Quality by Design in Pharmaceutical Manufacturing

- QTPP
- Design space and control strategy
- CQA, CMA and CPP
- ICH 8, 9, 10, 11, 12
- Role of Quality Risk Management in QbD
- How to implement QbD in generics
- PAT and QbD
- Examples and case studies

May 4-5, 2015

Holiday Inn – Pointe-Claire
6700 TransCanada HWY, Pointe-Claire, Québec, Canada H9R 1C2
(514) 697-7110

WWW.PROGAMMA.CA

Space is Limited
Act Today!
Stay Current
This course has been designed to provide a strong understanding of QbD concepts, objectives and techniques, that are the current thinking of FDA, EMA and Health Canada, we have provided several real study cases to link the theory and techniques to practice.
The course was designed for the pharmaceutical professionals with the responsibilities in product design, operation, management of the quality system, compliance and CMC application. They will learn all about the QbD requirement and how it relates to ICH Q8 and Q9 and how to integrate the different components effectively for a complete robust manufacturing system and relate it to Q 10 and 11.
By using QbD a new quality paradigm was born that will provide more robust processes as well as products, and true scientific understanding of the risk based critical quality attributes that can be properly controlled to continuously provide for a desired quality product that will meet its desired clinical performance.

Who will benefit?
Pharmaceutical, companies, who have some GMP background (at least 6 months) and need a step-by-step, understanding of QbD in pharmaceutical manufacturing:
QbD project Managers
QbD team
R&D
Regulatory Affairs
Production managers
Analytical Development
Compliance Auditing
QA and QC
Validation
This course is also of interest to Equipment Contractors and Consultants.

Learning Objectives
- Understand the Basic Fundamentals and Approach of QbD
- Understand Risk-Based GMP Compliance and FDA, ICH and ASTM Approaches
- Review Strategies for Defining Risk, Risk Factors and Risk Prioritization
- Use QbD to Mitigate Product Risk in Manufacturing Operations
- How to develop QTTP, how to use risk base tools to link to CQA
- How to develop design space, and define CPP
- Understand the Connection Between QbD and Process Analytical Technology (PAT) and laying the foundations for control strategy.
- How to use design of Experience (DoE)
- Implement the Concept of Continuous Improvement
- Case study that will demonstrate how we apply QbD in pharma manufacturing
Distinguished Speakers

Ady Sadek, M.Sc., P.Chem is president of proGamma Science Corporation, previously he spent 25 years in the pharmaceutical industry with BioResearch, Schering-Plough and Novartis Pharmaceuticals, holding positions such as Manager of Analytical & Development Labs, Director of Quality and Director of Quality Audit. He holds two master degrees in Organic and analytical chemistry. Ady’s vast experience in process design and validation started in 1981, when developing new formulations for FDA submissions. He has been involved in many validations and his experience extends from formulation development to scale up commercial batches and technology transfer. He provides strategic QbD and PAT projects management throughout Canada, USA and Europe to several multinationals.

Peter Bryla, Ph.D. is president of Bryla CMC-Reg Consulting, LLC, previously he spend more than 20 years in the pharmaceutical industry holding positions of increasing responsibility including vice president of Manufacturing and Process Development at Lux Biosciences and senior director or manager positions at Omeros Corporation, Barrier Therapeutics, Forest Laboratory, Bayer Corporation and Hoffmann-LaRoche having been responsible for development of drug substances and drug products, commercial launch preparations and global CMC regulatory submissions. He has worked on different pharmaceutical dosage forms for various dosage forms, including tablets, hard and soft gelatin capsules, injectables, silicone devices and implants, and utilized technologies like micelles systems, spray drying, hot melt extrusion and nano-milling for highly insoluble compounds. He holds a Ph.D. in pharmaceutical science and more than 20 papers and numerous presentations and posters.

David Tozer, Ph.D., CQE, Six Sigma black belt is president of Qualitiqua, Dr. Tozer has more than 25 years of experience in Quality management, in the pharmaceutical and software industries, after earning a Ph. D. in physics at the University of Waterloo. He then worked in the quality field for many years in the pharmaceutical, defence, aerospace, medical, manufacturing, and software industries. In industry, Dr. Tozer successfully led teams of people to improve their organizations using the Six Sigma methodology. He is an ASQ CQE and teaches quality courses for the ASQ and a joint ASQ McGill university program. Dr. Tozer trained over 500 people in various topics in the quality field.
Day 1

8:30 am  Registration- Continental Breakfast

**Introduction and Overview**
- What is QbD?
- QbD definitions
- QbD objectives
- Terminology
  - the current state vs. desired QbD state
  - characteristics of a successful QbD
- regulatory requirements FDA, Health Canada, and EMA
- FDA and EMA QbD pilot programs

**Considerations for Pharmaceutical Product by QbD**
- Product life cycle
- comparison of traditional approaches versus enhanced QbD approaches
- Risk-based, modern pharmaceutical manufacturing
- Brief review of ICH Q8, ICH Q9, ICH Q10, ICH Q11 and ICH Q12

**Implementation of Quality by Design in New Product Development**
- CMC, QbD and QbR role in Pharmaceutical Development
- Qbd development process
- How to develop QTTP, how to use risk base tools to link to CQAs
- Process understanding for effective technology transfer

**Using Quality Risk assessment to Determine criticality of product quality Attributes**
- what are the effective risk based tools used
- developing Qbd elements
- unit operations CQA examples

**Application of QbD and Risk Assessment for the development of Design Space**
- how to develop design space
- risk tools used
- software tools

4:30 pm  End of day 1
Day 2

8:30  Continental Breakfast

9:00  QbD Methodology
- The evolution of process understanding
- Target Quality Profile, Critical Quality Attributes
- Scale up considerations
- Process parameters ranking methods

QbD control Strategy - using Process Analytic Technology (PAT)
- PAT principles, levels of PAT implementation
- Control Strategies
- What tools are available for pharma applications?
- Understand the Connection between QbD and Process Analytical Technology (PAT) and laying the foundations for control strategy
- Advantages and challenges of continuous chemical processing

QbD: Design of Experiments (DoE)
- What is design of experiments?
- Advantages of design of experiments (DoE) vs. one factor at a time approaches
- The importance of pre-DoE experimentation and planning
  Factors, ranges, number of levels, responses
- Commercial DoE software

Interactive exercise: participants will be asked to develop an effective approach to handle certain problems.

Practical implementation of QbD
2- Using FEMA and DoE for the identification of main factors in formulation and process design space for Roller compacted IR Tablet

4:30 pm  End of Course
Registration Form

Quality by Design in Pharmaceutical Manufacturing

Montreal, Canada  May 4-5, 2015  □

Please return the completed registration form to:

By Mail:  By Fax: (514) 697-4355  By Phone: (514) 695-8622  Email: infoteck@progamma.ca
proGamma Science Corporation
6600 TransCanada, Suite 452,
Pointe Claire, Quebec, Canada H9R 4S2

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Venue: Holiday Inn  Air port, Dorval, Montreal, Quebec
Registration fee: $890.00, includes the presentation material, lunch and refreshments, for the registered delegate for the complete two days.
Group discount: Every 4 delegates the fifth is FREE, delegates must register at the same time.
Cancellation/Substitutions: You must notify us in writing (fax) one week before the conference date to cancel to receive a refund. No cancellation will be accepted after that date. Notify us by Fax for any substitutions. ASAP.
Accommodation Information: Registered delegates will have a corporate rate available through proGamma science Corporation at the Holiday Inn, Pointe Claire. To reserve a room and take advantage of this special rate call (514) 697-3540 for Montreal and ask for the proGamma Science Corp. discount.