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

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 Kitak1, Dejan Tomazevic1,2 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, Universita 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.
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. Kirschnecht4, M. Horn2, J. Khinast5  
1 Research Center Pharmaceutical Engineering GmbH, Inffeldgasse 13, 8010 Graz, Austria  
2 Institute of Automation and Control, Graz University of Technology, Inffeldgasse 21B, 8010 Graz, Austria  
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**

5:30 p.m.  
**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.
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 Rossinia, Gulier Bekiyevab Luigi Vaccaraoa aLaboratory of Green Synthetic Organic Chemistry, Dipartimento di Chimica Biologia e Biotecnologie, Universita’ 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 Scarabottinia, Francesco Minioa, Luigi Vaccaroa a Laboratory 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, Gary Fink, Pierantonio Facco,[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

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

**INDATECH**, 34, Rue Georges Besse, Clapiers, France
Tel: 33 480 7001 44; Email: f.chauuchard@indatech.eu: [www.indatech.eu](http://www.indatech.eu)

**MOLNAR-INSTITUTE for applied chromatography**, Berlin, Germany
Tel: 49 3042155910; Email: info@molnar-institute.com; Web: [www.Molnar-Institute.com](http://www.Molnar-Institute.com)

**SIEMENS AG**, Guido Gezellestraat 123, Huizingen 1654, Belgium, Tel: +3225364043; Email: jan.verelst@siemens.com; Web: [www.siemens.com/global/en/home.html](http://www.siemens.com/global/en/home.html)

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