# EFFECTIVE QbD (Quality by Design): A SECOND GENERATION APPROACH

## 29-30 October, 2014

Parc Científic de Barcelona

Baldiri Reixac, 10 - 08028 Barcelona - Spain

**Course Topics Include:**

- Pharmaceutical, Cosmetic, Nutraceutical & Food Industries
- QbD Concept
- The Operational Excellence concept
- Critical Circle Elements
- Analytical Tools
- Process evaluation
- Blend-uniformity monitoring

### Who Should Attend

This QbD course demonstrates the interaction of design space, knowledge basing, good analytical science and risk management with ICH Q2 principles, leading to successful analytical method validation. It is designed for:

- Pharmaceutical product developers
- Formulators
- Instrumental analysts
- Quality assurance scientists
- Product manufacturing managers
- Food scientists and managers

### Learning Objectives

Upon completion of this course, you will be able to:

- Structure a team for implementing Quality by Design
- Explain and apply ICH Q8, Q9 and Q10
- Construct a knowledge base for manufacturing processes
- Perform risk assessment, risk mitigation and management in the QbD context
- Define, test, assess and approve the Target Product Profile in QbD
- Characterize design space, develop experimental designs and assure program transferability

### Course Description

The course serves as a detailed overview of QbD, in its current evolution. Included are the tools needed to evaluate existing product manufacturing, assess QbD applicability and apply statistical process control to meet defined targets.

The Critical Circle concept– zero-sum proportioning between Knowledge Base, Risk State and Desired State (key QbD aspects) is applied to the Product Target Profile (PTP).

A blend uniformity case study serves as a proof-of-concept exercise. Course participants will evaluate the study and learn to adjust the Critical Circle accordingly.

The course content also includes a thorough grounding in Risk Management as defined and practiced in ICH Q9.

The topics apply equally well to pharmaceutical, cosmetic, nutraceutical and food science applications.

### Course Director

**Janet Bowen, CAI Consulting, Vice President, Compliance and Quality Systems.**

Janet Bowen is experienced in Quality Systems, Manufacturing Excellence, and US and Foreign GMP Compliance Professional with more than thirty years experience in the Pharmaceutical, Biotechnology, and Device manufacturing industries. She has significant experience in Compliance and QA management, Validation, and GMP compliance auditing of manufacturing facilities for production of sterile products by aseptic processing, solid dosage forms and other external forms, APIs made by biotechnology or chemical synthesis, clinical trial materials and medical device distribution and manufacturing.

Additionally, Ms. Bowen has considerable experience with contract manufacturing where products, test methods, and in some cases specific instruments were developed at the owner's site and transferred to the manufacturing site for both clinical and commercial material.

Ms. Bowen is a Subject Matter Expert in design, validation and operation of Sterile Product manufacturing and related equipment, cleaning and analytical methods.

Furthermore, she has demonstrated success in capital project delivery: new powder filling facility and new biotech upstream processing facility.

Course offered by The Center For Professional Advancement

COURSE OUTLINE

## FIRST DAY

8:30-9:00

**Registration**

9:00-17:00

**Review of Learning Objectives**
Introduction

**QbD Concept: overview and evolution**
- Understanding the underlying QbD principles, their origin and execution
- QbD trends in the manufacturing and regulatory aspects

**The Operational Excellence concept**
- Evaluating and establishing key performance indicators
- International conformance: ICH Q8, Q9 and Q10

Creating your QbD program
- Developing the team and its operating parameters
- Stepwise QbD program tasks

**Applying the Critical Circle Elements**
- Risk Management: Using the ICHQ9 flow chart, risk assessment tools and information parsing
- The Knowledge Base: Use what you know, apply "good science," test wisely

## SECOND DAY

9:00-17:00

**Augmenting the Knowledge Base**
- Analytical Tools: Static vs. dynamic, data vs. information
- Process evaluation: altering and controlling variation for significant gain

**Experimenting and stressing**
- The 3 D's: design space, design experiments, desired state
- Focus on unit operations: statistical control

**Putting the tools into practice**
- Blend-uniformity monitoring – a case example
- Technology transfer

**Acceptance: internal and external**
- Implementing the "QbD Factory"
- Regulatory aspect review: Consulting, documenting, testing and proving at QbD efficiency levels

**Assessment Opportunity**

## TUITION AND PAYMENT

**Early registration:**
(received before June 30th, 2014) - Euro 1400+VAT/1260+VAT (group discount*)

**Regular registration:**
(received after June 30th, 2014) - Euro 1600+VAT/1440+VAT (group discount*)

(Fee includes course materials, lunches and coffee breaks)
Participants are responsible for their own hotel reservations.

*Group discount is for two or more enrollments from the same company.

**Payable by bank transfer upon issuing an invoice. Payment instructions will be provided upon registration.**

## Registration

Name .....
Surname .....
Position .....
Organization .....
VAT.....
Address. .....
Postal Code .....
City .....
Country .....
Phone/Fax .....
Participant e-mail .....
Billing e-mail .....

PLEASE RETURN BY FAX OR E-MAIL


### General information

Cancellations received after October 10, 2014 will be invoiced completely. All cancellations will be subject to Euro 200 processing fee. Substitutions may be made at any time. Payment is due once the participant receives an invoice. Certificates will be issued to participants upon completion of the course.

**For Information please contact us at:**

**Office: +34 93 4487156**
**Cell: +34 691676055**
**Fax: +34 93 4037109**
**e-mail: info@sitec-pharmabio.com**