

ICH E6 GCP INTERACTIVE WORKSHOPS

WEDNESDAY-THURSDAY, NOV. 13-14: HOW TO BUILD A SPONSOR RISK MANAGEMENT PROGRAM
FRIDAY, NOV. 15: SUPPLIER/VENDOR/CONTRACTOR QUALIFICATION PROGRAM

NOV. 13-15, 2019
DOUBLETREE HOTEL PHILADELPHIA
CENTER CITY
PHILADELPHIA, PA

PRESENTED BY CENTERWATCH AND TECHNICAL RESOURCES INTERNATIONAL, INC.

Agenda

Course 1

How to Build a Sponsor Risk Management Program (2 days)

Day 1: Wednesday, Nov. 13, 2019

8:00 a.m. – 8:30 a.m.

Registration/Continental Breakfast

8:30 a.m. – 10:00 a.m.

Why Have a Sponsor Risk Management Program?

- Discuss the need for a sponsor risk management program
- Review ICH E6 (R2) updates
- Discuss the definition of risk.

10:00 a.m. – 10:15 a.m.

Break

10:15 a.m. – 11:15 a.m.

Review the Key Elements for a Successful Risk Management Program

- Executive engagement
- What is the role of a stakeholder
- Recommended structure for a risk management program

11:15 a.m. – 12:00 a.m.

How to Identify Risks at the System and Clinical Trial Level

- Different types of risks
- How to identify different types of risks.
 - Work through examples
 - **INTERACTIVE EXERCISE** Different types of quantitative and qualitative tools to identify risks

12:00 p.m. – 1:00 p.m.

Lunch

1:00 p.m. – 2:15 p.m.

Continued – How Identify Risks at the System and Clinical Trial Level

2:15 p.m. – 2:30 p.m.

Break

2:30 p.m. – 5:00 p.m.

How to Evaluate Risks

- Discuss evaluating risk using Likelihood, Detection, and Impact
 - **INTERACTIVE EXERCISE** Work through examples
- Discuss quantitative and qualitative evaluation approach
 - Pros and cons to both
 - **INTERACTIVE EXERCISE** Review tools

Day 2: Thursday, Nov. 14, 2019

8:00 a.m. – 8:30 a.m.

Registration/Continental Breakfast

8:30 a.m. – 10:00 a.m.

How to Control Risk

- Discuss how to develop practical mitigation strategies
- What is high risk?
- Know your risk level

10:00 a.m. – 10:15 a.m.

Break

10:15 a.m. – 12:00 p.m.

Reviewing and Communicating Risks

- When to review previously identified risks?
- Can a risk be closed?
- Who do you need to communicate with and when?
- Developing an overall communication strategy for your risk program
- Over communicating, how to avoid it

12:00 p.m. – 1:00 p.m.

Break

1:00 p.m. – 2:15 p.m.

How to Report Risks

- Clinical Study Report requirements
- Re-evaluation of vendors by quality
 - Re-auditing onsite or remotely
 - Frequency of re-evaluation of vendors based on risk

2:15 p.m. – 2:30 p.m.

Break

2:30 p.m. – 4:30 p.m.

Challenges with Risk Programs

- Stakeholder/Team challenges
- Executive management challenges
- Communication issues
- Lack of agreement with risk scoring

Course 2

Course 2 - Supplier/Vendor/Contractor Qualification Program (1 day)

Day 1: Friday, Nov. 15, 2019

8:00 a.m. – 8:30 a.m.

Registration/Continental Breakfast

8:30 a.m. – 10:00 a.m.

Why Have a Vendor Program?

- Discuss the need for a vendor qualification program
- Review guidance documents and regulations
- Discuss the different types of vendors an organization may have and how to approach them.

- Introduce the risk based approach to vendor qualification
 - Primary, secondary, consultants, others (software)
- Why have a qualified vendor's list and how to establish one?

10:00 a.m. – 10:15 a.m.

Break

10:15 a.m. – 12:00 p.m.

Review the Framework for a Risk-Based Approach to Selecting and Auditing Your Vendors

- What about preapproval surveys? How to develop them and when to use them?
- How to approach urgent vendor approvals/audits
- How to approach backup vendors
- Quality Agreements & supplier agreements
- How do you qualify consultants? Or do you qualify them?

12:00 p.m. – 1:00 p.m.

Lunch

1:00 p.m. – 2:15 p.m.

Periodic Reassessment of Your Vendors

- Annual review of vendors by process owner
- Re-evaluation of vendors by quality
 - Re-auditing onsite or remotely
 - Frequency of re-evaluation of vendors based on risk

2:15 p.m. – 2:30 p.m.

Break

2:30 p.m. – 4:30 p.m.

Challenges with Vendors and Solutions

- What do you do when your vendor fails to deliver?
- What if you do not have a qualified backup vendor and your primary vendor is having problems?
- What if top management prefers one vendor over another?
- How do you keep backup vendors approved if you do not send them work?
- What if a vendor audit report has multiple major findings?
- Review case studies