implementation of this regulation, the EBAA is sponsoring a QA Workshop, hosted by LifePoint, Inc., of Charleston, SC.

This two-and-a half day program will provide registrants with a review of the eight required elements of a quality program per CFR §1271.160. It will demonstrate how each element interacts with the entire regulation, creating a culture of quality starting with the referral call to the final distribution of the eye tissue.

Registrants will receive an in-depth look at three of the eight quality elements (training and training documentation, document control, process change/process validation). The aim of the workshop is to provide participants with the skills and tools needed to implement these three elements into their own eye bank.

Don't miss this exciting opportunity to come together to enhance your mind, share ideas, and prepare for the up and coming cGTP. Whatever your role, you and your organization will definitely benefit from this workshop and comprehensive take-home materials.

TRAINING AND TRAINING DOCUMENTATION

When the cGTP Rule becomes effective, Eye Banks will be required to establish and maintain training documentation of staff members involved in the processing of eye tissue.

Document Control is an essential part of any quality assurance system. The Document Control System supports the company's quality system by ensuring that procedures are approved, current, and readily available to the staff.

DOCUMENT CONTROL

PROCESS CHANGE/ PROCESS VALIDATION

When the cGTP becomes effective, eye banks will be required to establish and maintain procedures for making changes to their processing steps. Eye banks will also be required to verify or validate their processing steps.

SCHEDULE:

Tuesday, February 15

- 12:00 - 12:30pm Working LUNCH
- 12:30 - 2:30pm The Eight Requirements of a Quality System--**Mary Malarkey, FDA**
- 2:30 - 3:30pm Writing SOPs
- 3:30 - 4:30pm Document Control/Change Control

Wednesday, February 16

- 8:00am Breakfast
- Training and Training Documentation Overview--**Judy Brazell**
- Orientation/New Employee Training
- Training on Procedure Changes
- Annual Competency Requirements
- Train the Trainer/ Subject Matter Experts
- Training Record Management--Dos and Don'ts
- 12:00pm Working LUNCH
- Process Validation--An Overview--**Mary Malarkey, FDA**
- Culturing Flow Hoods Using a Risk-Based Analysis Approach
- Equipment Qualification--**Sereta Muse**
- Computer Software--Validated or Verified

Thursday, February 17

- 8:00am Breakfast
- Quality Audits--An Overview--**Sereta Muse**
- Quality Audits in Eye Banking
- 12:00pm LUNCH
- 1:00pm Applying What We Have Learned
- 4:00pm Wrap-up

SPEAKERS

Mary Malarkey is Director, Division of Case Management (DCM), Office of Compliance and Biologics Quality, at FDA's Center for Biologics, Evaluation and Research (CBER). DCM is responsible for enforcement actions for biologics, advertising and promotional labeling and all CBER recalls. Ms. Malarkey received her BS in Microbiology from the University of Maryland, College Park, in 1981. She worked in Research and Development in industry prior to joining the FDA, and has been with CBER since 1989.

Sereta Muse of Quality Management Associates (SC), Inc. is a Medical Technologist with a Master's degree in Public Administration. She has over 11 years of experience in Blood Center Operations. This experience includes Quality Assurance/Audits, Regulatory Compliance, Testing, Validation, and Donor Management. In addition, Ms. Muse is certified by the American Society of Quality as a Quality Auditor.

Judy Brazell of Quality Management Associates (SC), Inc. is a Medical Technologist with a specialization in Blood Banking. She has 12 years experience in both hospital transfusion services and Blood Center Operations. She has significant experience in Quality Assurance.



**EYE BANK
ASSOCIATION
of AMERICA**

EBAA QA WORKSHOP REGISTRATION FORM

PLEASE PRINT OR TYPE.

NAME _____

NAME OF ORGANIZATION _____

ADDRESS CITY, STATE, and ZIP _____

FAX NUMBER _____

EMAIL

Please Circle Registration Type

	Early Bird	After December 31st
EBAA Member	\$400.00	\$425.00
Non Member	\$700.00	\$725.00

TOTAL AMOUNT ENCLOSED \$ _____

Check enclosed in U.S. CURRENCY

(Please make checks payable to the EBAA)

CHARGE MY: Visa* AmEx Disc MC

(*if VISA, last 3 digits on back of card) _____

ACCOUNT # _____

EXPIRATION DATE _____

CARDHOLDER'S NAME (please print) _____

CARDHOLDER'S BILLING ADDRESS (ZIP CODE REQUIRED) _____

SIGNATURE _____

**TO MAKE HOTEL RESERVATIONS, PLEASE CALL THE DOUBLETREE HOTEL AT
843-577-2644 OR 800-222-TREE.**

THE EBAA HAS BLOCKED ROOMS AT A RATE OF \$129 SINGLE/DOUBLE.