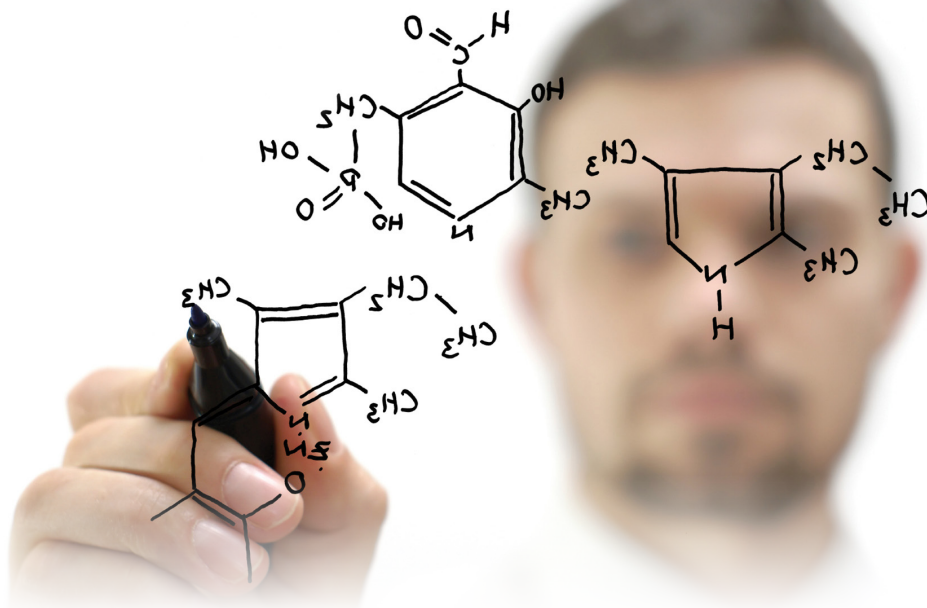




SAVE THE DATE:
OCTOBER 25 - 27, 2016



Mixing Consultants, Inc. Presents:

DESIGN AND IMPLEMENTATION OF CONTINUOUS PHARMACEUTICAL MANUFACTURING PROCESSES

by Academic Experts from Rutgers University and Recognized Industry Leaders
Sponsored by Coperion K-Tron, Freeman Technology, Gericke, Glatt and Optimal

OCTOBER 25 - 27, 2016: LONDON, U.K.

Completely NEW Program

Day 1: Fundamentals / Regulatory / Main Process Components. Review of main technology options for continuous direct compression, continuous dry granulation via roller compaction, continuous wet granulation, and hot melt extrusion. Regulatory issues in continuous manufacturing. Expectations, batch definition, compliance with in-process testing requirements, process validation. Ongoing efforts to develop regulatory documents. Review of process components: conveying systems, feeders, mills, blenders, granulators, tablet press.

Day 2: Integrated Product and Process Development / Material Properties / Process Parameters. The C-SOPS/Janssen collaboration and lessons learned from Prezista CM. Role of material properties in continuous manufacturing. Critical process parameters. Experimental design and fast product and process development.

Day 3: PAT, RTR, Process Modeling and Control. PAT strategies. RTR methods. Dissolution prediction. Modeling of individual process operations. Process integration. Attributes of a properly designed control system. Sensitivity and robustness. Process validation. Future trends.

ABOUT MIXING CONSULTANTS, INC.

Mixing Consultants, Inc. provides technical services, supporting research and development and technology transfer in all areas regarding characterization, design, optimization and control of mixing processes for powders, liquids and suspensions. Our focus are pharmaceutical, food, chemical and energy industries. Our mission is to support and educate industry in the application of technical knowledge and modern methods to achieve excellence in product and process design, manufacturing, scale-up, technology transfer and control.

Additional information and inquiries by e-mail to info@mixingconsultants.com or phone @ +1 (954) 727-3120.

Visit us at www.mixingconsultants.com

RADISSON BLU PORTMAN HOTEL LONDON, LONDON, U.K.

PROGRAM

Daily: Registration & breakfast 7:30 – 8:30 am

Day 1: Fundamentals / Regulatory / Main Process Components

- 8:30 - 10:00 Overview of continuous manufacturing of solid dose products – DC, WG, DG, HME (*Fernando Muzzio*)
- 10:15 - 12:15 Regulatory issues in continuous manufacturing – FDA expectations, emerging industry consensus – The C-SOPS/FDA collaboration, proposed guidance documents (*Fernando Muzzio*)
- 1:15 - 2:15 Accurate material handling, feeding and refill for continuous pharmaceutical manufacturing operations (*Sharon Nowak, Coperion K-Tron*)
- 2:15 - 3:00 Main design principles of continuous mixing processes (*Ralf Weinekötter, Gericke*)
- 3:15 - 4:00 Continuous granulation and drying (*Jochen Thies, Glatt*)
- 4:00 - 5:00 Hot melt extrusion as a continuous process (*Johannes Khinast, RCPE*)

Day 2: Integrated Product and Process Development / Material Properties / Process Parameters

- 8:30 - 10:15 The C-SOPS/Janssen partnership and the development of Prezista CM (*Fernando Muzzio*)
- 10:30 - 12:15 Role of material properties in continuous manufacturing – Cohesion, density, hydrophobicity, electrostatic, particle size distribution - Predictive material property databases (*Fernando Muzzio*)
- 1:15 - 2:15 Controlling API attributes via continuous crystallization (*Alastair Florence, CMAC*)
- 2:30 - 3:45 Measuring and understanding powder flow (*Tim Freeman, Freeman Technology*)
- 3:45 - 6:30 Critical process parameters: shear, strain, compression force and speed – Experimental design for fast product/process development (*Fernando Muzzio*)

Day 3: PAT, RTR, Process Modeling and Control

- 8:30 - 10:00 PAT and RTR (*Fernando Muzzio*)
- 10:00 - 10:45 The integration of data, knowledge and control in a continuous process (*Martin Gadsby, Optimal*)
- 11:00 - 2:00 Integrated predictive modeling methods for design, optimization, risk assessment (*Marianthi Ierapetritou*)
- 2:15 - 4:30 Model-based validation and control (*Marianthi Ierapetritou*)
- 4:30 - 5:30 Future trends and directions – Seminar wrap up (*Fernando Muzzio*)

MEET THE EXPERTS

Dr. Fernando Muzzio. Distinguished Professor, Rutgers University. Director, Engineering Research Center on Structured Organic Particulate Systems. Expert on Pharmaceutical Powder Processing.

Dr. Johannes Khinast. Professor Graz University of Technology (Austria), Director of the Research Center for Pharmaceutical Engineering (Graz, Austria). Expert on pharmaceutical processing, continuous manufacturing and process modeling.

Prof. Alastair Florence. Chair of Pharmaceutical Science, University of Strathclyde, Director of EPSRC Centre and Doctoral Training Centre for Continuous Manufacturing and Crystallization. Expert in continuous crystallization and molecular solid form control and characterization.

Dr. Marianthi Ierapetritou. Professor I, Rutgers University. Coordinator, Continuous Manufacturing, Engineering Research Center on Structured Organic Particulate Systems. Expert on process design, optimization, and control.

Ms. Sharon Nowak. Global Business Development Manager, Coperion K-Tron. She is a recognized leading expert in the fields of macro/micro feeding and conveying of pharmaceuticals, and in pharmaceutical process engineering/equipment design.

Mr. Tim Freeman. Managing Director, Freeman Technology. Expert in powder characterization and powder flow, in relation to product and process development.

Mr. Martin Gadsby. Co-owner and Director of the Optimal Group. Martin has experience in the practical application of PAT and is responsible for synTQ Business Development.

Dr. Jochen Thies. Head of new Technologies, Glatt Group. Core experience in powder mixing and granulation, fluid bed processing, tablet coating as well as continuous manufacturing of pharmaceuticals.

Dr. Ralf Weinekötter. General Manager, Gericke AG. He is one of the world's leading experts in the design and implementation of continuous powder handling, feeding, and mixing systems.



ENJOY THE LOCATION!

The crown jewels, Buckingham Palace, Big Ben, Camden Market...in London, history collides with art, fashion, food, and good British ale. A perfect day is different for everyone: culture aficionados shouldn't miss the Tate Modern and the Royal Opera House. For foodies, cream tea at Harrod's or crispy fish from a proper chippy offers classic London flavor.

Registration Fees (per attendee): 1-2 days: USD \$800 per day; 3 days: \$2,000 ♦ Early registration: 1-2 days: USD \$750 per day; 3 days: USD \$1,800 - Early registration expires on September 23, 2016 ♦ On-site registration: USD 900 per attendee per day ♦ **Multiple registrations:** Special fees are available for companies registering 5 or more full time participants. *All fees are expressed in United States dollars (USD).*

Registration:

Complete the following information and e-mail a signed scanned copy to info@mixingconsultants.com or fax to Mixing Consultants, Inc. +1 (954) 880-0228.

Please register me for the course on **Design and Implementation of Continuous Pharmaceutical Manufacturing Processes October 25 - 27, 2016** ~ London, UK

Last Name _____ First Name _____

Company _____

Title/Position in your Company _____

Company Address: Street _____

City _____ State _____ Zip _____ Country _____

Phone: _____ Fax: _____

E-mail: _____

Tuesday, October 25th Wednesday, October 26th Thursday, October 27th

Total days registered: _____ Total cost: _____

I agree to pay regardless if I attend. Signature: _____

How did you hear about this seminar: Coperion K-Tron Freeman Technology Gericke Glatt Mixing Consultants, Inc.

Optimal Colleagues, word of mouth, etc. _____

Cancellation policy: Cancellations will be assessed a non-reimbursable fee of USD 300 per attendee per day. Cancellations made after September 23, 2016 will not be reimbursable and will require full payment. Attendee replacements within the same company are welcome with prior express agreement by Mixing Consultants, Inc. **Mixing Consultants, Inc. reserves the right to change the place dates, and speakers of the event.** Discounted hotel rates are available but limited. Contact us for reservations.

Additional information and inquiries by e-mail to info@mixingconsultants.com or call +1 (954) 727-3120.

Payment method: Major credit cards (via PayPal) or wire transfer (wire instructions to be provided) or check to Mixing Consultants, Inc., 3962 Hawks CT, Weston, FL 33331 USA



MIXING CONSULTANTS, INC.