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PharmaED's

# QbD: Quality By Design

*A hands-on two day workshop covering the key components of QbD concepts, implementation and product risk mitigation*

**MARCH 4-5, 2010, RADISSON-PLAZA WARWICK, PHILADELPHIA, PA**

## **Key Learning Objectives:**

- **Understand Risk-Based GMP Compliance and FDA, ICH and ASTM Approaches**
- **Review Strategies for Defining Risk, Risk Factors and Risk Prioritization**
- **Understand the Basic Fundamentals and Approach of QbD**
- **Use QbD to Mitigate Product Risk in Engineering Drug Manufacturing Operations**
- **Understand the Connection Between QbD and Process Analytical Technology (PAT)**
- **Implement the Concept of Continuous Improvement**

## **About Your Trainer:**

*Instructor:*

**Gamal Amer, Ph.D.**

- *Experience includes over 25 years experience in the pharmaceutical and related industries*
- *Has held senior management positions with leading pharmaceutical and consumer products companies*
- *Comprehensive process design experience in bulk pharmaceutical chemicals manufacturing, biotechnology manufacturing, pharmaceutical solid dosage manufacturing, and containment of potent and radioactive therapeutics*
- *A recognized expert in Risk Management Planning (RMP), Risk Based GMP Compliance, and validation.*
- *Has lectured and published extensively, including in peer reviewed publication on Risk, Validation and GMP compliance.*

**Bring this workshop to your location:**

*For more information, contact PharmaEd Resources at (217) 721-5774.*



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## WORKSHOP AGENDA

### Day One

8:30 **Overview – Science and Risk-based Compliance**

Review the background and guidance dealing with risk based GMP compliance and the various approaches suggested by FDA, ICH, and ASTM to mitigate risk and ensure proper compliance is achieved. The documents that will be reviewed include:

- a. FDA Guidance “Pharmaceutical CGMP for the 21st century – A Risk-based Approach” and its implication. Additionally subsequent progress reports issued by the FDA regarding suggested approaches to mitigate risk will be discussed
- b. Review ICH Q8, Q9, Q10, and ASTM Standard E2500
- c. How does QbD fit within the big picture - ICH Q8 (R1)
- d. What is meant by Product Life Cycle
- e. The jargon and acronym definitions

10:00 **Refreshment Break**

10:30 **Risk and Risk Levels**

Strategies for defining risk, risk factors, and risk prioritization.

- f. Review ICH Q9 and Risk based Compliance principles.
- g. Defining risk factor levels and Risk Priority Number (RPN)
- h. Discuss the concept of “Action Commensurate with the Level of Risk”
- i. Risk Based Compliance and how to use the RPN to prioritize mitigation efforts and resource utilization.
- j. Outline a suggested risk assessment form.

11:30 **Survey Review**

10:00 **Lunch**

1:30 **Interactive Exercise**

Risk causing scenarios will be detailed and attendees will be guided, using a risk assessment form, through the appropriate steps required to define an RPN for each scenario.

2:00 **Understanding the Basic Approach and Fundamentals of Qbd**

Review ICH Q8 (R1) and ASTM E2500 to understand the QbD concept.

- k. Define the QbD systematic process/approach.  
Discuss the need for User Requirement Specifications (URS). Learn about the Ishakawa Fishbone diagram and how it is developed. Discuss using root cause analysis techniques to identify risk factors. Review and discuss the principles of Design Of Experiments (DOE), Knowledge Space (Science base), Design Space (DS), the Normal Operating Space (Range)/Control Space (Range), and Design Reviews and how these can be used to support QbD implementation.
- l. A step-by-step QbD implementation roadmap.

3:00 **Refreshment Break**

3:30 **Interactive Exercise**

A User Requirement Specification (URS) will be defined and the attendees as a group will develop a Fishbone diagram to address developing a design to address the requirement.

4:30 **Refreshment Break**

### Day Two

8:30 **Review of Day One Learning Activities**

9:00 **Using QbD to Mitigate Product Risk in Engineering Drug Manufacturing Operations**

Designing a drug manufacturing operation so as to minimize or eliminate the potential risks associated with the eventual operation can be achieved using an established systematic approach. Good Engineering Practices (GEP) and the principles of Quality by Design

(QbD) represent the current FDA thinking to achieve such objectives. Applying QbD principals during the engineering of the facility and process (operation) for producing a drug product requires good scientific understanding of both the product's characteristics and the processing approach. Understanding the potential risks associated with the proposed operation requires utilizing Subject Matter Experts (SME) and risk analysis techniques. GMP principles must also be addressed by the eventual design thus ensuring process consistency.

10:00 *Refreshment Break*

### 10:30 **Interactive Exercise**

The entire group will have an open discussion of approaches to be taken to mitigate the risk associated with several real life design related issues.

### 11:30 **Questions and Answers**

12:00 *Lunch*

### 1:30 **QbD, Process Analytical Technology (PAT) and the Concept of Continuous Improvement**

In this timeframe we will review the connection between QbD and PAT. QbD is fundamentally based on identifying the correlation between Critical Quality Attributes (CQA) for the product and Critical Processing Parameters (CPPs). This information is usually identified using, process development information, experiments, data collected from the process, and previous knowledge. Once this information is well defined, it can be used to develop the required control strategies to ensure that quality is built into the design.

Additionally this information is valuable in developing the models which could be used to implement PAT for the operation. Using PAT and collecting data throughout the product life cycle would allow for continuous process improvement and real time product release. We will explore the advantages of properly defining design space in regulatory applications.

2:30 *Refreshment Break*

### 3:00 **Open Discussion - A look at the future**

- m. How QbD is one of the tools that allows industry to build quality in the product and improve its compliance quotient.
- n. What is driving the concept – Technological advances and the need to reduce cost are obvious drivers; What else?
- o. Are changes to GMP regulations needed to accommodate real time release and risk based compliance?
- p. Verification instead of qualification and the concept of continuous validation.

4:30 *Close of Workshop*

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### **About the Instructor:**

Dr. Amer has over 25 years experience in the pharmaceutical and related industries. He has held senior management positions with leading pharmaceutical and consumer products companies. His experience includes comprehensive process design in bulk pharmaceutical chemicals manufacturing, biotechnology manufacturing, pharmaceutical solid dosage manufacturing, and containment of potent and radioactive therapeutics. He is also experienced with facility development for therapeutic products operations. Dr. Amer is a recognized expert in Risk Management Planning (RMP), Risk Based GMP Compliance, and validation. He has lectured extensively in the US, Europe, Asia, and the Middle East and taught many courses on subjects such as controlled release technology, GMP trend, Validation and Change Control, and implication of GMP compliance on process and facility design in the biotechnology industry. He has also published extensively in peer reviewed publication on Risk, Validation and GMP compliance.



**About your conference destination:**

The Radisson-Plaza Warwick is located in the heart of downtown Philadelphia, and adjacent to beautiful Rittenhouse Square. From the conference venue, you can access many points of interest in Philadelphia including Independence Hall, the Kimmel Center and the Avenue of the Arts and numerous shops, hotels and excellent restaurants!



**REGISTRATION INFORMATION**

Register for the conference using one of four options:

Online: [www.pharmaedresources.com](http://www.pharmaedresources.com) Phone: (217) 355-7322 Fax: (847) 589-0708

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**QbD: QUALITY BY DESIGN:**

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*March 4-5, 2010, Radisson-Plaza Warwick, Philadelphia, PA*

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**VENUE INFORMATION:**

**Dates:** March 4-5, 2010  
**Hotel:** Radisson Warwick Plaza Hotel  
**Hotel Address:** 1701 Locust Street  
Philadelphia, PA 19103  
**Reservations:** (888) 201-1718 US  
**Hotel Telephone:** (215) 735-6000  
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