

AGENDA

Day 1: Tuesday, Dec. 11, 2018

7:30 a.m. – 8:00 a.m. Registration/Continental Breakfast

8:00 a.m. – 9:30 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

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

9:30 a.m. – 9:45 a.m. Break

9:45 a.m. – 10:45 a.m. **Continue with Review the Key Elements for a Successful Risk Management Program**

10:45 a.m. – 11:30 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

11:30 a.m. – 12:30 p.m. Lunch

12:30 p.m. – 2:15 p.m. **Continue with 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**

- Explore how to identify critical data and processes
- 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: Wednesday, Dec. 12, 2018

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. **Continue with How to Control Risk**

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. **Continue with Reviewing and Communicating Risks**

How to Report Risks

- Clinical Study Report requirements
- Deviations to quality tolerance limits
- Risk reporting strategies

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