SCIENTIFIC UPDATE

We've got chemistry

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

16-18 OCTOBER 2018

Frankfurt, Germany
Radisson Blu Frankfurt

"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

PROFESSIONAL DEVELOPMENT TRAINING

Scientific Update provides training courses for industrial chemists and chemical engineers in chemical development and scale-up and many other specialist topics in organic and process chemistry. Our short intensive training courses enable scientists to learn about highly relevant topics, to broaden their knowledge and to keep abreast of new science, new technology and new techniques.

www.scientificupdate.com | info@scientificupdate.com

Register for this course by using our fast online booking system or form on page 4 or call +44 (0)1435 873062

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

A 3 day course given by Dr Andrei Zlota

16-18 October 2018 Frankfurt, Germany, Radisson Blu Frankfurt

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

Radisson Blu Frankfurt
Franklinstraße 65, 60486
Frankfurt am Main, Germany

+49 69 7701550

www.radissonblu.com/en/hotel-frankfurt

Featuring a unique circular architectural structure, this modern upscale hotel is a 13-minute walk from the Frankfurt Main West S-bahn station. There's also an indoor heated pool, a health club and a spa.

SCIENTIFIC UPDATE

We've got chemistry

Start 8.30am - Tuesday 16 October
Finish 5.00pm - Thursday 18 October
Course Dinner 6.30pm - Tuesday 16 October
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."
Recordati

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 (Mastercard or Visa). 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
Group discounts are available on two or more attendees - see registration form. This offer only applies if bookings are made simultaneously and from the same billing address.

Confirmation of your registration
These will be sent via email.

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

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.

PRACTICAL APPROACHES TO QUALITY BY DESIGN (QbD)

16-18 October 2018 Frankfurt, Germany

NEW FAST ONLINE REGISTRATION

Why not register quickly online and receive instant confirmation? Look for the **register** button on the event of your choice.
www.scientificupdate.com

No. of attendees _____ **@ €2370**

Special Offer!
Register 2 delegates and receive 5% on 2nd booking
Register 3 delegates and receive 10% on 3rd booking
Register 4 or more delegates and receive a 15% discount

First attendee

Company
Title (Dr/Prof/Mr/Mrs/Ms)
First name
Surname
Job Title
Address
Post Code / Zip
Country
Tel
Fax
Email
Mobile
Special Diet

I would like to subscribe to your FREE bi-monthly newsletter What's new in Process Chemistry? ☐

Second attendee SAVE 5%

Title (Dr/Prof/Mr/Mrs/Ms)
First name
Surname
Job Title
Tel
Fax
Email
Special Diet

I would like to subscribe to your FREE bi-monthly newsletter What's new in Process Chemistry? ☐

Third attendee SAVE 10%

Title (Dr/Prof/Mr/Mrs/Ms)
First name
Surname
Job Title
Tel
Fax
Email
Special Diet

I would like to subscribe to your FREE bi-monthly newsletter What's new in Process Chemistry? ☐

Invoice Address (if different to delegate address)

Address
Post Code / Zip
Country
Tel
Fax

☐ Please invoice my company

Purchase Order:
Promotion Code:

Payment Methods

Payment will be made by:
☐ Cheque ☐ Bank Transfer ☐ Credit Card

In Currency:
☐ Euros ☐ GBP* ☐ or Dollars*

We accept the following credit cards:
Amex* Mastercard Visa

To pay by credit card a secure link will be provided once you receive your booking confirmation email, this will then take you to a secure payment gateway.
*payments via Amex can only be made in US dollars

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

Discounts
Complete the details for either two or three delegates and your discount will automatically be applied. This offer only applies where all delegates are booked simultaneously and at the same billing address.

Cancellations
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 fee less £300 (or equivalent in €/$) processing fee. Unfortunately refunds are not possible within 1 month of the course date. Substitutions can be made at any time.

Data Protection
Scientific Update Ltd is registered under the Data Protection Act 1998. We will store your information securely and only share your contact details with other attendees at this event. If you are happy for your details to be passed to any third parties please tick here: ☐

For full terms of business and payment details please see our website

Please complete this form and fax to +44 (0)1435 872734

You can also download the PDF from www.scientificupdate.com, complete the form online and email back
Scientific Update, Maycroft Place, Stone Cross, Mayfield, E. Sussex TN20 6EW, UK
+44 (0)1435 873062 sciup@scientificupdate.com