

## PAYMENT

\$2150.00 PER PERSON (INCLUDES BREAKFAST & LUNCH)

## EARLY BIRD DISCOUNT

If you register at least thirty days in advance you will receive a \$200 discount on the course.

## ADDITIONAL DISCOUNTS

Contact us at 610-648-7550 or [info@cfpie.com](mailto:info@cfpie.com) for information regarding partnership discounts or how your organization can become a partner with CfPIE.

## CANCELLATION POLICY

All cancellations must be in writing and are subject to a \$350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the \$350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to [info@cfpie.com](mailto:info@cfpie.com). Registrants are responsible for contacting the hotel and canceling their room reservations.

CfPIE reserves the right to alter the venue, if necessary.

### ***Substitution Policy - Classroom Courses***

Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to [info@cfpie.com](mailto:info@cfpie.com).

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CfPIE also offers on-site courses for 10 or more attendees. Contact us at [info@cfpie.com](mailto:info@cfpie.com).

## ABOUT CfPIE

Learn from the Leader

In a life sciences industry that has faced nearly \$15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

## HOW TO REGISTER

1.

Go to <http://www.cfpie.com>

2.

Go to “REGISTER HERE” and select your course.

3.

Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.  
7 Great Valley Parkway  
Suite 295  
Malvern, Pennsylvania 19355



<http://www.CfPIE.com>



## EFFECTIVE INTERNAL AND EXTERNAL QUALITY ASSURANCE AUDITING FOR FDA REGULATED INDUSTRIES™

March 1 - 2, 2018 - Malvern, PA

October 11 - 12, 2018 - Boston, MA

April 24 & 25, 2019 - Boston, MA

## COURSE DESCRIPTION

A robust audit program is a key stone of an effective Quality System. The need for internal (self-inspection) quality auditing has been recognized, and is required, by all active pharmaceutical ingredient (API)/bulk pharmaceutical chemical, medical device and finished pharmaceutical cGMP regulations published worldwide. In addition it is starting to become the industry expected “norm” in the area of pre-market clinical development.

Experience reveals that many internal company quality audits and many external supplier/contractor quality audit programs are ineffective. This course provides the rationale, strategies, techniques and tips, on how to plan and perform effective audits.

The course explores the politics, psychology and all the technical aspects of auditing, including discussions of their logistics, tools, and frequency. The course evaluates the talents and personnel characteristics required of those who consistently perform thorough audits which yield optimal compliance results.

The name of the game is effecting change. Determining operational deficiencies is only one aspect of an audit. The key issue is how to effect change to bring about compliance to company and legal standards. This course considers how to effect change and how to make audits a positive experience for the auditor and auditee.

## INSTRUCTOR CREDENTIALS

Lee Truax-Bellows is a founder, President and CEO of Norwich Clinical Research Associates Ltd. (NCRA). This full-service clinical CRO in upstate NY consults on study development, monitoring and analysis; clinical and data-management-department development; regulatory consulting; SOP consulting; GCP and clinical regulatory training/auditing services.

Lee has over 20 years of experience in the pharmaceutical and medical device industries; having served as Monitor, Medical Communications Associate, Project Manager, Senior Quality Auditor, Senior Trainer and Regulatory/SOP Consultant in both industry and CRO roles.

Ms. Truax-Bellows received her MS in Nursing Administration/Advanced Nurse Family Practitioner from SUNY Binghamton, her MS in Nursing Administration/Family Nurse Practitioner from Binghamton University School of Management and her BS in Nursing from Hartwick College.

Lee is an active member of the Association of Clinical Research Professionals, the New York State MedTech Association and the Society of Quality Assurance (SQA). She is a Certified Clinical Research Associate and a Registered Quality Assurance Professional in Good Clinical Practices.

## WHO SHOULD ATTEND

This two-day course is designed for quality managers, quality auditors, regulatory/compliance professionals, production managers and top management interested in learning the value of an effective internal and external quality audit system. Those interested in how to prepare for a QA audit and how to enhance their internal/external quality audit system as a valuable regulatory compliance tool will also benefit from this course. Consultants and government inspectors will find this course particularly useful in enhancing their inspections and capabilities.

## HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CfPIE room rate of \$152/night if booked 3 weeks in advance of the course date)

The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of \$136/night if booked 3 weeks in advance)

Club Quarters Hotels, Boston, MA (CfPIE room rate of \$230/night if booked 4 weeks in advance).

The Berlin Hilton, Berlin, Germany (CfPIE room rate of Standard Single Room is €179.00 and Double Occupancy is €199.00 inclusive of VAT and Breakfast if booked 4 weeks in advance.)

## FIRST DAY

### Overview and general considerations:

- Scope and purpose of the internal and external Quality Audit System
- Regulatory background – requirements for each type of operation
- Understanding the politics of auditing
- Auditing / Regulatory Inspections – the tie-in

### Contractor and supplier audits

- When to audit – initial evaluation versus re-certification
- Steps for conducting supplier audits
- Problem resolution audits

### What makes a good audit?

- Audit objectivity
- Auditing standards
- Creating a win-win audit- turning the audit into a positive coaching experience for yourself, your company, and those you are auditing

### Selling quality assurance audits to management

- Learn why top management should care about audit findings
- Discover how to get management to listen, buy-in, and take action on your audit findings

### Audit System

- Define responsibilities
- Ensure auditor qualifications and training
- Developing an audit schedule – Risk Based
- Preparation for the audit (developing audit conduct tools):
  - Audit Plans
  - Audit Checklists
  - Review of past history and additional background data
- Auditor Best Practices:
  - Key questions
  - Techniques
  - The importance of documentation
  - Listening & observation skills
  - What to do and what not to do
- Conclusion-Audit reports
  - Categories of observations
- Effecting change

### Audit Follow-Up and Closure

- Follow-up and final documentation
- Audit Closure
- Audit Reports
- Relation to CAPA

## SECOND DAY

### Conducting Audits

- **Review key areas for each type of audit focus. Will include what to look for and questions to ask when conducting the following types of audit**
- **Good Clinical Practice Audits**
  - Planning
  - Scheduling
  - Audit Conduct – key areas of focus
  - Reporting of audit results
- **Good Laboratory Practice Audits**
  - Planning
  - Scheduling
  - Audit Conduct – key areas of focus
  - Reporting of audit results
- **Good Manufacturing Practices/Quality System Audits**
  - Planning
  - Scheduling
  - Audit Conduct – key areas of focus
  - Reporting of audit results



Write [info@cfpie.com](mailto:info@cfpie.com) for more information on our GLP Facility Certification Program.