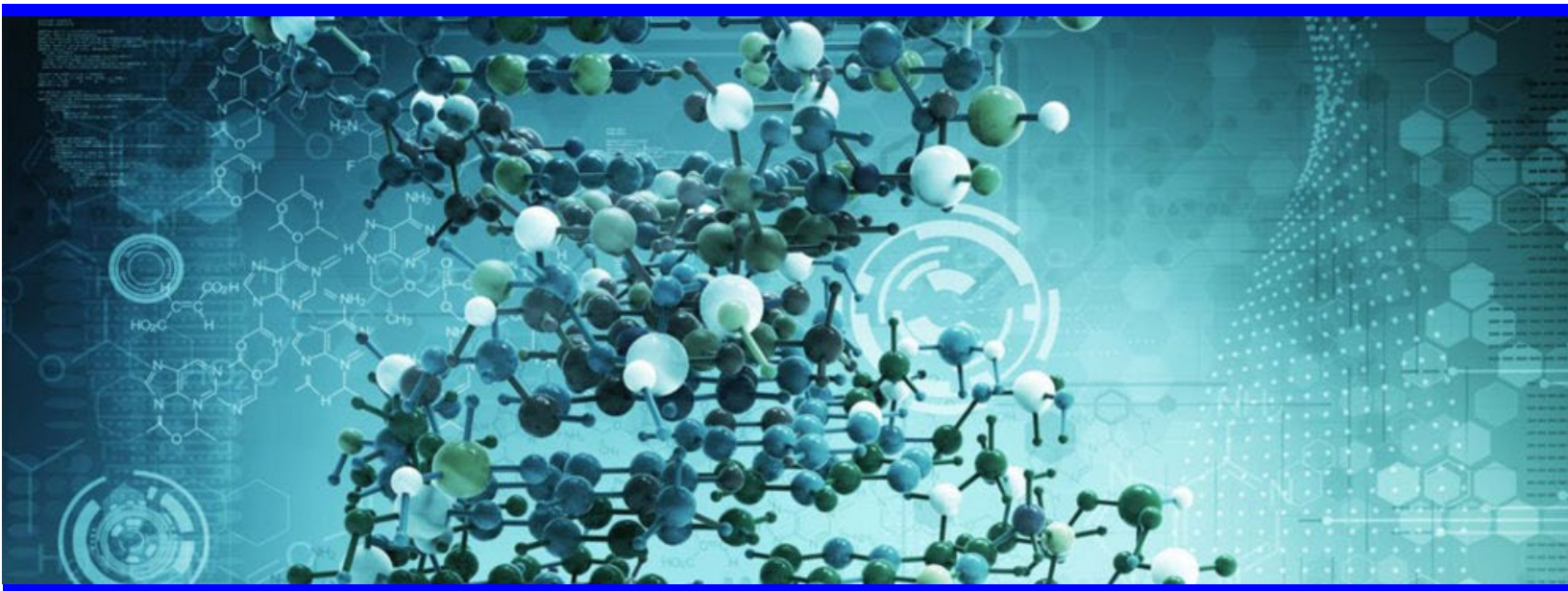
TZC THE ZLOTA COMPANY, LLC
RAPID PROCESS SCALE-UP and ROBUST PROCESS DEVELOPMENT



“Crystallization and Micronization Scale-Up for Improved API Processability”

COURSE INSTRUCTOR:
Dr. Andrei A. Zlota

NEW COURSE

“I was very impressed with the diversity of topics covered and Andrei’s mastery of multiple disciplines.”

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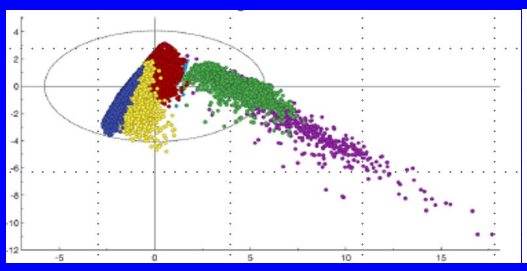

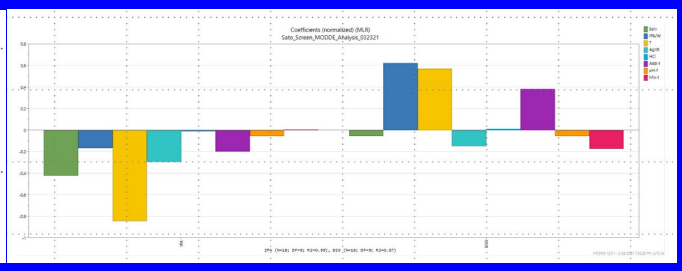

“Crystallization and Micronization Scale-Up for Improved API Processability”

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

- Advanced course for process scientists with a basic understanding of statistical design of experiments and chemical process scale-up presented in our QbD courses
- Discusses advanced statistical methods for selection of relevant API bulk powder properties to predict processability
- Demonstrates the use of Machine Learning and Principal Component Analysis (PCA)
- Includes reviews of crystallization and micronization process development and scale-up
- Hands-on learning: two workshops 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 for improved API bulk powder processability

WHO SHOULD ATTEND

Chemists, engineers, project managers and supervisors who seek to learn about scientifically meaningful and cost-effective approaches to crystallization and micronization scale-up. 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

- Processability of API bulk powder
- Risk analysis
- Practical approaches to processability model development

2. Crystallization process scale-up

- Highlights of crystallization process development
- Practical approaches to crystallization process scale-up
- Downstream operations

3. Micronization process scale-up

- Highlights of micronization process development
- Practical approaches to micronization process scale-up

4. API bulk powder physical properties of interest and their measurement

- Particle size and shape
- Rheology
- Electrostatic properties
- Flowability

5. Data Analysis

- Big data analysis
- Machine Learning analysis
- Principal Component Analysis (PCA) for unstructured data
- Case studies

6. Hands-on workshops

- Crystallization scale-up example
- Micronization scale-up example
- Machine Learning analysis example
- Principal Component Analysis example

THE ZLOTA COMPANY, LLC

RAPID PROCESS SCALE-UP and ROBUST PROCESS DEVELOPMENT

"Andrei Zlota gave us a very interesting course. The topics were well balanced. Andrei answered every question with a high degree of competence and kindness. Thank you very much!"

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 API bulk powder processability improvement for 40 pharmaceutical companies. Andrei also trained 3,100 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 for API bulk powder Critical Quality Attributes (CQAs)
- Effectively use a practical approach to identify API bulk powder physical properties that could predict processability
- Develop statistical models that correlate API bulk powder processability with API particle physical properties
- Develop and scale-up robust crystallization and micronization processes
- Use Machine Learning and Principal Component Analysis (PCA) to analyze unstructured data

IN-HOUSE WEBCOURSES

For groups larger than seven participants, a customized webcourse 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 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**..

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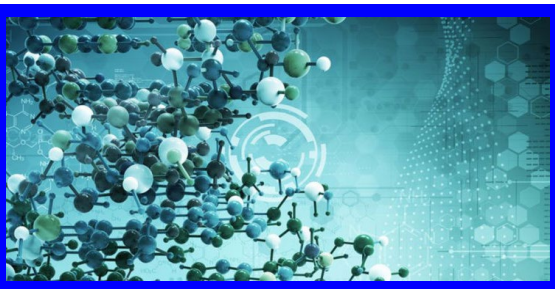

"Crystallization and Micronization Scale-Up for Improved API Processability"

REGISTRATION FORM

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..

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: _____