

## AGENDA

### Course 1 - How to Build a Sponsor Risk Management Program (2 days)

#### Aug. 8, Day 1:

- 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 p.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

**Aug. 9, Day 2:**

**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 - Supplier/Vendor/Contractor Qualification Program (1 day)**

**Aug. 10**

**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 you vendor fails to deliver?
- What if you do not have a qualified back up 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