WHO SHOULD ATTEND

Quality-by-Design (QbD) is a concept that applies logic to assessing and controlling variance. It is often applied to manufacturing process operations, but its concepts are equally valuable when it is applied to supporting operations such as analytical chemistry, instrumental analysis and line-based process analysis. When doing so, the core QbD elements – Knowledge Base, Risk Management and Design Space – apply. The key to making the concept work is to establish Target Profiles. These profiles serve as the intended limits of the QbD application and also as guides to establishing design experiments. This course provides guidance for establishing, assessing not only those profiles, but the tools used to make them happen. It is intended for:

- QbD project managers
- QbD team members
- Formulation scientists
- Analytical method developers
- Technology transfer specialists
- Personnel concerned with process analysis and control
- Unit operations staff

LEARNING OBJECTIVES

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

- Define a Product Target Profile
- Define an Analytical Target Profile
- Parse the physical science that establishes the limits for sensors and analyzers
- Develop an Uncertainty/Acceptability Profile for selecting instruments and materials
- Use the developed knowledge base to assure fitness-for-purpose

COURSE DESCRIPTION

This 90-minute accredited training course will help both analysts and formulators assess uncertainty that stems from instrumental limits, issues of detectability, noise, false signals and reagent contributions to error. With this information, the participant will be able to define a robust analytical target profile for use as a QbD program element. Using parallels to product target profiling in manufacturing-oriented QbD, reagents, excipients and APIs can be coordinated with robust analytical methods to refine overall efficiency.

Review of Learning Objectives

Module 1:
- Examining a Product Target Profile (PTP)
- What a profile tells us
- What we can do to adjust a PTP
- How the Knowledge Base helps profiling

Module 2:
- The Analytical Target Profile (ATP)
- ICH documents: a hidden resource for ATP
- Appropriate sensor selection
- Fitness for intended purpose

Module 3:
- Uncertainty: avoid stack-ups
- Handling multivariate inputs
- Data observation and interpretation

Question and Answer Session

TUITION AND REGISTRATION

TUITION*— Single Rate: U.S.$295.00 per person  Group Rate: U.S.$245.00 per person**

Register at www.cfpa.com. Enter Course ID# 2579 into Search. To register click Register Now.

For Questions and Information call Customer Service at 732-613-4500.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

System Requirements: PC-based attendees: Windows(R) 7, Vista, XP or 2003 Server/Macintosh(R)-based attendees: Mac OS(R) X 10.4.11 (Tiger(R)) or newer

For more information see reverse side
COURSE DIRECTOR

John E. Carroll, C.Ph.C., CEO, Carroll Brands, Director, Cadrai Group

John E. Carroll, C.Ph.C., is CEO of Carroll Brands and Director, Cadrai Group. The Cadrai Group develops and presents focused training programs for issues germane to the current needs of the pharmaceutical industry including small-molecule, biologic and nutraceutical preparations. Cadrai has an equally strong focus in both training and business development for the analytical instrument industry. Among Cadrai successes are: ion-mobility spectrometry for cleaning verification, NIR dedicated to tablet & capsule analysis, laser induced breakdown spectroscopy, chemical imaging and automated dissolution.

As Pharmaceutical Business Unit Manager for Perstorp Analytical Instruments (now Foss), Mr. Carroll built a global, sustainable business that saw over 8,000 NIR test instruments placed within the pharmaceutical manufacturing industry. Mr. Carroll has a B.A.S in Engineering Technology/Chemistry, an M.B.A. (c) in International Marketing, sixty publications and numerous technical presentations. He is the author of “The NIR Desk Reference” (Carroll, He and Landa) and “The Handbook of FTIR” (Carroll). He is also the editor of “IR-MS: High sensitivity and selectivity for organic analysis” (Mattson and Carroll). Professional memberships include AAPS, ACS, CNIRS and ISPE.

ACCREDITATIONS

The Center for Professional Advancement has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 12100 Sunset Hills Rd., Suite 130, Reston, VA 20190. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. The Center for Professional Advancement is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEU will be awarded for participation in The Center for Professional Advancement’s courses at the rate of .1 CEU per contact hour. CEU will be awarded only upon successful completion of the entire course and 70% accuracy in the required Learners’ Assessment. This course offers a total of 1.5 contact hours or .2 CEUs (CEUs rounded up).

WHO WE ARE

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately four hundred and fifty short courses in 15 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. CfPA courses are offered in a variety of formats – Public offering, Client Site and Online – to fit you or your company’s training needs.

For more information visit our website at www.cfpa.com

COURSES OF INTEREST

• Cost Effective Quality-by-Design and Critical-to-Quality Tools for PAT–An Online Course
course ID# 2127

• Effective QbD (Quality by Design): A Second Generation Approach
course ID# 2525

• Enhancing and Defining Analytical Testing using QbD (Quality by Design)
course ID# 2526

• Key PAT Concepts: Focus on Design of Experiment –An Online Course
course ID# 2304

• Key PAT Concepts: Focus on Design Space –An Online Course
course ID# 2289

• Key PAT Concepts: Focus on Desired State –An Online Course
course ID# 2305

• QbD Beyond Concepts: A Practical Implementation Plan–An Online Course
course ID# 2577

• Selecting a Drug Product Candidate Using Quality Risk Management: PAT & QbD–An Online Course
course ID# 2126

• The QbD Toolbox: Resources That Help New QbD Programs –An Online Course
course ID# 2578

TERMS AND CONDITIONS

*Payment: Tuition payable in US funds net of all charges. Payment is due at time of registration in the form of a credit card. Please contact CfPA’s Customer Service for other payment options.

**Group Rate: The Group Rate is for two or more enrollments, up to five registering from the same company at the same time. For groups of six or more, please contact Customer Service for group pricing.

Cancellations/No Show: “Live”- Registrants may cancel up to two working days prior to the course start date and will receive a letter of credit to be used towards a future course up to one year from date of issuance. No credit will be issued for no-shows and/or cancellations less than two working days prior to the course. “On-Demand”- No refund or credit will be issued for no-shows and/or cancellations of on-demand training courses. CfPA is not responsible for any outside related costs incurred by registrant’s cancellation.

ID 2579