



SCIENTIFIC UPDATE

We've got chemistry

PRACTICAL APPROACHES TO QUALITY AND DEVELOPMENT BY DESIGN (QD&D)

for Robust Chemical Processes

4-6 JUNE 2019

"Dr Zlota provided an outstanding seminar. The material was well referenced, and presented in an engaging manner. I would highly recommend the course to anyone involved in developing a chemical process."

**San Francisco,
USA**

AMA Executive
Conference Center

A 3 day course
presented by
Dr Andrei Zlota

PRACTICAL APPROACHES TO QUALITY AND DEVELOPMENT BY DESIGN (QbD)

for Robust Chemical Processes

Early Bird Rate
SAVE 20%
if registered before
15/03/2019

4-6 June 2019 San Francisco, USA, AMA Executive Conference Center

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
- > Quality and Development by Design (QbD)
- > Current status of QbD implementation

ICH Guidelines

- > Risk-based, modern pharmaceutical manufacturing
- > Brief review of ICH Q8, ICH Q9, ICH Q10 and ICH Q11
- > NEW: ICH Q12
- > ICH guidance updates (2010 - 2015)
- > EMA guidance: Design Space, NOR's, PAR's (2017)

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

AMA Executive Conference Center
55 4th St, San Francisco,
CA 94103, USA

www.amaconferencecenters.org/san-francisco.htm

Located in the San Francisco Marriott Marquis Hotel, AMA's San Francisco Executive Conference Center is

just minutes from the Cable Cars, Chinatown, shopping, museums and only 15 miles from the San Francisco International Airport.

For accommodation, a list of nearby hotels will be sent to you once you register for the course.





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Start 9.00am - Tuesday 4 June

Finish 3.30pm - Thursday 6 June

Course dinner 7.00pm - Tuesday 4 June

Course Fee: \$2,599 / **Early Bird Rate:** \$2,079

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

Course fee: \$2,599 / **Early Bird Rate:** \$2,079

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.

"Dr Zlota is an expert in the field of QbD, and I highly recommend this course."

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

REGISTRATION

You can either use our fast online booking system or mail or fax the attached registration form to:
Scientific Update
Maycroft Place, Stone Cross, Mayfield, East Sussex, TN20 6EW, UK
Fax Number +44 1435 872734

How to Pay

When you register online, you can have the option to pay via credit card (Amex, Mastercard or Visa). For email payments please include course title, card number, expiry date and security code. A receipted invoice will be automatically generated once paid and sent via email. Should your company wish to pay by cheque or bank transfer bank details will be supplied with an invoice.

Bank Transfer or Cheque

Should your company wish to pay by cheque or bank transfer, on booking you can choose between paying in either €, \$ or £. All bank details will be supplied with an invoice.

Group Discounts

If you are booking a large group of delegates, further discount may be applicable. Please contact us directly to find out more.

Confirmation of your registration

These will be sent via email.

Late Applications

Late applications are permitted depending on availability, please register online and pay by credit card only.

Cancellations/Refunds

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.



4-6 June 2019 San Francisco, USA

No. of attendees @ \$2,599

SAVE 20% Early Bird Rate \$2,079

if registered before 15/03/2019

First attendee

Company
Title (Dr/Prof/Mr/Mrs/Ms)
First name
Surname
Job Title
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Country
Tel
Fax
Email
Mobile
Special Diet
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What's new in Process Chemistry?

Second attendee

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Surname
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Third attendee

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Dollars GBP* or Euros*

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*payments via Amex can only be made in US dollars

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If you select to pay in GBP, or Euros the amount charged will be based on the exchange rate at the time of preparing the invoice.

Discounts

If you are booking two or more people on to this course, please contact us directly to find out whether a further discounts can be applied.

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