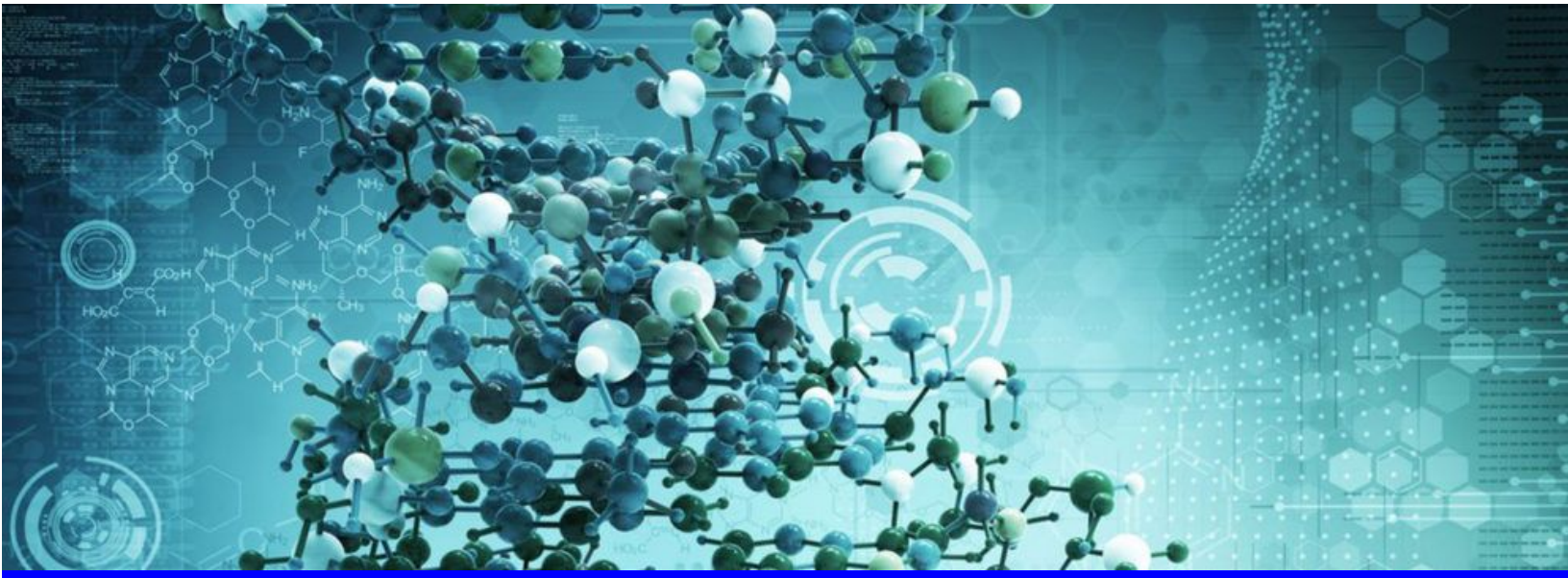
TZC **THE ZLOTA COMPANY, LLC**

RAPID PROCESS SCALE-UP and ROBUST PROCESS DEVELOPMENT



Practical Quality and Development by Design (QDbD) for Robust Chemical Process Development

COURSE INSTRUCTOR:
Dr. Andrei A. Zlota

Bucharest, Romania

Mercure BUCHAREST
City Center Hotel

15-17 October, 2019

info@thezlotacompany.com

www.thezlotacompany.com

"For a practicing organic chemist QbD is a fairly abstract concept. This course does a wonderful job of conceptualizing the entire process and make it understandable. It is also well balanced in terms of showcasing the strengths and weaknesses. I found myself absolutely engaged for the full three days, even in the areas that I thought I wouldn't be."

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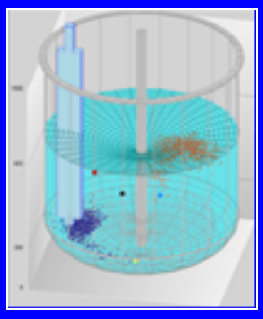

SAVE more than 400 EUR | REGULAR FEE 1,963 EUR | **EARLY BIRD FEE (before 16 July, 2019)** 1,560 EUR

Additional discounts available for multiple registrations, please inquire: info@thezlotacompany.com.

Fee includes thorough course manual, refreshments during coffee and tea breaks, lunches, and one group dinner featuring both international as well as authentic Romanian cuisine.

COURSE OVERVIEW

- Clarifies the distinction between robust process development and regulatory flexibility afforded by QDbD implementation
- Practices a balanced approach between the theory and the practice of QbD
- Demonstrates the business value generated by QDbD
- Includes a unique blend of all the QbD methods: risk analysis, statistical design of experiments (DoE), scale-up science, process analytical technology (PAT) and regulatory guidelines
- Hands-on learning: two hands-on workshops (DoE and scale-up) and several interactive discussions based on real-life examples
- Facilitation by a chemist and chemical engineer with over 25 years experience in QbD and process R&D, offering realistic advice for robust process development and scale-up, and Design Space implementation

WHO SHOULD ATTEND

Chemists, engineers, project managers and supervisors who seek to learn about scientifically meaningful and cost effective approaches to QbD implementation. Typical attendees include process chemists, process engineers, analytical chemists, manufacturing engineers, QA/QC and Regulatory Affairs personnel, as well as formulation scientists.

COURSE SYLLABUS

1. Introductory concepts
- QbD business benefits, status of implementation
- Sources of risk, risk mitigation, the cost of poor quality
- Target Quality Profile, Critical Quality Attributes

2. Risk analysis
- Process understanding
- Fit-for-purpose risk analysis
- Factor ranking methods

3. Screening the Experimental Space
- Pre-DoE experimentation
- DoE methodology: responses; factors: types, number, levels, ranges
- DoE data analysis, statistical significant factors
- Case studies

4. Response Surface Methodology to define a Design Space
- Optimization designs and analysis
- Design Space strategies, verification experiments
- Critical Process Parameters
- Case studies

5. Design Space Scale-Up
- Fundamentals of scale-up theory
- Mixing and scale-up calculations, scale-up factors
- Chemical engineering-driven chemistry experiments
- Case studies

6. Process robustness
- Strategies for the development of robust processes
- Risk quantification, process capability indexes
- Control strategy
- Case studies
- Process validation (QbD)

7. Process Analytical Technology
- Definitions, strategies
- PAT benefits and challenges
- Continuous processing
- Examples

8. API Crystallization (QbD)
- Crystallization fundamentals
- Mixing impact on crystallization processes
- Crystallization technology transfer and scale-up (QbD)
- Examples

9. ICH, FDA, EMA Guidelines
- ICH Q8, Q9, Q10 Q11, and ICH Q12
- ICH Q11 examples discussion
- Follow-up guidance documents
- Regulatory submissions
- Quality metrics, enabling technologies, KASA initiative

10. Hands-on workshops (DoE, chemical process scale-up)

COURSE VENUE

Mercure BUCHAREST City Center Hotel

15-17 George Enescu St. Bucharest 10302, Romania

+40-372-426-000

h9680@accor.com

A block of single rooms has been booked for the October 15-17, 2019 QDbD course participants, for 95 EUR/night, when reservations are made prior to 30 August, 2019. An Accor property, this hotel has received 2018 and 2019 Trip Advisor Traveler's Choice awards. It is located minutes walking distance from several Bucharest landmarks such as the Romanian Athenaeum concert hall, the Romanian National Art Museum, the Parliament House, and the University Square.

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"The excellence of the course is a tribute to the knowledge and understanding of the presenter, Dr. Andrei Zlota, whose ability and willingness to answer and discuss questions were remarkable."

COURSE INSTRUCTOR

Dr. Andrei A. Zlota

Dr. Zlota is the President and Chief Chemical Engineer at The Zlota Company which he founded in 2006. During this time Andrei provided consulting for risk analysis, statistical design of experiments (DoE), chemical process scale-up, crystallization process development, and process analytical technology (PAT) for 36 pharmaceutical companies. Andrei also trained 2,500 scientists from 200 companies worldwide on QbD methodology. Previously, Andrei worked for Sepracor, Gillette, Monsanto and Biopharm. Dr. Zlota obtained his PhD in Chemistry from the Weizmann Institute of Science, his MSc in Chemistry from the Technion and his MSc in Chemical Engineering from the Bucharest Polytechnic Institute.

Note: *Andrei's full bio is available at www.thezlotacompany.com*

COURSE OBJECTIVES

Upon completion, the course participants will be able to:

- Execute rapid fit-for purpose risk analysis
- Design, execute and analyze effective DoE matrixes for screening, optimization, and robustness assessment
- Effectively use PAT tools at small scale towards the development of process understanding in support of robust process development and scale-up
- Establish scale-up factors, and develop meaningful process models that include both scale- independent and scale-dependent factors
- Propose, verify and defend a Design Space, identify critical process parameters and develop a control strategy for low risk technology transfer

IN-HOUSE COURSES

For groups larger than seven participants, a customized course can be delivered in-house, please inquire: info@thezlotacompany.com.

REGISTRATION

Go to thezlotacompany.com and register on-line, or e-mail the pdf scan of the form below to: **info@thezlotacompany.com**.

Upon confirmation of registration an invoice shall be e-mailed to the registrant for payment by electronic bank transfer.

CANCELLATION POLICY

Cancellations must be made in writing at **info@thezlotacompany.com**, and they are subject to a 360 EUR cancellation fee. If cancellation is made more than thirty (30) days prior to the course, a refund equal to the fee paid minus the 360 EUR cancellation fee shall be issued. If cancellations are made less than thirty (30) days prior to the course, a voucher for the value of the fee paid minus 360 EUR cancellation fee will be issued for use towards the fee of another course offered by The Zlota Co., either by the same registrant, or by anyone else in that company. If a registrant fails to attend but has not cancelled the registration, neither a refund nor a voucher shall be issued. Requests for substitutions must be made in writing to: **info@thezlotacompany.com**. Hotel cancellations are the responsibility of the registrant.

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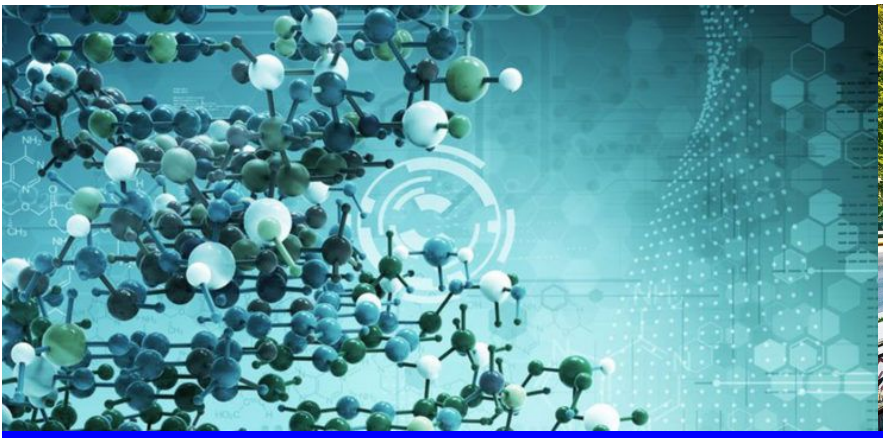

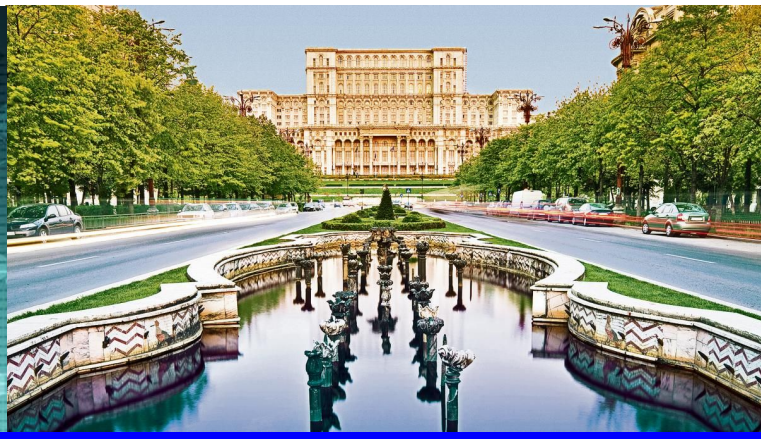

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REGISTRATION FORM

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Company Name	
Title (Dr/Mr/Ms)	
First Name	
Last Name	
Job Title	
Street Address	
City	
Post/Zip Code	
Country	
e-Mail Address	
Office telephone number	
Mobile telephone number	

I agree with the cancellation policy described above, please initial here: _____

We will store your contact information securely, and use it for the purpose of communicating course updates, sharing it only with participants of the same course for which you registered. Additional details regarding our privacy policy can be found at **http://www.thezlotacompany.com**.

If you agree to have your contact information shared with third parties, please initial here: _____