

ACCELERATING ACCESS TO MEDICINES

MARCH 27 & 28, 2023 // WASHINGTON, D.C.

MADE POSSIBLE BY:



WORKSHOP SCHEDULE

TICKETS:

\$690

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DAY 1 // MARCH 27, 2023

WELCOME AND INTRODUCTION

JOHANNES KHINAST

RCPE / GRAZ UNIVERSITY OF TECHNOLOGY

09:00 - 09:20

THOMAS O'CONNOR

FDA

09:20 - 09:50

**Experience in Pharmaceutical Innovation:
Perspective on CDER Advanced Manufacturing
Initiatives**

DRUG SUBSTANCE MANUFACTURING

SESSION CHAIR: AMRIT PAUDEL

MALCOM BERRY

MB CHEMISTRY CONSULTING

10:00 - 10:30

**Continuous API Manufacturing: The Benefits, and
the Hurdles to Implementation**

NIMA YAZDANPANA

PROCEGENE

10:30 - 10:45

**Rapid and Efficient Product and Process
Development, Scale-Up, and Tech-Transfer**

JASON WILLIAMS

RCPE / KAPPE LAB

10:45 - 11:00

**Automation, PAT and Modelling Strategies for
Data-Rich Continuous Process Development**

HAICHEN NIE

TEVA

11:00 - 11:15

**Understanding Excipient Induced Recrystallization
of Spray-Dried Amorphous Solid Dispersions**

MARTIN SPÖRK

RCPE

11:15 - 11:30

**Advanced Continuous Manufacturing: From API
Synthesis to the Final Dosage Form**

LUNCH BREAK 11:30 - 12:45

WORKSHOP SCHEDULE



DRUG PRODUCT MANUFACTURING

SESSION CHAIR: MARTIN SPÖRK

MARTIN WARMAN
MARTIN WARMAN CONSULTANCY

12:45 - 13:15

Realizing the Full Potential of Continuous Manufacturing in the Pharmaceutical Innovator Space

THOMAS BRINZ
SYNTEGON

13:15 - 13:30

Fully Automated and DoE Based Development of an Oral Solid Dosage Form

THOMAS KIPPING
MERCK

13:30 - 13:45

Advanced Manufacturing Concepts for Oral Solid Dosage Forms

ANDREA RAFFA
PHYLLON

13:45 - 14:00

OSeeT - Optical Coherence Tomography for In-Line Measurement of Film Coating

ANDREW BIRKMIRE
GEA

14:00 - 14:15

A Streamlined Approach to Continuous Direct Compression

KIERAN DRAIN
AMAT

14:15 - 14:30

Novel Technology to Accelerate Drug Product Development and Enable Pharma Manufacturing ESG Compliance

COFFEE AND REFRESHMENTS
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14:30 - 15:00

DIGITALIZATION

SESSION CHAIR: NIMA YAZDANPANA

LUCA EMILI
INSILICOTRIALS

15:00 - 15:30

Hyper Accelerate R&D with In Silico Trials

SARAH STRYECK
RCPE

DANIEL NEUHOLD
LOCONIQ

15:30 - 15:45

Leading Pharmaceutical Sustainability and Digitalization

WORKSHOP SCHEDULE



SALVADOR GARCÍA MUÑOZ

ELI LILLY

15:45 - 16:00

Model Based Multivariate Monitoring of Drug Product Processes

ANTHONY TANTUCCIO

HOVIONE

16:00 - 16:15

Bridging the Divide Between R&D and Manufacturing through Digitalization: An Example of Continuous Tableting

JOHAN REMMELGAS

RCPE

16:15 - 16:30

Development of a DEM-Based Digital Twin of a CDC Line for the Evaluation of Continuous Manufacturing Control Strategies

TOBIAS MIUNSKÉ

HARRO HÖFLIGER

FALK PFITZER

HARRO HÖFLIGER

16:30 - 16:45

A Disruptive Approach of a Digitalization Kit for Pharmaceutical Machines

MICHAELA LAUSSEGER

AUSTRIAN BUSINESS AGENCY

16:45 - 17:00

Austria: Top Center for Life Sciences

DINNER & SOCIAL EVENT

SPONSORED BY ABA

17:00 - 20:00

DAY 2 // MARCH 28, 2023

MODELING AND SIMULATION

SESSION CHAIR: JOHANNES KHINAST

NICOLIN GOVENDER

CERN / UNIVERSITY OF JOHANNESBURG

09:00 - 09:30

Towards Manufacturing Digital Twins Using GPU Based Physics Simulations: A Particle Perspective

GENG TIAN

FDA

09:30 - 09:45

Applications of Modeling and Simulation for Quality Risk Management of Advanced Manufacturing

AVIK SARKAR

MERCK

09:45 - 10:00

The Emerging Significance of Predictive Modeling and Simulation in Large Molecules Pharmaceutical Manufacturing

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CHRISTIAN WITZ

SIMVANTAGE

10:00 - 10:15

Achieving Rapid Transfer from Lab to Production Floor with a Novel Digital Tool for Scaling and Optimizing Bioreactors

MATTHEW FLAMM

MERCK

10:15 - 10:30

Computational Fluid Dynamics (CFD) Model for Predictive Scale Up/Down of Large Molecule Drug Product Formulation

DANA BARRASO

SIEMENS

SEAN BERMINGHAM

SIEMENS

10:30 - 10:45

Application of Mechanistic Modeling to Quantify Risks and Inform Control Strategies

COFFEE & REFRESHMENTS

10:45 - 11:15

NOVEL PRODUCTS / NANO-SYSTEMS

SESSION CHAIR: SARAH STRYECK

CARSTEN LOSCH

KNAUER

11:15 - 11:45

Scalable Lipid Nanoparticle Formulation using Impingement Jets Mixing Systems

XIAOMING XU

FDA

11:45 - 12:15

Opportunities in Continuous Manufacturing of Nanomaterials

STEVE MESITE

MICROFLUIDICS

12:15 - 12:30

Scalable Technology Helps Overcome Pharmaceutical Nanoparticle Manufacturing Challenges

PATRIK JOHANSSON

LYNDRA

12:30 - 12:45

Continuous Manufacturing Enabling Early Development through Commercialization

EMRE TÜRELI

MYBIOTECH

12:45 - 13:00

Bridging Nanomedicines Towards Clinic

LUNCH BREAK 13:00 - 14:00

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PHARMACEUTICAL SCIENCE AND TECH

SESSION CHAIR: ELISABETH FINK

JAE YOO

FOUNDATIONLAYERS

14:00 - 14:30

Pharmaceutical Applications of 3DP/Additive Manufacturing: Challenges and Opportunities

FILIP FRANQUI

GRANUTOOLS

14:30 - 14:45

Powder Characterization for Continuous Manufacturing with a Focus on Electrostatics

DANIEL MÜLLER

HARRO HÖFLIGER

14:45 - 15:00

Direct API Filling into Capsules

DANIEL TREFFER

MELTPREP

15:00 - 15:15

Free-D Molding: Helping 3D Printing to Deliver its Rapid Prototyping Potential

BRIAN HAIGHT

LEISTRITZ EXTRUSION TECHNOLOGY

15:15 - 15:30

Reducing Degradation of Ritonavir by Managing Melt Temperature in a Twin Screw Extruder

CLOSING AND SUMMARY

JOHANNES KHINAST

RCPE / GRAZ UNIVERSITY OF TECHNOLOGY

15:30 - 15:45

NIMA YAZDANPANA

PROCEGENE

RCPE is funded within the framework of COMET - Competence Centers for Excellent Technologies by BMK, BMAW, Land Steiermark and SFG. The COMET program is managed by the FFG.