

## “Design Space Strategies and Case Studies (chemical reaction, crystallization and milling)”

COURSE INSTRUCTOR:  
Dr. Andrei A. Zlota

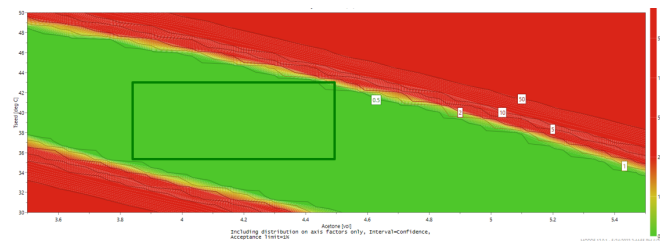
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**NEW Webcourse**

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*“Andrei is a great presenter,  
very knowledgeable, and  
talented.”*

# "Design Space Strategies and Case Studies (chemical reaction, crystallization and milling)"



## WEBCOURSE FEE: \$1,703 (1651 EUR)

Additional discounts available for multiple registrations, please inquire: [info@thezlotacompany.com](mailto: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](mailto:info@thezlotacompany.com). Groups preferring different times please inquire at [info@thezlotacompany.com](mailto:info@thezlotacompany.com).

## COURSE OVERVIEW

- Clarifies the Design Space concept
- Explains the theory of developing a Design Space
- Design Space verification
- Describes common errors made when building a Design Space
- Case studies: chemical reaction, crystallization and milling
- Practical tips for proposing a justifiable Design Space
- 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 practical 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 QbD 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

- 1.1 QbD fundamentals
- 1.2 QbD business benefits
- 1.3 Design Space definition

### 2. Developing a Design Space, the Theory

- 2.1 Risk analysis
- 2.2 Identifying potential Critical Process Parameters
- 2.3 Suitable DoE's for developing a Design Space
- 2.4 Fit-for-purpose DoE data analysis
- 2.5 Determine the actual Critical Process Parameters

### 3. Design Space verification

- 3.1 Reliable process models
- 3.2 Design Space verification strategies
- 3.3 Quantifying process robustness
- 3.4 Define a control strategy

### 4. Common errors made when developing a Design Space

- 4.1 Statistical errors
- 4.2 Experimental errors
- 4.3 Scale-up challenges

### 4. Practical tips for proposing a justifiable Design Space

- 4.1 Regulatory expectations
- 4.2 Regulatory challenges

### 5. Case Studies

- 5.1 Chemical Reaction (and work-up)
- 5.2 Crystallization
- 5.3 Wet and Dry milling

### 6. Hands-on workshops

### 7. Review, Q&A, 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 over 40 pharmaceutical companies. Andrei also trained over 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:

- Understand the concept of Design Space
- Avoid common mistakes in defining a Design Space
- Rapidly develop and verify a justifiable Design Space
- Determine Critical Process Parameters
- Understand the different approaches for developing Design Spaces for chemical reactions, crystallizations and milling processes
- Establish a reliable control strategy for low risk scale-up

### IN-HOUSE WEBCOURSES

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

### REGISTRATION

Please e-mail the pdf scan of the form below to: [info@thezlotacompany.com](mailto: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](mailto: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 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](mailto: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](mailto: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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Job Title	
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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: \_\_\_\_\_