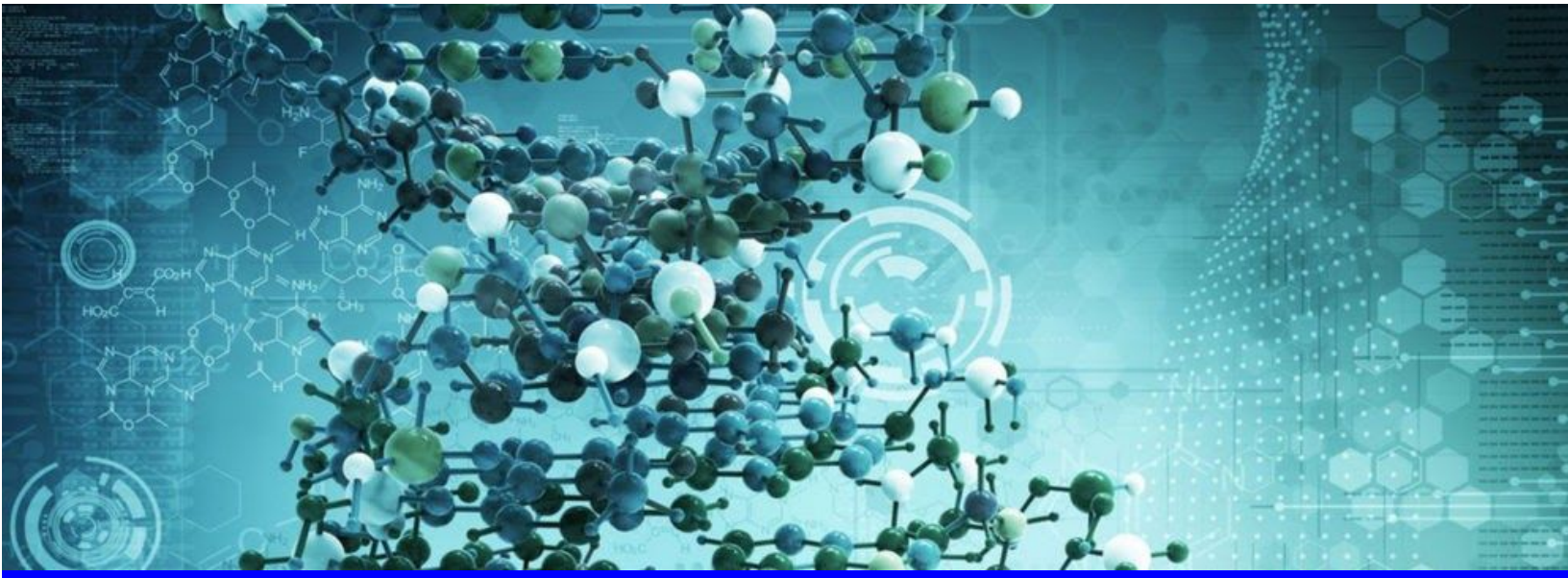
TZC **THE ZLOTA COMPANY, LLC**

RAPID PROCESS SCALE-UP and ROBUST PROCESS DEVELOPMENT



QbD Elements (A): Robust Process Scale-Up and Statistical Design of Experiments (DoE)

COURSE INSTRUCTOR:
Dr. Andrei A. Zlota

Basel, Switzerland

Der Teufelhof Basel, Switzerland

April 21-22, 2020

info@thezlotacompany.com

www.thezlotacompany.com

"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."

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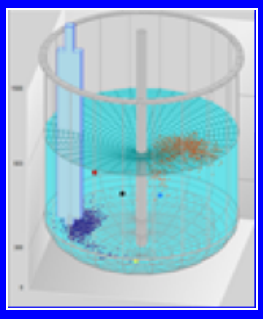

SAVE more than 200 EUR | REGULAR FEE 1,690 EUR | **EARLY BIRD FEE (before Feb 21, 2020)** 1,482 EUR

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

The fee includes course manual, coffee and tea breaks, lunches, and one group dinner.

BONUS: each course participant is entitled to a free of charge webcourse ($1,300 value):
"QbD Elements (C): Process Analytical Technology, Continuous Manufacturing and QbD Regulatory Guidance Documents"

Delivered within six months from completion of the QbD Elements (A) or (B) courses | up to five participants can attend

COURSE OVERVIEW

- Two critical Quality by Design (QbD) elements are meaningfully discussed: chemical process scale-up, and statistical design of experiments (DoE)
- Effective strategies for screening and optimization DoEs
- A practical approach for the identification of scale-up factors
- Demonstrates the valuable synergy between process scale-up and DoE
- Practical learning: two hands-on workshops (DoE and scale-up) and several interactive discussions based on real-life examples
- A balanced approach between the theory and the practice of DoE and scale-up methodology
- Facilitation by a chemist and chemical engineer with over 25 years of 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 chemical process scale-up and statistical design of experiments. Typical attendees include process chemists, process engineers, analytical chemists, and manufacturing engineers.

COURSE SYLLABUS

1. Introduction
- Robust processes development using QbD methodology, low technology transfer risk
- DoE vs. One-Variable-at-A-Time experimentation, the power of statistics when used in conjunction with chemical knowledge
- The structure of a DoE experiment
- Commercially available DoE platforms

2. Screening DoEs
- Strategies for effective screening DoEs; risk analysis and pre-DoE experimentation; responses, factor types, and their ranges
- Categorical variables
- Factorial, definitive screening, and Plackett-Burman designs, confounding
- Frequently investigated factors in reaction and crystallization screening
- The quality of a screening DoE; randomization, replication, blocking
- Fit-for-purpose screening DoE data analysis; balancing practical and statistical significance; model quality, model manipulation, Analysis of Variance (ANOVA)
- Key DoE statistical concepts and the power of data visualization
- Design augmentation
- Case studies: chemical reaction, crystallization process

3. Optimization DoEs
- The structure of Response Surface Methodology (RSM) DoEs
- Central Composite and Box-Behnken designs
- RSM DoE data analysis, model verification
- Optimizing multiple responses
- Sweet spot, design and control space
- Critical Process Parameters
- Robustness assessment, probabilistic risk calculations, process capability
- Case studies: chemical reaction, crystallization process

4. Hands-on DoE workshop (group work)

5. Batch Process Scale-Up: Introduction
- Design Space defined using reaction kinetics, examples
- Fundamentals of scale-up theory, similarity
- Scale-up challenges in the pharmaceutical industry
- Mixing mechanisms and their characteristic times
- Mixing and scale-up calculations, scale-up factors
- Chemical engineering-driven chemistry experiments, meaningful experimentation scale

6. Reliable Process Scale-Up Strategies
- Homogeneous processes, mixing impact on selectivity
- Heterogeneous liquid-liquid and gas-liquid processes
- Crystallization processes
- The synergy between DoE and Scale-Up science

7. Hands-on scale-up workshop (group work)

8. Review, Questions and Answers, References

COURSE VENUE

Der Teufelhof Basel

Leonhardsgraben 49, 4051, Basel, Switzerland

+41-61-261-1010

www.teufelhof.com

A block of single rooms has been booked for the course participants,, at 218 CHF per night, when reservations are made prior to February 21, 2020.

THE ZLOTA COMPANY, LLC

RAPID PROCESS SCALE-UP and ROBUST PROCESS DEVELOPMENT

"I was very impressed with the diversity of topics covered, and Andrei's mastery of multiple disciplines."

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 more than 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:

- Design meaningful screening DoEs to identify statistically significant factors using the minimum number of experiments
- Design practical optimization DoEs for the development of a robust process, the definition of a scaleable design space, and for a robust control strategy
- Design relevant scale-up investigations to understand the mixing controlling mechanism in order to reduce scale-up and technology transfer risk
- Use tips for rapid robust process development, and for the determination of critical process parameters

IN-HOUSE COURSES

For groups larger than five participants a customized webcourse can be offered. For groups larger than eight 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 390 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 390 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 390 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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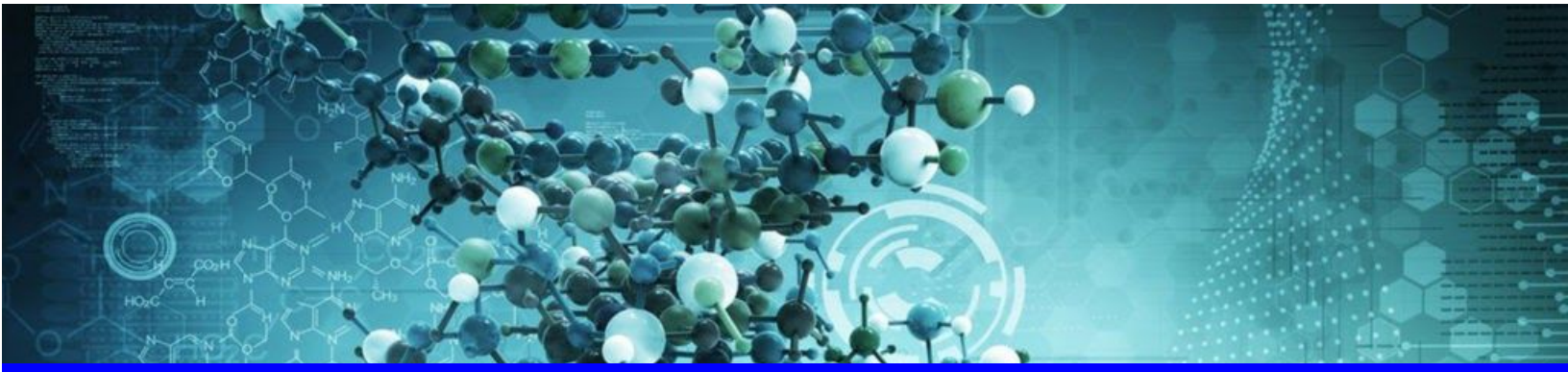

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Basel, Switzerland, April 21- 22, 2020

REGISTRATION FORM

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.

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: _____