

Practical Approaches to Quality by Design (QbD) for Pharmaceutical Process Research, Development and Manufacturing

presented by Dr Andrei Zlota, The Zlota Company LLC

24 - 26 April 2012

The Sheraton Sand Key, Clearwater, FL, USA



“Andrei is a gifted speaker with tons of experience & background. I learned a lot and realized there’s still a lot to learn.”

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Introduction

Attaining the "desired state" requires effective Quality by Design (QbD) implementation.

This course focuses on practical approaches to accelerated QbD implementation, and it makes practical recommendations for realistic implementation of QbD elements.

Participants will learn how to prioritize process parameters for screening designs, how to design robust processes using statistical design of experiments (DoE), how to bridge the bench and the commercial design spaces using mixing and scale-up calculations, how to quantify process risk, how to select suitable process analytical technology tools (PAT) and more.

For the benefit of process scientists, engineers, formulators, analytical chemists and manufacturing personnel, this course includes highly interactive, hands-on workshops, based on several case studies.

Effective technology transfer to pilot and manufacturing plants is also discussed, including process validation in the QbD paradigm.

Course Outline

Introduction

- Course objectives
- QbD in the context of the ICH guidelines for pharmaceutical manufacturing industry in the 21st century
- Overview and definitions; how new is the QbD concept?
- Current status of QbD implementation

ICH Guidelines

- Risk-based, modern pharmaceutical manufacturing
- Brief review of ICH Q8, ICH Q9, ICH Q10 and ICH Q11
- Status of implementation (US and Europe)
- ICH guidance covering questions and answers on Q8, Q9 and Q10 (2010)

QbD Methodology

- The evolution of process understanding
- Target Quality Profile, Critical Quality Attributes
- Process parameters ranking methods

Screening the Experimental Space

- 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
- Design quality: resolution and efficiency
- Commercial DoE software (sometimes a second opinion can be useful)

Robust Process Design

- Key and Critical Process Parameters
- Response surface methodology, process optimization (at small or intermediate scale)
- Using DoE to define a design space
- Process validation in the QbD paradigm
- Continuous process improvement

Risk Analysis

- Semi-quantitative risk estimates
- Process risk quantification using Monte Carlo simulations

Pharmaceutical Process Scale-Up

- Design space and scale-up factors
- Scale-up theory; scaling-up by scaling-down
- Mixing and scale-up calculations in turbulent regime, mixing times calculations (micromixing, mesomixing, and macromixing)
- Effective scale-up of heterogeneous solid-liquid processes (catalytic, API crystallization process scale-up)
- Process understanding for effective technology transfer
- The value of an equipment database
- Advantages and challenges of continuous chemical processing

Process Analytical Technology (PAT)

- PAT principles, levels of PAT implementation
- Control strategies
- Real time release

Regulatory Advantages

- QbD submissions
- QbD mock submissions in Europe and the US
- FDA and EMEA QbD pilot programs
- Learning from QbD "pioneers"

Register for this course by using the form overleaf or call:

“A very good course, placing
the concepts into context”

Course Tutor



Andrei Zlota obtained his Ph.D. in Organometallic Chemistry from the Weizmann Institute of Science in 1991. Prior to

his Ph. D. studies, he earned an M.S. in Chemical Engineering (Magna Cum Laude) in 1980 from the Bucharest Polytechnic Institute (Organic Chemical Technology), and an M.S. in Organic Chemistry from the Technion. He spent the first three years of his career in the biotechnology industry at Biofarm (Bucharest) where he was responsible for the successful implementation and scale-up of various technologies for products of natural origin and for semi-biosynthetic products. After postdoctoral stints at Indiana University and the University of Chicago, he worked in the technology development group at Monsanto (Searle) where he was involved in process scale-up and mechanistic investigations. In 1997 he joined Gillette, as Lead Technologist in the personal care division, where he was

responsible for the first scale-up of formulation processes, and for the process understanding of complex active ingredient delivery systems. In 2001 he joined Sepracor as Principal Engineer and during the next 5 years he was responsible for the scale-up of synthetic, diastereomeric resolution, and crystallization processes, including their successful transfer to manufacturing plants in Canada and India. He is now President and Chief Chemical Engineer of the Zlota Co., LLC that he founded in 2006. The firm specializes in the design and scale-up of robust chemical processes, and data mining. Services provided include consulting and training on methods for QbD implementation, accelerated process scale-up, the use of statistical design of experiments (DoE) for reaction innovation and development, pharmaceutical process scale-up, crystallization R&D, as well as formulation process R&D. More than 350 scientists from nearly 100 companies have benefited from these services to date.

Venue

Sheraton Sand Key Resort

1160 Gulf Blvd, Clearwater, Florida 33767-2799 USA
Tel: +1 727 595 1611 Fax: +1 727 596 1117
www.sheratonsandkey.com

The Sheraton Sand Key Resort, situated by white sandy beaches on the Gulf coast, provides a stress-free environment for both business and pleasure. Watersports are widely available and a marine aquarium, Nature Park and Reserve are nearby.

Accommodation

Accommodation has been reserved at the hotel at the special rate of \$185 + taxes per night, if booked before 24 March 2012. Reservations after this date will be accepted on a space available basis only, at the prevailing rack rate.

An accommodation booking form, for faxing your reservation directly to the hotel will be sent to you when you register.

Who Should Attend?

Organic Chemists – working in the pharmaceutical, pigment, agrochemical, explosives or fine chemicals industries

Development and Production Chemists

Chemical Engineers and Analysts

At the end of the course, participants will be able to:

- **Prioritize** process parameters prior to screening investigations
- **Design effective** DoE screening matrixes
- **Design robust** processes and assess key and critical process parameters
- **Execute** key mixing and scale-up calculations to bridge the bench and the commercial design spaces
- **Use** an equipment data base for effective technology transfer to pilot and manufacturing plants, and CMO's
- **Estimate** process risk
- **Make strategic decisions** on PAT implementation

Fee & General Information

\$1850.00

Includes lunch & refreshments, course dinner and comprehensive course manual.

The course begins with registration at 8.30 am on Tuesday 24 April and finishes at approximately 4pm on Thursday 26 April.



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Please register attendee(s) @ \$1850.00

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