SCIENTIFIC UPDATE

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PRACTICAL APPROACHES TO STATISTICAL DESIGN OF EXPERIMENTS (DoE)

For Chemical Process Research & Development and Manufacturing

10-11 APRIL 2018

Boston, MA USA
Boston Metro Meeting Center

"Andrei does an exceptional job conveying key concepts and applications in this introductory DoE course."
Apotex Pharmachem Inc

A 2 day course given by **Dr Andrei Zlota**

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Multiple attendees discounts **UP TO 15% available**

INTRODUCTION

The synergy between fundamental science and statistical design of experiments (DoE) has been demonstrated to create more significant process understanding than that achieved by the same number of one-variable-at-a-time (OVAT) experiments.

This course takes a balanced approach presenting basic DoE theory as well as numerous examples of DoE use in the pharmaceutical industry. The course will discuss statistical and practical significance, assumptions and limitations of DoE methodology, together with practical approaches for the process scientist to be in control of the DoE investigation (and not the computer).

Precedent and experience compel many chemists to use OVAT experimentation in spite of its incomplete nature, and in spite of its inability to detect factor interactions, e.g., cases when the impact of one factor depends on the level of another factor. When such interactions occur between scale dependent and scale independent factors, ignoring such factor interactions can lead to high risk process scale-up and technology transfer.

Participants will learn how to design effective screening experiments, how to use response surface methods for reaction and analytical method development, how to design robust processes, and how to quantify the risk associated with the implementation of the processes developed. Several commercial DoE software platforms will be reviewed.

For the benefit of process scientists, engineers, formulators*, analytical chemists and manufacturing personnel, this course includes highly interactive, hands-on workshops.

COURSE OUTLINE

Introduction
- Why DoE?
- Statistics for chemical process R&D: friend not foe
- Synergy between statistical, kinetic and engineering models
- Univariate experimentation limitations
- Design of experiments (DoE), a multivariate method to investigate multivariate processes

Statistical Design of Experiments (DoE)
- Requirements for a successful DoE
- Responses
- Scale independent and scale dependent factors
- Meaningful use of categorical factors
- Factor ranking; factors to be fixed, factors to be varied
- Ranges, number of levels
- Randomization, replication, centerpoints, blocking

Screening the Experimental Space
- DoE commercial software platforms
- Full factorial designs
- Fractional factorial designs: advantages and challenges
- Plackett-Burman designs
- Design efficiency, design resolution, statistical power of a design
- Chemical reaction, and workup: together or separate?
- Design augmentation; practical strategies for cost-effective screening
- Using DoE to set raw material specifications

Analyzing DoE screening investigations
- Objectives
- Key statistical concepts
- The value of redundancy, the power of visualization tools
- Practical vs. Statistical significance
- Case studies: chemical reactions, API crystallizations

Response Surface Methodology (RSM)
- Types of "optimization"
- RSM design options
- Analysis of RSM designs, model manipulation
- Model verification experiments
- Case studies: chemical reactions, API crystallizations

DoE and Quality by Design (QbD)
- The concept of design space; risk calculations using the DoE model
- Critical Quality Attributes and Critical Process Parameters
- DoE for process robustness assessment, and for process validation; process capability indices

"Advanced Topics" (time permitting)
- DoE and Principal Component Analyisis (PCA)
- DoE for process troubleshooting
- DoE investigating scale-dependent and scale-independent factors
- Mixture designs

A DoE course dedicated to drug product development is also available; if interested, please inquire.

IN-HOUSE COURSE

For 13+ people contact us to discuss holding this event In-House - **sciup@scientificupdate.com**

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Start 9.00am - Tuesday 10 April
Finish 3.30pm - Wednesday 11 April
Course dinner 6.30pm - Tuesday 10 April

Course Fee: $1,905

Which includes comprehensive course manual, refreshments throughout the day, lunches and one course dinner.

Course Fee: $1,905

COURSE TUTOR

Dr Andrei Zlota

The ZLOTA Company LLC

Andrei obtained an M.Sc. in Chemical Engineering from the Bucharest Polytechnic Institute (Organic Chemical Technology, 1980). After working in the industry for several years, he obtained an M.Sc. in Chemistry from the Technion (Organic Chemistry, 1986).

Subsequently he obtained a Ph.D. in Chemistry from the Weizmann Institute of Science (Organometallic Chemistry, 1991). He has been a regular contributor to the Organic Process R&D Journal (OPRD) Highlights from the Literature section since 2003, and he also participates in the review of papers submitted for publication in OPRD. In 2006 Andrei founded his consulting firm, The Zlota Co., LLC, specializing in Quality by Design (QbD) implementation, including practical statistical design of experiments, accelerated process scale-up, and meaningful Process Analytical Technology practice.

Andrei provided QbD training to more than 2,000 scientists from 180 companies in the US, Europe and Asia. Thirty five companies obtained, and continue to obtain project support from The Zlota Co. with their successful implementation of various elements of QbD methodology.

Note: A full version of Andrei's biographical note is available on our website.

Upon completion of the course participants will be able to:

> Meaningfully include numerical continuous, numerical discreet, and categorical variables in DoE matrixes
> Know when to separate and when to combine scale dependent and scale-independent parameters in a DoE investigation
> Design effective DoE screening matrixes, suitable for the objectives at stake
> Design robust processes, capable of tolerating variability in raw materials and process parameters
> Quantify process risk
> Use the DoE generated process understanding for Quality by Design (QbD) implementation

VENUE

The Metro Meeting Centers
101 Federal Street, 4th Floor
Boston
MA 02110
USA
(617) 737 1200

www.metromeetingcenters.com

Transport

Metro Meeting Centers is 10 minutes from Boston's Logan International Airport and within a short distance to public transportation.

A list of nearby hotels will be sent to you when you register.

REGISTRATION

You can either use our fast online booking system or mail or fax the attached registration form to:
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Group discounts are available on two or more attendees - see registration form. This offer only applies if bookings are made simultaneously and from the same billing address.

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These will be sent via email.

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