Learn not just from the direct or, but tap into the knowledge of your peers: Participants will have the opportunity to anonymously submit their challenges, problems, and issues for classroom discussion.

Participants will also have the opportunity for one-on-one consulting with the course director during course breaks and in the evenings. The course director has over 25 years of industry experience.

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.

Pharmaceutical Production Batch Record Review

INSTRUCTOR: KERRY POTTER

November 14 & 15, 2019 - Boston, MA

COURSE DESCRIPTION

Efficient and effective batch record reviews provide pharmaceutical companies with two strategies. First, reviews are key to maintaining control of your firm’s operations, eliminating any guesswork and aiding in the resolution of atypical occurrences. Secondly, they enable a company to maintain and demonstrate a compliant posture—sure way to avoid any quandary with the regulatory agencies. This course is intended to take the mystery out of the batch record review process. The class examines the FDA and EU regulatory requirements for documentation and batch record reviews, explains the elements of the batch record review process, and clarifies the pathway to effective deviation investigations. Interactive sessions are included for identifying reviewer responsibilities, establishing good documentation practices, and writing procedures for the review process. Additionally, participants will be able to analyze their company’s compliance with these requirements and identify missing elements of the batch review process. Ample time is provided to address specific problems and questions of individual participants. Additional benefits of this class include:

- Learn not just from the director, but tap into the knowledge of your peers: Participants will have the opportunity to anonymously submit their challenges, problems, and issues for classroom discussion
- Participants will also have the opportunity for one-on-one consulting with the course director during course breaks and in the evenings. The course director has over 25 years of industry experience
INSTRUCTOR CREDENTIALS

Mr. Kerry Potter is the founder of Summit Consulting, Inc. He has more than 30 years of experience in project management, regulatory compliance systems, quality assurance, quality systems audits, regulatory training, employee development, GMP and documentation.

During the past 10 years, Kerry has provided consulting, training and mentoring services to several pharmaceutical firms in the United States and Europe through regulatory remediation activities (e.g. Consent Decree, Warning Letters), training and training systems development, documentation control, and project management.

Mr. Potter gained his pharmaceutical-manufacturing experience during his 28-year career with Merck. His experience spanned quality operations, audits/inspections, laboratory, human resources, and learning & development. His responsibilities included quality inspector, analytical chemist, quality motivation administrator, laboratory quality-management assessment manager, GMP lead auditor, FDA quality-management system manager, SS coordinator, GMP trainer, OSHA regulations trainer, process safety management training, and internal and external public relations management.

Mr. Potter received his B.S. in Chemistry from James Madison University. He has received qualifications and certifications in quality auditing, facilitation and training – including instructional design and competency-based curricula. His past and current affiliations include ASQ, ASTD, PDA, GMP-TEA, ASPI and AQP.

WHO SHOULD ATTEND

This two-day course is designed for pharmaceutical production, quality assurance and compliance personnel who are responsible for the review and audit of production batch records, and batch record deviation investigations. This includes, but is not limited to, such positions in Quality Control, Quality Assurance, Manufacturing, and Packaging groups. Those who supervise, manage, or oversee these activities would also benefit from this program.

HOTEL INFORMATION

<table>
<thead>
<tr>
<th>Location</th>
<th>Room Rate</th>
<th>Booking Window</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Hilton LAX, Los Angeles, CA</td>
<td>$167/night</td>
<td>3 weeks in advance</td>
<td>CfPIE room rate if booked 3 weeks in advance</td>
</tr>
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<td>The Desmond Hotel &amp; Conference Center, Malvern, PA</td>
<td>$141/night</td>
<td>3 weeks in advance</td>
<td>CfPIE room rate if booked 3 weeks in advance</td>
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<td>Club Quarters Hotels, Boston, MA</td>
<td>$255/night</td>
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<td>CfPIE room rate if booked 4 weeks in advance</td>
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<td>DoubleTree by Hilton London - Victoria</td>
<td>£199.00/night</td>
<td>4 weeks in advance</td>
<td>CfPIE room rate if booked 4 weeks in advance</td>
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</tbody>
</table>

FIRST DAY

Session 1
- Introduction and Expectations
- Components of a Batch Record
- Regulatory Requirements

Session 2
- Elements of the Batch Record Review Process
- Skills and Responsibilities of Batch Record Reviewer
- Production and Quality Review Processes

Session 3
- Documentation Practices
- Electronic Batch Records
- Tools for Effective Batch Record Review

Session 4
- Preparing for the Batch Record Review
- Handling and Responding to Batch Record Deviations
- Industry Trends: Observations and Warning Letters

SECOND DAY

Session 1
- Reintroduction and Recap
- Training Program for the Batch Record Reviewer

Session 2
- Metrics and Record Keeping

Session 3
- Writing Batch Record Review Procedures and SOPs

Session 4
- Communication Between Production and Quality
- Questions, Issues, Expectations and Answers

Course Wrap-up and Conclusions