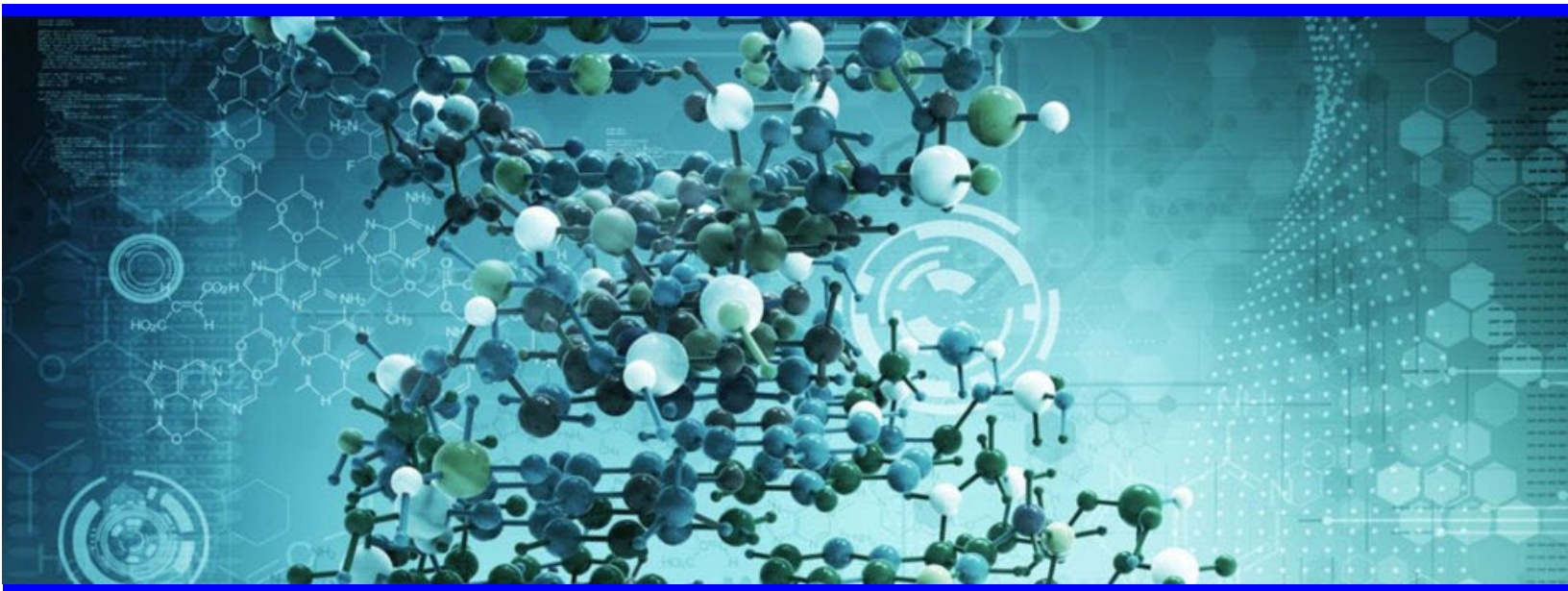
TZC **THE ZLOTA COMPANY, LLC**

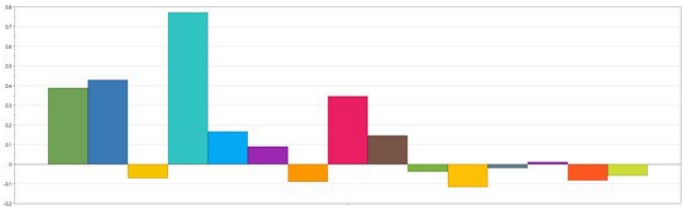
RAPID PROCESS SCALE-UP and ROBUST PROCESS DEVELOPMENT



Reaction Development Using Statistical Design of Experiments (DoE)

COURSE INSTRUCTOR:

Dr. Andrei Zlota



info@thezlotacompany.com

https://thezlotacompany.com

"Excellent course. Lots of information covered... pitched at a perfect level. Andrei really made the course enjoyable-he is a fantastic teacher...very patient, answering all the questions posed to him!"

Reaction Development Using Statistical Design of Experiments (DoE)

WEBCOURSE FEE: $1,651 (1391 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

- Uses a case study-based approach to discuss DoE methodology
- Practices a balanced approach between the theory and the practice of DoE
- Includes tips for solutions to a unique blend of several representative problems in the practice of DoE for reaction development
- Hands-on learning: two workshops and several interactive discussions
- Facilitation by a chemist and chemical engineer with over 25 years experience in DoE, QbD and process R&D, offering realistic advice for robust process development, 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 DoE implementation. Typical attendees include process chemists, process engineers, analytical chemists, and Regulatory Affairs personnel.

The course discusses DoE at an intermediate level, and basic DoE knowledge is assumed (such as that acquired by attending our QbD Elements (A) or (B) courses).

COURSE SYLLABUS

1. Introductory concepts

- Review of key DoE concepts
- DoE feasibility
- Pre-DoE experimentation

2. DoE for Reaction Screening in Discovery

- DoE screening strategies
- Categorical factors
- Design discussion
- Fit-for-purpose data analysis
- Machine learning tool
- Statistical vs. practical significance
- Case studies

3. DoE for Reaction Screening in Process Development

- Screening and optimization strategies
- Categorical factors challenges
- PCA and DoE for reaction development
- DoE for reaction and work-up
- Statistical concepts for DoE
- Fit-for-purpose data analysis
- Case studies

4. Design Augmentation

- Design quality
- Design augmentation strategies
- Scale-independent and scale-dependent factors
- Case studies

5. Optimization (RSM) Designs

- Optimization (RSM) designs
- Meaningful PAT use
- Model editing strategies
- Verification experiments
- Case studies

6. Design Space, Process Robustness

- Process robustness quantification
- Probabilistic risk calculations
- Design Space, PARs/NORs
- Critical process parameters
- Technology transfer
- Principal component analysis for historical batch data analysis
- Case studies

7. Review, Q&A, references

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"Andrei is a great presenter, very knowledgeable, and talented."

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 machine learning analysis of unstructured data for 40 pharmaceutical companies. Andrei also trained 3100 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:

- Rapidly design the best fit-for-purpose reaction screening DoE
- Meaningfully balance matrix size with the amount of screening information required
- Execute relevant data analysis using statistical, chemical and practical considerations
- Select appropriate factor ranges and star-points for the design of suitable optimization (RSM) DoEs
- Propose, verify and defend a Design Space, and PARs/NORs, identify critical process parameters and develop a control strategy for low risk technology transfer

IN-HOUSE WEBCOURSES

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

REGISTRATION

Please 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 360 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 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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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.

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 **https://www.thezlotacompany.com**.

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