



# SCIENTIFIC UPDATE

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## PRACTICAL APPROACHES TO QUALITY BY DESIGN (QbD) for CHEMICAL PROCESS R&D AND MANUFACTURING

15-17 MAY 2018

**Basel, Switzerland**  
Hotel Basel

"Very comprehensive overview of a broad subject. I attended expecting a refresher and actually left feeling I had learnt a lot."

**CSIRO**



A 3 day course given by  
**Dr Andrei Zlota**

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# PRACTICAL APPROACHES TO QUALITY BY DESIGN (QbD) for CHEMICAL PROCESS R&D AND MANUFACTURING

A 3 day course given by Dr Andrei Zlota

15-17 May 2018 Basel, Switzerland, Hotel Basel

Multiple attendees discounts  
**UP TO 15% available**

## INTRODUCTION

**QbD is no longer just a regulatory initiative; because QbD is good development, QbD is an industry initiative supported by regulators.**

**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.

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

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.

\*A QbD course dedicated to drug product development is also available; if interested, please inquire.

## COURSE OUTLINE

### Introduction

- > Course objectives
- > QbD in the context of the ICH guidelines for pharmaceutical manufacturing in the 21st century
- > Overview and definitions
- > Current status of QbD implementation

### ICH Guidelines

- > Risk-based, modern pharmaceutical manufacturing
- > Brief review of ICH Q8, ICH Q9, ICH Q10 and ICH Q11
- > ICH guidance updates (2010, 2011 and 2012)

### 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; prior knowledge
- > Factor types, ranges, number of levels, responses
- > Design quality: resolution and efficiency
- > Commercial DoE software

### Robust Process Design

- > Critical Process Parameters
- > Response surface methodology, process optimization to define a design space
- > Strategies in defining and presenting a design space
- > Process validation in the QbD paradigm
- > Control strategy

### Risk Analysis

- > Semi-quantitative risk estimates
- > Process risk quantification using Monte Carlo simulations
- > Design space borders

### Chemical Process Scale-Up

- > Design space and scale-up factors
- > Scale-up theory
- > Mixing and scale-up calculations in turbulent regime, mixing times calculations (micromixing, mesomixing, and macromixing)
- > Effective scale-up of heterogeneous solid-liquid processes
- > Process understanding for effective technology transfer
- > Advantages and challenges of continuous chemical processing

### Process Analytical Technology

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

### Regulatory Advantages

- > QbD submissions

### Hands-on Workshops

- > Crystallization process
- > Successful scale-up of a fast reaction system
- > ICH Q11 example 10.1
- > QbD HPLC method development

## VENUE

**Hotel Basel**  
Münzgasse 12  
4001 Basel  
Switzerland

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[www.hotel-basel.ch/en/home/](http://www.hotel-basel.ch/en/home/)

Set in the city's Old Town and pedestrian zone, this refined hotel is a 5-minute walk from the Rhine and has a great central location.





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**Start** 8.30am - Tuesday 15 May  
**Finish** 5.00pm - Thursday 17 May  
**Course Dinner** 6.30pm - Tuesday 15 May  
**Course Fee:** €2,370

Which includes comprehensive course manual, refreshments throughout the day, lunch and one course dinner.

**Course Fee: €2,370**

## COURSE TUTOR

### Dr Andrei Zlota

The ZLOTA  
Company LLC



Andrei obtained an M.Sc. in Chemical Engineering from the Bucharest Polytechnic Institute (Organic Chemical Technology, 1980). After working in the industry for several years, he obtained an M.Sc. in Chemistry from the Technion (Organic Chemistry, 1986).

Subsequently he obtained a Ph.D. in Chemistry from the Weizmann Institute of Science (Organometallic Chemistry, 1991). He has been a regular contributor to the Organic Process R&D Journal (OPRD) Highlights from the Literature section since 2003, and he also participates in the review of papers submitted for publication in OPRD. In 2006 Andrei founded his consulting firm, The Zlota Co., LLC, specializing in Quality by

Design (QbD) implementation, including practical statistical design of experiments, accelerated process scale-up, and meaningful Process Analytical Technology practice.

Andrei provided QbD training to more than 2,000 scientists from 180 companies in the US, Europe and Asia. Thirty five companies obtained, and continue to obtain project support from The Zlota Co. with their successful implementation of various elements of QbD methodology.

Note: A full version of Andrei's biographical note is available on our website.

"Enlightening on a new approach (for me) to face process development."

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## Upon completion 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 critical process parameters
- > Execute key mixing and scale-up calculations to bridge the bench
- > and the commercial design spaces
- > Estimate process risk, define control and design spaces
- > Make strategic decisions on PAT implementation

## IN-HOUSE COURSE

For 8+ people contact us to discuss holding this event In-House - [sciup@scientificupdate.com](mailto:sciup@scientificupdate.com)

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For late applications, please register online or fax the completed registration form, including credit card payment information.

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Should you be unable to attend and cancel in writing no later than 1 month before the start of the course, Scientific Update will refund your registration less £300 (or equivalent in €/€) processing fee. Unfortunately refunds are not possible after that date. Substitutions can be made at any time.

# PRACTICAL APPROACHES TO QUALITY BY DESIGN (QbD)

15-17 May 2018 Basel, Switzerland



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