

Aug. 13–14, 2009 • Gleacher Center • Chicago, IL  
Oct. 29–30, 2009 • Hyatt Regency Princeton • Princeton, NJ



# Applying Quality Risk Management

Moving ICH Q9 from Theory to Practice

## Discover 6 Tools To Estimate Severity of Failure Events

PRA, HazOp, FEMCA, FTA, ETA, HACCP

## Real World Case Studies

Product Development, Handling Samples, Distribution Practices

## Prepare for Risk-Based Inspections

Applying quality risk management strategies that satisfy regulators

## Building Effective Risk Management Teams

Choosing team members that are qualified and proactive



**James Vesper**  
President  
LearningPlus

**Workshop Exclusive:** Attendees Will Perform a Mock Risk Management Assessment — Documenting and Communicating the Results With Fellow Attendees

*"James is an awesome trainer."*

**Kelly Mumma**, HR Manager, Pathway Medical

Visit [www.RiskManagement09.com](http://www.RiskManagement09.com) or call (888) 838-5578

Workshop presented by LearningPlus and **FDANEWS**

# Applying Quality Risk Management

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### WORKSHOP AGENDA

#### Day 1

##### 8:30–9:00 a.m. Registration and Continental Breakfast

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

- The what and why behind QRM
- The basic elements of quality risk management
  - 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?

##### 10:15–10:30 a.m. Break

##### 10:30–11:00 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

##### 11:00–12:00 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

##### 12:00–1:00 p.m. Lunch

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

##### INTERACTIVE EXERCISE: Risk perceptions – recreating 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

##### 2:30–2:45 p.m. Break

##### 2:45–4:30 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)

##### 4:30 p.m. Session Wrap-up, End of Day 1

#### Day 2

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

##### 9:00–10:30 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?

##### 10:30–10:45 a.m. Break

##### 10:45–12:00 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

**"Jim's approach to the information and training was intelligent, well-paced, meaningful and relevant. I learned a lot from his training style as well as the content of the course. I appreciate the numerous opportunities we had to interact with our co-trainees and to engage in learning."**

**Denise Klausner**, Training Administrator, Fort Wayne Metals

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?

**12:00–1:00 p.m. Lunch**

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

**REAL WORLD CASE STUDIES:** 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.

**2:30–2:45 p.m. Break**

**2:45–4:15 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 quality risk management 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. Adjourn**

## YOUR INSTRUCTOR



**James Vesper** designs and develops instructional courses and workshops for the pharmaceutical and medical device industries. He is founder and president of the firm LearningPlus, Inc. and has had 25 years of experience in the pharmaceutical industry. During those 25 years, Mr. Vesper has been creating innovative instructional training products and working as a consultant with a wide variety of clients. His firm continues to create integrated curricula for personnel as well as customized training courses that are targeted to their specific needs. Since 1991, Mr. Vesper has been creating innovative instructional training products for the pharmaceutical and healthcare industries using video and computer technologies as more effective and efficient delivery media. Working as a consultant with a wide variety of clients, his firm creates integrated curricula for personnel and customized training courses targeted to specific needs. He presents papers and workshops at various international technical and professional meetings, including those of the International Society for Pharmaceutical Engineering, GMP TEA, PDA, Pharmaceutical Sciences Group and PharmTech. In 2001, he was awarded the PDA's Agalloco Award for Excellence in Training.

## COURSE BINDER MATERIALS

- Slides from PowerPoint presentation
- Case review worksheets
- Interactive exercise worksheets
- Reference docs:
  - ICH Q8
  - ICH Q9
  - ICH Q10

## WHO SHOULD ATTEND

- Risk management specialists
- QA/QC personnel
- R&D management
- Engineering and design controls teams
- Executive management
- Manufacturing directors and supervisors
- Auditors
- Regulatory/legislative professionals
- Compliance officers
- Laboratory management
- Validation specialists, scientists, engineers

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# Applying Quality Risk Management

## Moving ICH Q9 from Theory to Practice

### LOCATIONS AND HOTEL ACCOMODATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **FDAnews** workshop to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. Hotel may require first night's room deposit with tax. Room cancellations within 72 hours of the date of arrival or "no-shows" will be charged for the first night's room with tax.

#### Aug. 13-14, 2009 • Chicago, IL

##### Conference Venue:

Gleacher Center  
450 North Cityfront Plaza Drive  
Chicago, IL 60611  
+1 (312) 464-8787  
www.gleachercenter.com

##### Lodging:

Omni Chicago Hotel  
676 North Michigan Avenue  
Chicago, IL 60611  
+1 (312) 944-6664  
Toll free: (800) 809-OMNI (6664)  
www.omnihotels.com  
Room rate: \$189.00 (plus 15.4% tax)  
Reservation cutoff date: 7/21/09  
(Approx. 2 blocks to the Gleacher Center)

#### Oct. 29-30, 2009 • Princeton, NJ

##### Conference Venue:

Hyatt Regency Princeton  
102 Carnegie Center  
Princeton, NJ 08540  
+1 (609) 987-2584  
Toll free: (800) 233-1234  
www.princeton.hyatt.com

##### Lodging:

Hyatt Regency Princeton  
102 Carnegie Center  
Princeton, NJ 08540  
+1 (609) 987-2584  
Toll free: (800) 233-1234  
www.princeton.hyatt.com  
Room rate: \$169.00 (plus 15% tax)  
Reservation cutoff date: 10/15/09

### TUITION

Tuition rate is \$1,897 per person and includes all workshop sessions, workshop written materials, two breakfasts, two luncheons and daily refreshments.

### TEAM DISCOUNTS

Significant tuition discounts are available for teams of three or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Call (888) 838-5578 for details.

### ACCREDITATION

Applying Quality Risk Management: *Moving ICH Q9 from Theory to Practice* has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

**FDAnews** is a Regulatory Affairs Professionals Society (RAPS) RA Professional Development Portal provider. **FDAnews** is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. **FDAnews** has agreed to follow RAPS-established operational and educational criteria.

### CANCELLATIONS AND SUBSTITUTIONS

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund — less a \$200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days of the start date of the event. A credit for the amount paid may be transferred to any future **FDAnews** event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that **FDAnews** cancels the event, **FDAnews** is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.



I will attend Applying Quality Risk Management: *Moving ICH Q9 from Theory to Practice*. I understand the fee of \$1,897 includes all workshop sessions, workshop written materials, two breakfasts, two luncheons and daily refreshments.

# FDANEWS

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Choose Date/Location:  Aug. 13-14, 2009 • Chicago, IL

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