Multi-attendee discounts are available!

DRUG QUALITY RISK MANAGEMENT

BEYOND FMEA — DEVELOPING A COMPREHENSIVE RISK TOOLKIT

OCT. 26-27, 2017
COURTYARD ARLINGTON CRYSTAL CITY/
REAGAN NATIONAL AIRPORT
ARLINGTON, VA (WASHINGTON, DC)

AN INTERACTIVE WORKSHOP PRESENTED BY VALSOURCE LEARNING SOLUTIONS AND FDANEWS

AGENDA

Day 1

8:00 a.m. – 9:00 a.m. Registration/Continental Breakfast

9:00 a.m. – 10:15 a.m. **Workshop Introduction and Objectives: Quality Risk Management (QRM) Defined**

- The what and why behind QRM
- The basic elements of QRM
- Analysis of all available information
- Determine the likelihood of a risk
- Assess the risk using methods to determine potential impact and severity
- Evaluate and decide which risks to control
- Control and mitigate the significant risks
- Monitor
- Communicate with all stakeholders
- **INTERACTIVE EXERCISE** Exchange ideas with colleagues about why risk is so important within the pharmaceutical industry and discover various perspectives and ideas in this "two-minute talk."
- How have recent events shaped our thinking of risk management?

10:15 a.m. – 10:30 a.m. Break

10:30 a.m. – 11:00 a.m. **The Evolution of Quality Thinking**

- The movement from specifications and testing to process understanding
- Changes in GMP requirements and expectations related to QRM
- Exploring quality by design to gain the knowledge of how the process reduces risks
- QRM and regulatory harmonization — recent ICH guidelines that discuss risk management: ICH Q8, Q9, and Q10
- FDA's new draft validation guideline: how it incorporates risk-based thinking
- The growing importance of needing to have product and process understanding
- Recent FDA warning letters concerning risk assessment and process understanding
- ISO-31000:2009 — the international standard for risk management

11:00 a.m. – 12:00 p.m. **Key Concepts and How They Apply to Risk- Based Thinking**

- Discuss how the vulnerabilities of a product or process may make it more susceptible to hazards
- Learn the expanded and working definitions of what a hazard is as applied to QRM for the pharmaceutical industry
- Understand and integrate the 4 types of recognized ICH risks into your risk assessment

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:30 p.m. **How We Think About Risk**

- **INTERACTIVE EXERCISE** Risk perceptions — re-creating an important study that showed how perceptions affect how we as people perceive and react to risks.
- Who should think about risk?
- Who should be involved in the firm's risk management process?
- Where does quality risk management apply within the pharmaceutical industry?
- Accident theory: the basis for many risk assessment tools
- Historical and current models used to describe how accidents (and incidents) occur
- How accident models can be used in a predictive way

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:30 p.m. **The QRM Process: What It Is All About**

- Defining each task, what is accomplished and how it is done
- Preliminary tasks: Coming up with the risk question
- Define the system or process
- Identify the hazards
- Assess the risks
- Evaluate the risks
- Control and mitigate the significant risks
- Monitor
- Communicate to stakeholders
- **INTERACTIVE EXERCISE** How can you apply the quality risk management process?
- The risks of too much and too little documentation during the QRM process
- The risk assessment toolset: a look at some of the tools used in risk assessment and their origin
- Risk ranking
- Preliminary risk assessment
- Hazard and operability studies (HAZOP)
- Hazard analysis and critical control points (HACCP)
- Failure mode effects and criticality analysis (FMECA)
- Fault tree analysis (FTA)
- Event tree analysis (ETA)

Day 2

8:30 a.m. – 9:00 a.m. Continental Breakfast

9:00 a.m. – 10:30 a.m. **Applying Quality Risk Assessment Tools**

- Now that you know the process and some of the tools, you can apply them using several different scenarios
- **INTERACTIVE EXERCISE** A warm-up exercise using some of the risk assessment tools.
- **INTERACTIVE EXERCISE** Practical example #1 — risk and outsourcing. An overview of the outsourcing process and then a small group activity where learners can use one of the risk assessment tools. Ideas to control significant outsourcing risks will be identified. (This can apply to contract givers as well as contract receivers.)
- A closer look at control and mitigation strategies: prevention or protection?

10:30 a.m. – 10:45 a.m. Break

10:45 a.m. – 12:00 p.m. **Applying QRM Tools To Audit and Inspection Preparation**

- **INTERACTIVE EXERCISE** Practical example #2 — risk and preparing for audits and inspections. If compliance priorities are identified, preparing for an audit can become less complicated. This large and small group activity will first examine areas that regulatory agencies are currently emphasizing. Then participants will apply one of the risk assessment tools and use risk rating approaches described by regulatory agencies.
- A closer look at the "risk library" — how much detail should you include in your formalized risk assessment?

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:30 p.m. **Applying QRM Tools To Real Situations**

- **INTERACTIVE EXERCISE** Attendees will review and evaluate a case study in mock risk management teams to correctly document and communicate all risk assessment conclusions. Then they will deliver mini-presentations of the results with co-attendees. Several case studies have been prepared covering product development, handling of samples, distribution practices (cold and secure chain) where small groups will apply one or more of the risk assessment tools and then evaluate the risks.

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:15 p.m. **Integrating QRM Into Your Organization**

- Setting up a QRM activity: Critical success factors to consider when you are setting up or evaluating a QRM program, including the importance of management support
- Suggestions for early risk assessment projects: maintaining focus on what is important

- Writing a risk assessment and risk management procedure: key steps to include
- What can we learn from recent risk management failures in other industries? What can happen when you don't understand the limitations of the risk model? What can happen when nobody thinks of "residual risk" or "unidentified risk?"
- Discussion: taking the next steps. What actions can you take? What will you be able to do with this information?

4:15 p.m. Adjournment