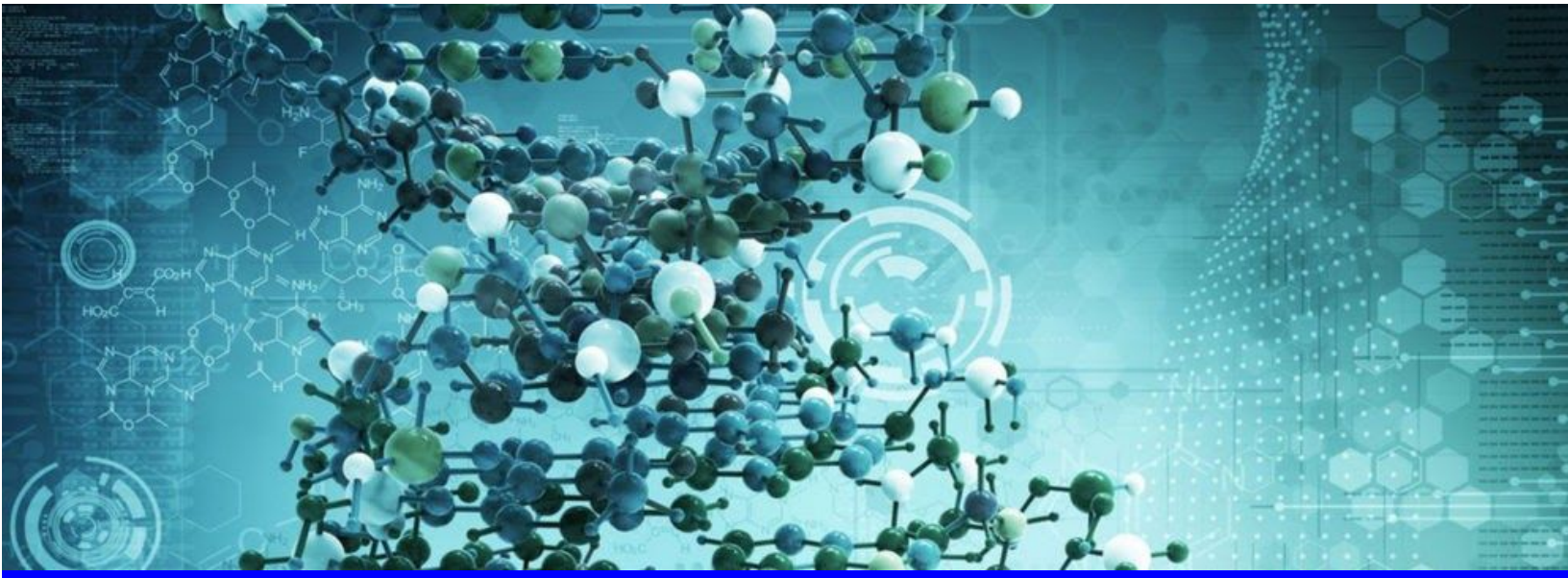
TZC **THE ZLOTA COMPANY, LLC**

RAPID PROCESS SCALE-UP and ROBUST PROCESS DEVELOPMENT



QbD Elements (C): Process Analytical Technology, Continuous Manufacturing and Quality by Design (QbD) Regulatory Guidance Documents

Webcourse

COURSE INSTRUCTOR:

Dr. Andrei A. Zlota

"Sincere thanks to Dr Andrei Zlota for the much appreciated QbD course. Amidst apparently conflicting directions concerning QbD, Andrei Zlota was able to present a very clear, pragmatic and down to earth grounding in QbD principles and practice, in terms of intrinsic benefits, and regulatory requirements....borne out of extensive and erudite first hand experience and expertise ".

June 15-17, 2021

November 16-18, 2021

info@thezlotacompany.com

www.thezlotacompany.com

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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 February 9-11, 2021 or June 15-17, 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

- Three important Quality by Design (QbD) elements are discussed: Process Analytical Technology (PAT), continuous manufacturing, and QbD regulatory guidelines
- A practical approach for relevant PAT and continuous manufacturing implementation
- PAT strategic decisions: balancing process understanding with costs
- Case studies for PAT use for reaction and crystallization process development and monitoring
- Examples of batch processes converted to continuous processes
- Clarification of QbD guidelines and their follow-up documents
- 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

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. Process Analytical Technology (PAT)

- Introduction, definitions
- PAT for crystallization process development
- PAT for reaction monitoring and for kinetic investigations
- PAT for drying monitoring
- PAT for process control

2. Continuous Manufacturing

- Advantages of continuous processing
- Continuous processing concepts, and equipment selection
- Process intensification opportunities
- International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Quality document #13: Continuous Manufacturing of Drug Substances and Drug Products

3. Quality by Design Regulatory Guidelines

- PAT-A Framework for Innovative Pharmaceutical Development, Manufacturing and Quality Assurance
- ICH Q8, Q9, Q10, Q11 and follow-up documents
- ICH terminology challenges; critical process parameters
- Design Space case study (ICH Q11)
- QbD submissions

4. Review, Q&A Session, References

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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 36 pharmaceutical companies. Andrei also trained 2,600 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:

- Understand the value of PAT tools for reaction and crystallization process development
- Design powerful scale-up investigations using the synergy of automated lab reactors, PAT, DoE and scale-up science
- Understand the merits of continuous manufacturing and related challenges
- Use the QbD concepts presented in ICH, FDA, and EMA guidelines, and be able to navigate QbD terminology
- Be able to build effective QbD implementation strategies for robust process development, and for design space development towards design space approval

IN-HOUSE COURSES

For groups larger than seven 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 of 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 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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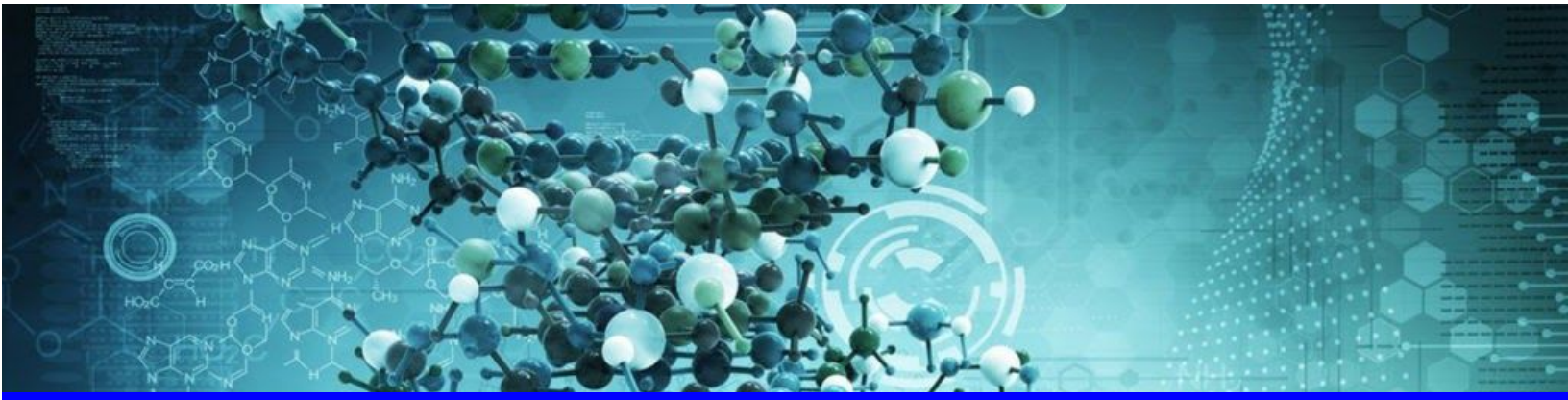

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REGISTRATION FORM

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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: _____