

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

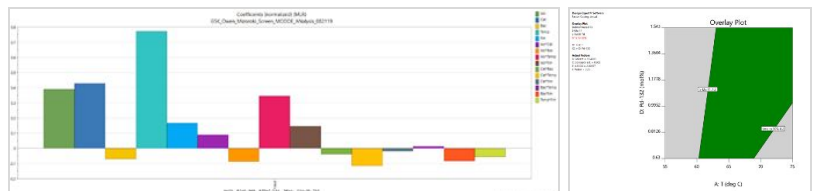
Webcourse

COURSE INSTRUCTOR:
Dr. Andrei A. Zlota

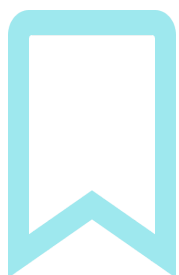
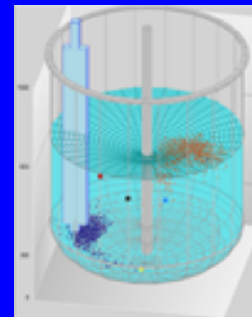
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“The excellence of this course is a tribute to the knowledge and understanding of the presenter, Dr. Andrei Zlota, whose ability and willingness to answer and discuss questions were remarkable”.



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WEBCOURSE FEE: \$1,560 (1482 EUR)

Additional discounts available for multiple registrations, please inquire: info@thezlotacompany.com. A hard copy of the manual can be shipped to interested participants (handling and shipping fees only)

Three sessions, three hours each, on three consecutive days, 8:30 AM -11:30 AM (EST), 14:30-17:30 (CET)

Webcourse dates posted at <https://thezlotacompany.com>, or please inquire at info@thezlotacompany.com

Groups preferring different times please inquire at info@thezlotacompany.com

COURSE OVERVIEW

- Two critical Quality by Design (QbD) elements are 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
- 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 for 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 effective DoE

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, low risk technology transfer
- DoE vs. One-Variable-at-A-Time experimentation
- The structure of a DoE experiment
- Commercially available DoE platforms

2. Screening DoEs

- Risk analysis: Data mining tool, and FMEA
- Fit-for-purpose DoEs
- Screening DoE strategies
- Frequently investigated factors in reaction and crystallization screening
- The quality of a screening DoE
- Fit-for-purpose screening DoE data analysis; practical and statistical significance; model quality, Analysis of Variance (ANOVA)
- DoE statistical concepts, 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 & Box-Behnken designs
- RSM DoE data analysis, model verification
- Optimizing multiple responses

- Sweet spot, design and control space
- Critical Process Parameters
- Robustness assessment, probability of process failure, process capability
- Case studies: chemical reaction, crystallization process

4. Hands-on DoE workshop

5. Batch Process Scale-Up: Introductory Concepts

- Design Space defined using reaction kinetics
- 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
- Design Space defined using reaction kinetics

6. Reliable Process Scale-Up Strategies

- Homogeneous process scale-up, mixing impact on selectivity
- Heterogeneous process scale-up, crystallization scale-up
- The synergy between DoE and Scale-Up science

7. Hands-on scale-up workshop

8. Review, Questions and Answers, References

"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 40 pharmaceutical companies. Andrei also trained 3000 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 <https://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 the risk of scale-up and technology transfer
- 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 in-house webcourse can be delivered, please inquire: info@thezlotacompany.com.

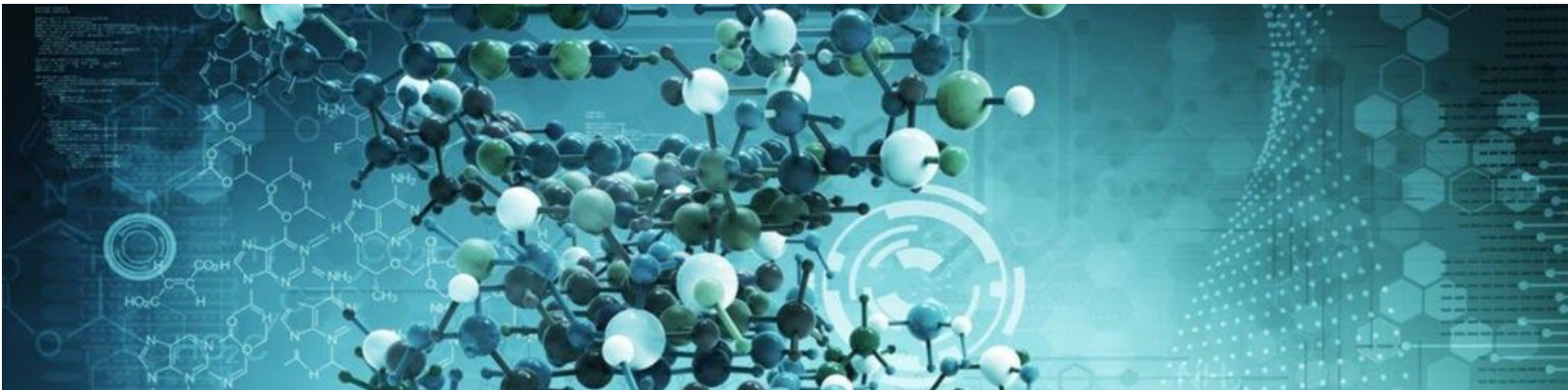
REGISTRATION

Go to www.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 wire 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 for another course offered by The Zlota Co., either by the same registrant, or by anyone else in the same company. If a registrant fails to attend but has not canceled the registration, neither a refund nor a voucher shall be issued. Requests for substitutions must be made in writing to: info@thezlotacompany.com.



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REGISTRATION FORM

Go to <https://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.

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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 <https://thezlotacompany.com>. If you agree to have your contact information shared with third parties, please initial here: _____