

Robust Crystallization Process Development and Scale-Up Using QbD Tools

WEBCOURSE INSTRUCTOR:
Dr. Andrei A. Zlota

Online training



April 20-22, 2021
September 21-23, 2021



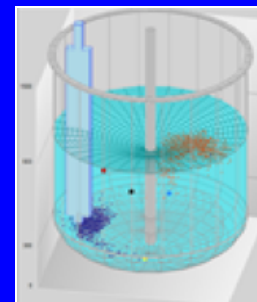
info@thezlotacompany.com



www.thezlotacompany.com

“One of the best courses I have attended! The lectures were well presented with many relevant examples.”

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WEBCOURSE FEE: \$1,274 (1040 EUR)

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

Three sessions, three hours each on January 12-14, 2021 or April 20-22, 2021, 8:30 AM - 11:30 AM EST (EDT), 14:30-17:30 CET (CST)

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

COURSE OVERVIEW

- Provides a fit-for-purpose strategy for robust crystallization process development using QbD tools.
- Practices a balanced approach between the theory and the practice of QbD for crystallization process development
- Includes a unique blend of all the QbD methods: risk analysis, statistical design of experiments (DoE), scale-up science, process analytical technology (PAT).
- Practical learning: two hands-on workshops (DoE and scale-up) 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 crystallization process development and scale-up.

WHO SHOULD ATTEND

Chemists, engineers, project managers and supervisors who seek to learn about scientifically meaningful and cost effective approaches to QbD implementation for crystallization process development and 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. Introduction

- Quality by Design deliverables, methodology
- Target Quality Profile, Critical Quality Attributes
- Form selection, polymorphs
- Particle Engineering
- Integrated process development at the drug substance-drug product interface

2. Risk analysis

- Cause and effect analysis
- Early development risk analysis
- Factor ranking methods
- Crystallization case study

3. Product understanding

- Solvent selection, solubility, supersaturation
- Metastable Zone Width
- Crystal nucleation and growth
- Crystal morphology
- Agglomeration

4. Desupersaturation methods

- Cooling crystallization (batch)
- Cooling protocols
- Precipitation, oiling out challenges
- Antisolvent crystallization (batch)
- Seeding technology

5. Statistical Design of Experiments (DoE)

- Analytical methods for particle characterization
- Crystallization screening DoEs
- Crystallization process optimization DoEs
- Crystallization solvent optimization
- Case studies
- DoE workshop

6. Crystallization process scale-up

- Mixing impact on crystallization process results
- Mixing and scale-up calculations
- Crystallization scale-up factors
- Combination DoE's
- Process robustness assessment
- Crystallization design space
- Successful crystallization technology transfer
- Scale-up workshop

7. Process Analytical Technology

- PAT strategies for robust crystallization process development
- PAT tools: FBRM, PVM, FTIR, other
- PAT benefits and challenges

8. Downstream processing

- Filtration, washing
- Drying
- Delumping
- Dry milling
- Powder flow, processability

9. Review, round table discussion

"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."

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 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:

- Meaningfully define a Quality Target Profile for crystallized API
- Execute fit-for-purpose risk analysis for crystallization process development
- Design relevant DoE matrixes for the development of process understanding in support of robust process development and scale-up
- Establish scale-up factors, and develop process models that include both scale- independent and scale-dependent factors
- Identify critical process parameters and develop a control strategy for low risk crystallization technology transfer

IN-HOUSE WEBCOURSES

For groups larger than seven 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 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.

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REGISTRATION FORM

E-mail the pdf scan of the form below to: info@thezlotacompany.com, or register at www.thezlotacompany.com. Upon confirmation of registration an invoice shall be e-mailed to the registrant.

Company Name	
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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: _____