

Selecting a Drug Product Candidate Using Quality Risk Management: PAT & QbD

Location: Your Computer Offering # 0903-706 Priority Code: 520

This course presented by CfPA in conjunction with



and



WHO SHOULD ATTEND

This course is intended to help pharmaceutical industry professionals charged with enhancing and improving manufacturing efficiency for existing drug products (PAT) and those who are developing new drugs according to USFDA and EMEA product life cycle initiatives (QbD). The concepts presented in this course can establish a blueprint for QRM team formation, experimental and monitoring tools and wide aspects of applicable drug formulation and dosage forms. It is intended for:

- PAT & QbD team managers
- Formulators
- New product developers
- Regulatory affairs personnel
- Function cross-over personnel
- In-process analysts
- Tech transfer personnel
- Quality program managers
- Production managers
- Product financial planners
- PAT & QbD team members
- Product release analysts

LEARNING OBJECTIVES

After participating in this course, you will have a grounding in product optimization according to ICH Q8, Q9 and Q10, risk management associated with dosage form production methods, tools for risk assessment, identification of Critical Quality Attributes and Critical Process Parameters, and dosage form selection guidelines.

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

- Summarize the basics in product optimization according to ICH Q8, Q9 and Q10
- Determine risk management associated with dosage form production methods
- Choose the proper tools for evaluating risk assessment
- Identify Critical Quality Attributes and Critical Process Parameters
- Review and use dosage form selection guidelines

COURSE DESCRIPTION

This 90-minute **accredited** training course provides critical decision-making tools, from dosage form design through predictive operation control to product release and patient use. The three modules include an overall exploration of the current QRM climate, benchmarking tools, selection strategies for new and mature drugs and smooth regulatory interaction.

Module 1:

- Product optimization and life cycle
- Quality Risk Management embraces PAT and QbD
- Birth and death processes of a drug candidate
- Corporate vs. QRM implementers' benchmarks

Module 2:

- Using batch history in the decision process
- Identifying CQA's and CPP's
- Selecting a mature drug product
- Selecting a developmental drug product

Module 3:

- Comparing conventional and QRM life cycles
- Tools for parsing the drug product operation
- Factorial decision-making for product characteristics
- Drug substance influence on the drug product and dosage form

Question and Answer Session



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For more information see reverse side ➡

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COURSE DIRECTOR

John E. Carroll, C.Ph.C., President, Carroll Ventures, Inc., Managing Partner, Cadrai Technology Group

John E. Carroll is Managing Partner, Cadrai Technology Group and President, Carroll Ventures, Inc. The Cadrai Technology 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, a 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.

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 Offering #0903-706** into **Quick Jump**. To register use **Priority Code: 520**.

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.

ACCREDITATIONS



The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. 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. As a result of their Authorized Provider membership status, The Center for Professional Advancement is authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards.

WHO WE ARE

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately three hundred and fifty short courses in 18 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.

ABOUT WILEY-BLACKWELL

Wiley-Blackwell was formed in February 2007 as a result of the acquisition of Blackwell Publishing Ltd. by John Wiley & Sons, Inc., and its merger with Wiley's Scientific, Technical, and Medical business. Together, the companies have created a global publishing business with deep strength in every major academic and professional field. Wiley-Blackwell publishes approximately 1,400 scholarly peer-reviewed journals and an extensive collection of books with global appeal. For more information on Wiley-Blackwell, please visit www.blackwellpublishing.com or <http://interscience.wiley.com>.

COURSES OF INTEREST

- **Choosing Sensors, Monitors and Instruments for PAT Programs—An Online Course**
course id# 2128
- **Cost Effective Quality-by-Design and Critical-to-Quality Tools for PAT—An Online Course**
course id# 2127
- **DQ: A Guide to Protecting Your Interests When Procuring Sensors—An Online Course**
course id# 2200
- **ICH Q9: Managing Risk in Pharmaceutical Manufacturing**
course id# 2158
- **Near Infrared Spectroscopy**
course id# 1583
- **PAT Online Process Analysis**
course id# 2030
- **Process Analytical Technology**
course id# 2085

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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.