

The Cortona Conference: Manufacturing Innovation and the Global Regulatory Harmonization



**October 8 - 11, 2023
Centro Convegni Sant'Agostino
Cortona, Italy**

VIEW PROGRAM DETAILS HERE:



Active Participants/Session Leaders

Philip Deamer, GlaxoSmithKline, Ware, Hertfordshire, UK

Pierantonio Facco, University of Padova, Padova, Italy

Filipe Gaspar, Ph.D., Hovione FarmaCiencia SA, Lisboa, Portugal

Steve Hammond, ExpoPharma Engineering Services

Melvin V. Koch, Ph.D., Center for Process Analysis and Control, (CPAC), Seattle, WA

Colm O'Donnell, UCD School of Biosystems and Food Engineering, University College
Dublin, Belfield, Dublin, Ireland

Prof, Luigi Vaccaro, Universita degli Studi di Perugia, Perugia, Italy

Robert S. Zulkis, IFPAC

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Monday, 9 October 2023

DAY ONE – AM Pharmaceutical/Bio Manufacturing Innovation Plenary Session Session Chair: Mel Koch, CPAC, Seattle, WA, USA

The plenary session will provide an introduction to the IFPAC Cortona conference and an overview of what it intends to accomplish. There will be presentations on innovations in the pharma industry and from government regulatory agencies. This provides opportunities for interaction on topics of advances in technology and improved Regulatory Harmonization between the U.S. and Europe. This will be an engaging and diverse plenary session to begin the conference!

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| 8:30 a.m. | Registration |
| 9:00 a.m. | Conference Logistics and Introduction
Robert Zutkis, IFPAC, USA |
| 9:10 a.m. | Introduction to the Plenary Talks
Summary of the topics presented in the IFPAC Europa Webinars (2020-2022)
Mel Koch, CPAC, Seattle, WA, USA |
| 9:30 a.m. | The Role of Innovative Engineering, Systems Thinking and New Unit Operations in the Circular Bioeconomy
Harald Sverdrup, Inland University of Applied Sciences and Norse Metal, Norway |
| 10:00 a.m. | The Future Scale and Mode of Manufacture for the Sustainable Supply of Medicines
Andrew Rutter, Rutter Design, UK |
| 10:30 a.m. | Break |
| 11:00 a.m. | International Agency Presentation: Innovation in Pharmaceutical Assessment and Inspection
Evdokia Korakianiti, et al., European Medicines Agency, Amsterdam, The Netherlands |
| 11:30 a.m. | Ensuring Access to Medicines in a Post-Pandemic World
Frank Gupton, Virginia Commonwealth University-Medicine for All Institute, USA |
| 12:00 PM | Spectroscopic Sensors in Bioprocess Monitoring and Optimization
Erik Tengstrand and Nils Kristian Afseth, Norwegian Institute of Food, Fisheries and Aquaculture Research (NOFIMA), Norway |
| 12:30 p.m. | Sponsor/Exhibitor Introductions |
| 1:00 p.m. | Lunch |

Table Top Exhibits – 10:00 a.m. – 4:30 p.m.
Set up 8:00-10:00 a.m.

Monday, 9 October 2023

DAY ONE – PM Industry 4.0: Machine Learning, IT & Data Information Management

Session Chairs: Pierantonio Facco, University of Padova, Padova, Italy and Prof, Luigi Vaccaro, Università degli Studi di Perugia, Perugia, Italy

This session describes how to provide rapid & comprehensive access to Product and Process knowledge (both data and text) through information systems that are efficiently, effectively and securely networked across Development, Quality and manufacturing to facilitate Continuous Improvements.

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|-----------|-------|---|
| 2:00 p.m. | I-002 | Machine learning to support the revolution of the (bio) pharmaceutical Industry 4.0
Pierantonio Facco, University of Padova, Padova, Italy |
| 2:30 p.m. | I-019 | The Future of Digitalization and Smart Labs & Manufacturing
Paul Gillham, Optimal Industrial Technologies Ltd,
Yate, Bristol, UK |
| 3:00 p.m. | I-015 | Deep Learning-Based Machine Vision for Enhanced In-Line Monitoring of High-Shear Granulation Processes
Adraz Mehle, Sensum, Computer Vision Systems, Domen Kitak ¹ ,
Dejan Tomažević ^{1,2} ¹ Sensum, Computer Vision Systems, Ljubljana,
Slovenia ² Laboratory of Imaging Technologies, Faculty of Electrical
Engineering, University of Ljubljana, Slovenia |
| 3:30 p.m. | | Break – Table-Top Exhibits & Posters |
| 4:30 p.m. | | Modern Innovative Technologies for API
Prof, Luigi Vaccaro, Università degli Studi di Perugia, Perugia, Italy |
| 5:00 p.m. | | Panel Discussion
All Speakers |
| | | Recap of Student Posters
Poster Chair: Mel Koch, CPAC, Seattle, WA, USA |
| 5:30 p.m. | | Close |
| 6:30 p.m. | | Evening Cocktail Event/Light Dinner |

Table Top Exhibits – 10:00 a.m. – 4:30 p.m.

Tuesday, 10 October 2023

DAY TWO – AM PAT and Analytics

Session Chair: Philip Deamer, GlaxoSmithKline, Ware,
Hertfordshire, UK

Process Analytical Technologies, whilst not a new concept in the manufacturing space, are fast becoming integral to the pharmaceutical industry. The recent push towards designing quality into the process, accelerated by release of regulatory guidance (ICH Q8) has highlighted the importance of PAT for providing data linked to enhanced process understanding. Coupled with analytics and automation, this supports the transition towards Pharma 4.0; a new industry standard connecting external information (patient experience, market demand) with internal information (process data) to enable real time responsiveness, monitoring and control.

- 9:00 a.m. I-010 **Utilizing Process Spectroscopy in the Tablet Press Feedframe: From Development to Manufacturing on a Continuous Direct Compression (CDC) Line**
Philip Deamer, GlaxoSmithKline
- 9:30 a.m. I-020 **New Applications: NIR for PAT on Solid and Liquid Forms**
Emiliano Genorini, Viavi Solutions
- 10:00 a.m. **PAT Approaches using NMR Analytical Techniques (TBA)**
Michael Hammer, Bruker BioSpin GmbH, Etingen, Germany
- 10:30 a.m. **Break/Posters**
- 11:00 a.m. **Blend monitoring of a Low Dose formulation Using Sam-Spec Spectroscopy**
fabien Chauchard, INDATECH, clapiers, HERAULT, France
- 11:30 a.m. I-014 **Contribution of high-speed in-line inspection to automated and DoE-based development of tablets**
Sven Borchert, Pharma Technology
Co-Authors: Freddy Vandenbroucke Pharma Technology sa, Rue Graham Bell 8, 1402 Nivelles, Belgium, Francois Bovart Pharma Technology sa, Rue Graham Bell 8, 1402 Nivelles, Belgium,
- 12:00 p.m. **Panel Discussion**
All Speakers
- Poster Session Recap**
Poster Chair: Mel Koch, CPAC, Seattle, WA, USA
- 12:30 p.m. **Lunch**

Table Top Exhibits and Posters – 10:00 a.m. – 4:30 p.m.

Tuesday, 10 October 2023

DAY TWO – PM

Continuous Manufacturing

Session Chairs: Filipe Gaspar, Hovione FarmaCiencia SA and Steve Hammond, ExpoPharma Engineering Services

1:30 p.m.

Process Modeling to Accelerate Product Development

Barrie Cassey, Technical Director, MMIC: Medicines Manufacturing Innovation Centre, Paisley, UK

2:00 p.m.

I-012 Merging API synthesis and solid dosage processing: Automation aspects of end-to-end manufacturing

Stephan Sacher, Research Center Pharmaceutical Engineering (RCPE)
Co-Authors: S. Sacher¹, L. Kuchler¹, J. Williams¹, J. Rehr¹, S. Martinuzzi¹, M. Tranninger², J. Poms¹, M. Sipek³, E. Hofreiter⁴, D. Kirschneck⁴, M. Horn², J. Khinast⁵
¹ Research Center Pharmaceutical Engineering GmbH, Inffeldgasse 13, 8010 Graz, Austria
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³ Evon GmbH, Wollsdorf 154, 8181 St. Ruprecht an der Raab, Austria
⁴ Microinnova Engineering GmbH, Europapark, 8412 Allerheiligen bei Wildon, Austria
⁵ Institute for Process and Particle Engineering, Graz University of Technology, Inffeldgasse 13/3, 8010 Graz, Austria

2:30 p.m.

SIPAT as part of a Digital Process Twin in bio

Jan Verelst, Siemens, Brussels, Belgium

3:00 p.m.

Break/Group Photo

3:30 p.m.

I-008 The use of simulation to reduce the complexity and cost of PAT applications for Continuous Manufacturing

Stephen Hammond, ExpoPharma Engineering Services
Co-Authors: Philip Doherty, ExpoPharma Engineering Services

4:00 p.m.

I-011 Steps to Accelerate Adoption of Continuous Tableting for Oral Solid Dosage Drug Products: A CDMO Perspective

Filipe Gaspar, Hovione FarmaCiencia SA
Co-Authors: Anthony Tantuccio (Hovione) José Luis Santos (Hovione)

4:30 p.m.

Innovative Technologies Panel

Topics to be Announced

5:00 p.m.

Panel Discussion – All Speakers

Student Posters: Continued Discussions

5:30 p.m.

Close

6:45 p.m.

Gala Dinner - Town Centre

Table Top Exhibits – 10:00 a.m. – 4:30 p.m.

Student Posters

I-021 A NOVEL ROUTE TO ACCESS THE SYNTHESIS OF BIOLOGICALLY ACTIVE COMPOUNDS FROM LIGNIN: Csp²-H FUNCTIONALIZATION OF PHENOLS

Giulia Brufani, Università degli Studi di Perugia, Co-Authors: Giulia Brufani,^a Benedetta Di Erasmo,^a Edoardo Bazzica,^a Federica Valentini,^a Luigi Vaccaro^a
Dipartimento di Chimica, Biologia e Biotecnologie - Università degli Studi di Perugia, Perugia (IT)

I-022 DESIGN AND SYNTHESIS OF ANTIBODY DRUG CONJUGATES (ADC) FOR THE TREATMENT OF COVID-19

Gbariele Rossini, Università degli Studi di Perugia, Co-Authors: Gabriele Rossini¹, Andrea Diana², Filippo Bocerani¹, Daniela Lanari², Luigi Vaccaro¹ ¹Laboratory of Green S.O.C. – Dipartimento di Chimica, Biologia e Biotecnologie, Università degli Studi di Perugia, Via Elce di Sotto 8, Perugia 06123, Italy; ²Dipartimento di Scienze Farmaceutiche, Università degli Studi di Perugia, Via del Liceo 1, Perugia 06123 Italy. City: Perugia

I-023 Design of new and sustainable processes to achieve Benzo[b]furans, important scaffolds for the pharmaceutical industry.

Alessandro Maselli, Co-Authors: Gabriele Rossini^a, Guller Bekiyev^b Luigi Vaccaro^a ^aLaboratory of Green Synthetic Organic Chemistry, Dipartimento di Chimica Biologia e Biotecnologie, Università di Perugia, Via Elce di Sotto, 8-06123 Perugia, Italy. ^b Bolu Abant Izzet Baysal University, Bolu, Turkey.

I-024 Waste minimized C–H functionalization, as powerful synthetic tool

Tommaso Scarabottini, Co-Authors: Tommaso Scarabottini^a, Francesco Minio^a, Luigi Vaccaro^a ^aLaboratory of Green Synthetic Organic Chemistry, Dipartimento di Chimica Biologia e Biotecnologie, Università di Perugia, Via Elce di Sotto, 8-06123 Perugia, Italy.

I-025 MICELLAR AND MICROWAVE CATALYSIS FOR SUSTAINABLE HYDROFORMYLATIONS AND HYDROAMINOMETHYLATIONS

simone zurzolo, university of siena, Co-Authors: Simone Zurzolo,^a Giulia Romagnoli,^a Andrea Porcheddu,^b Francesca Migliorini,^a Maria Lura Parisi,^a Matthias Vogt,^c Robert Langer,^c Elena Petricci.^a ^a) Department of Biochemistry, Chemistry and Pharmacy - University of Siena, Via A. Moro, 2, 53100 Siena, Italy ^b) Department of Chemical and Geological Sciences, University of Cagliari, Cittadella Universitaria, SS 554 bivio per Sestu, 09042 Monserrato, Italy ^c) Naturwissenschaftliche Fakultät II - Institut für Chemie, Martin-Luther-Universität Halle-Wittenberg, Kurt-Mothes-Str. 2, D-06120 Halle, Germany

Student Posters

I-026 Hybrid models to enhance process understanding in CHO cell cultures

Edoardo Tamiazzo, University of Padova, Department of Industrial engineering

Co-Authors: Gianmarco Barberia, Paloma Diaz-Fernandez^b, Gary Fink^{a,b},

Pierantonio Faccoa,^[1] ^a CAPE-Lab – Computer-Aided Process Engineering

Laboratory, Department of Industrial Engineering, University of Padova, via Marzolo,

9 – 35131 Padova PD, Italy ^b Biopharm Process Research, Drug Substance

Development, GSK, Gunnels Wood Rd, SG1 2NY Stevenage, UK ^[1]

Correspondence regarding this paper should be addressed to Pierantonio Facco

**I-027 APPLICATION OF MACHINE LEARNING MODELS FOR THE
PREDICTION OF BIOCONJUGATION PROCESSES IN ANTIBODY DRUG
CONJUGATES DEVELOPMENT**

Lorenzo Angiolini, Co-Authors: Anna Visibelli Università degli studi di Siena Andrea

Tafi Università degli studi di Siena Ottavia Spiga Università degli studi di Siena

Elena Petricci Università degli studi di Siena

Wednesday, 11 October 2023

DAY THREE – AM BioProcessing – Cell and Gene Therapy

Session Chairs: Colm O'Donnell, UCD School of Biosystems and Food Engineering, University College Dublin, Belfield, Dublin, Ireland

The emergence of new, more sensitive analytical methodologies which improve the ability to characterize biotherapeutic products introduce challenges of where this increased sensitivity has potential impact to patients. *Acceptable* specification criteria are largely defined only by in vitro empirical data for product that has been used in clinical studies. This session will focus on innovative, risk-based approaches to develop and establish effective specifications and adaptive process controls that are predictive of product safety, efficacy and quality.

- 9:00 a.m. **Introduction: BioProcessing Engineering**
Colm O'Donnell, UCD School of Biosystems and Food Engineering, University College Dublin, Belfield, Dublin, Ireland
- 9:30 a.m. I-018 **PAT to the Future: Spectroscopy and Chemometrics for Vaccine Drug Product Development**
Angelo Palmese, GSK Vaccines, L. Di Meola¹, S. Luckham¹, D. Pasqui¹, A. Restivo², D. Bianciardi³, A. Albano¹, A. Marcelli¹, A. Moriconi¹, C. Pergola¹ ¹ Global Drug Product Development, Technical R&D, GSK Siena ² CMC Chemometrics Delivery, Technical R&D, GSK Siena ³ Vx CMC Statistics Unit, Technical R&D, GSK Siena
- 10:00 a.m. I-009 **A Risk-Based Scientific Approach to Qualify Replenishment KING CELL BANKS, AN INDUSTRY VIEW**
Scott Wensel, Janssen R&D LLC
Co-Authors: Pamela Pegman - Pfizer Stephanie Robichaud - Regeneron Karan Middleton - BioPhorum James Giulianotti - Roche Melanie Marchand - Sanofi Nicholas Moore - BMS
- 10:30 a.m. **Break**
- 11:00 a.m. **Panel Discussion**
All Speakers
- 11:30 a.m. **Innovative Technologies Panel**
Topics to be Announced
- 12:00 p.m. **Poster Awards and Displays**
Session Chair: Mel Koch, CPAC, Seattle, WA, USA
- 12:30 p.m. **Lunch**

Table Top Exhibits – 10:30 a.m. – 1:00 p.m. - Tear down – 1:00 p.m. – 3:00 p.m.

Wednesday, 11 October 2023

DAY THREE – PM Session Chair: Mel Koch, CPAC, Seattle, WA, USA

1:30 PM Wrap-Up Session/Action Plan Meeting

Numerous opportunities are provided during the conference for pharmaceutical thought leaders to discuss and evaluate progress made to date and to propose new ways to introduce innovation and improve manufacturing control and process optimization. Participation of key regulators is fundamental to achieve successful outcomes. In this session, we plan to assess Cortona 2018 progress and seek feedback from participants, vendors and speakers. Future Cortona meeting planning will be based on the outcome of this session. It is also likely to publish a white paper summarizing Cortona 2023 presentations, posters and wrap-up session key findings.

All meeting attendees are invited to join the organizing committee to participate in the wrap-up session.

3:00 p.m. **Close**

Table Top Exhibits – 10:00 a.m. – 1:00 p.m. – Tear down – 1:00 p.m. – 3:00 p.m.

IFPAC CORTONA 2023 EXHIBITORS

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