COURSE FEE

$2150.00 PER PERSON

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 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. 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.

CfPIE also offers on-site courses for 10 or more attendees. Contact us at 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

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AUDITING AND QUALIFYING SUPPLIERS AND VENDORS - AN EFFECTIVE RISK BASED APPROACH

ALL 2020 COURSE DATES WILL BE OFFERED VIRTUALLY THROUGH LIVE INTERACTIVE SEMINARS

Sept 24 & 25, 2020 (BST)

Oct 15 & 16, 2020 (PDT)

COURSE DESCRIPTION

Regulatory agencies hold companies accountable for delivering high qual-ity products that meet all established requirements and specifications. Suppliers and vendors play a key role in accomplishing these mandates and it is the company’s responsibility to ensure their suppliers/vendors meet all regulatory specifications for the supplied materials, components, equipment and/or services.

For many years, industry has implemented procedures for selection, approval and qualification of suppliers and vendors. However, in many cases these protocols were not being implemented effectively or formally doc-umented. Making these programs part of a risk-based quality system ap-proach that the FDA and other regulatory agencies have come to expect from industry is critical. The course includes a process for selection, audit, approval and qualification of vendors/ suppliers based on the material/equipment/service being delivered. These decisions must be documented and must be based on the impact (risk) to the final product.

Initially, the course will discuss the regulatory expectations and other industrial references/ standards that will impact your system and will include the general requirements of a vendor/supplier (outsourcing) control program followed by specific requirements for different types of supplied materials/equipment/services. During these sections, attendees will establish the documentation requirements, applicable audits and the impact of the quality agreement/contract details.

In conclusion, participants will learn the maintenance aspects of such a program including handling of non-conformances, and timing and nature of additional audits. During the course, several interactive exercises will be included to provide opportunities for discussion and sharing of experiences.

INSTRUCTOR CREDENTIALS

Sean Develin – with nearly 20 years in regulated industry – is co-founder of DevRose Systems. This UK and US-based consultancy provides information technology, validated cloud, auditing and compliance services to regulated clients worldwide. He is also an adjunct faculty member of the Temple University School of Pharmacy; where he teaches Bioethics, Auditing and Validation.

Prior to launching DevRose Systems, Mr. Develin built and managed the validation practice for Falcon Consulting Group and was Director of Validation for Omnicare Clinical Research. His expertise ranges from human research protections to vendor management and data integrity. His work has been extensively audited by regulatory agencies, study sponsors and hosting clients.

Mr. Develin received his MA and BA in Philosophy from Villanova University. He is currently completing his JD at Widener University School of Law.

Mr. Develin is an active member of the Health Law sections of both the American Bar Association and the Massachusetts Bar Association. He is also an Executive Board member of the Food and Drug Law Association (FDLA) at Widener University – working with the FDA and US Attorney's Office to conduct continuing legal education on FDA Enforcement issues.

WHO SHOULD ATTEND

The course will be valuable for those in the pharmaceutical, biotechnology and medical device industries who are responsible for, or involved in, supplier/vendor management, qualification, procurement or maintenance. Manufacturing, Development, R&D, Validation and QA/RA personnel will benefit as the course details all the steps necessary to carefully document and conduct the process of vendor selection while working within the confines of a risk-based audit system.

Third-parties looking to gain insight into how firms select and manage their outside vendors will also find this course extremely useful.

LEARNING OBJECTIVES

By the end of this course, attendees will:

- Understand the requirements for Annual Product Reviews.
- Understand the impact of recent International and FDA actions and guidances on the Annual Product Review.
- Understand the role of the Product Review in corrective actions, preventive actions and continuous improvement.
- Be aware of systems that may be involved in the preparation of the product Review
- Be aware of the role of management in an effective Product Review Program.
- Be aware of potential future regulatory expectations that relate to the Product Review or Quality System Review.

FIRST DAY

Regulatory Background and Industry References and Standards

- FDA and EU perspectives on outsourcing management for medical devices, pharmaceuticals and Biotech products
- Impact from ISO, ICH
- Industry perspectives

Fundamentals of an Outsourcing Management System

- Procedure and Documentation
- Pre-requisites – specifications and internal agreements
- Selection of vendors/suppliers/service providers
- Audits – a risk-based approach to determine the requirements and levels of the assessments
- Approval of supplier/vendors – Quality Agreement/Contracts
- Qualification (Certification) of Vendors and Suppliers
- Maintenance of the program

Audit System

- Types of suppliers/vendors and impact levels to determine extent of audit
- Preparing for the audit – checklist and plan
- Execution and Documentation of the audit
- Professional Ethics, Conduct, and Social Engineering
- Remediation and conclusions of the audit
- Maintenance of the control system – periodic audits of approved/certified/qualified vendors and suppliers

Impact of the Quality Agreement/Contract

- Vendor/supplier perspective
- User perspective
- Purpose and scope of the agreement
- Requirements of the agreement/contract – formal communication and documentation
- Change Control
- Handling of Non-Conformances and deviations from contract

SECOND DAY

Practical aspects of an Outsourcing Management Systems for Materials and Components

- Establish specifications and expectations – internal agreement
- Selection and approval process
- Key areas to audit/assess before approval and adequate documentation
- Acceptance of the COA
- Qualification requirements and documentation
- On-going monitoring (data collection and analysis)
- Handling of non-conformances – change of vendor/supplier status when applicable

Specifics related to Equipment/System Suppliers

- Selection and audits
- Approval
- Quality Agreement and responsibilities
- Documentation
- User review and handling of non-conformances
- Aspects related to computerized controlled systems –Hosting/Cloud, hardware and software development, specifications, testing, audits

Specifics related to Contract Services – Manufacturing, Packaging, Calibrations, Laboratories, Equipment/System Maintenance

- Selection and audits
- Approval
- Quality Agreement and responsibilities
- Documentation
- User review and handling of non-conformances

Specifics related to GCP Contract Services

- Selecting and Managing CROs, Phase I units, GCP Labs and others
- EDC and Data Hosts
- GCP and 21 CFR 11

Management of Change within the Outsourcing Management System

- Communication and documentation – agreement requirements
- Internal review of changes from the supplier/vendor

Recent FDA Observations and Perspectives

Group Discussion Forum and Final Exercises