The Cortona Conference: Manufacturing Innovation and the Global Regulatory Harmonization

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

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

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Monday, 9 October 2023

DAY ONE – AM **Pharmaceutical/Bio Manufacturing Innovation**
Plenary Session
Session Chair: Mel Koch, CPAC, MK Optimization & Control, 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!

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, Consultant, 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 and Posters – 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 Industry 4.0 revolution in the pharmaceutical industry**

Pierantonio Facco, University of Padova, Padova, Italhy
Co-Authors: Simeone Zomerb, Antonio Benedettib, Ruth C. Rowland-Jonesc, Paloma Diaz-Fernandezc, Gary Finkac, Fabrizio Bezzoa, and Massimiliano Baroloa aCAPE-Lab –Computer-Aided Process Engineering Laboratory Department of Industrial Engineering University of Padova via Marzolo 9, 35131 Padova PD (Italy) bProduct & Process Engineering GlaxoSmithKline Research & Development Ware (U.K.) cBiopharm Process Research GlaxoSmithKline Research & Development Stevenage (U.K.)

2:30 p.m. **Digital Transformation in Pharmaceutical Development and Manufacturing**

Applied Materials, Inc., (TBC)

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 Tomaževič1,2 1 Sensum, Computer Vision Systems, Ljubljana, Slovenia 2 Laboratory of Imaging Technologies, Faculty of Electrical Engineering, University of Ljubljana, Slovenia

3:30 p.m I-019 **The Future of Digitalization and Smart Labs & Manufacturing**

Paul Gillhan, Optimal Industrial Technologies Ltd,
Yate, Bristol, UK

4:00 p.m. **Break**

4:30 p.m. **Data & Information Management–Non Pharmaceutical Company Approach**

TBA

5:00 p.m. **Modern Innovative Technologies for API**

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

5:30 p.m.	**Panel Discussion** All Speakers and Agency Representatives
	Introduction of Student PostersStudent Posters Poster Chair: Mel Koch, CPAC, Seattle, WA, USA
5:45 p.m.	**Close**
6:45 p.m.	**Evening Cocktail Event/Light Dinner**

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

Tuesday, 10 October 2023

DAY TWO – AM **BioProcessing – Cell and Gene Therapy**
Session Chairs: Colm O'Donnell, UCD School of Biosystems and Food Engineering, University College Dublin, Belfield, Dublin, Ireland

Among the most significant risk concerns with large molecule biotherapeutic products, i.e., mAbs, ADCs, GTx & CTx products, is the uncertainty associated with the source and magnitude of immunogenic responses (safety) particularly those that may be induced by changes in the quality of a product. Technical strategies that demonstrate process consistency and product control and reduce the uncertainty/unpredictability of product attributes that impact safety and immunological responses, are critical for improving biotherapeutic manufacturing processes. While analytical controls measure and confirm process robustness and consistency, their relevance to product safety and efficacy is not absolute. 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. The value of prior therapeutic experience, attribute understanding/performance models and translation of process capability to predict patient impact is frequently perceived as a subjective characterization of risk and not generally accepted by regulatory authorities. 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.

Registration

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-004 **Implementation of Scalable Intensified Bioprocessing Strategies enabled by Advanced PAT Tools**
Melisa Carpio, Sartorius Stedim Biotech

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. 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

Agency Perspective BioProcessing (TBC)

11:00 a.m. **Break**

11:30 a.m. **Pharmaceutical Product Lifecycle Management: ICH Q12**
Novo Nordisk, TBA

12:00 p.m.	**Panel Discussion** All Speakers
12:15 p.m.	**Fast Track Presentations/Solution Providers – Part II** Session Chair: Mel Koch, Consultant, 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

Reinventing Pharmaceutical Delivery Systems
Lyndra Therapeutics, USA (TBC)

2:00 p.m. I-006 **MTP standard for automating modular plants in pharma: status and perspectives**
Marco Banti, Independent Consultant

2:30 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. Rehrl1, 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 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

3:00 p.m. **Break/Group Photo**

3:30 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)

Continuous Manufacturing Case Study – II:

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. **Lowering the threshold of PAT integration into continuous pharmaceutical manufacturing lines Part II**
Jan Verelst, Siemens, Brussels, Belgium

4:30 p.m. I-016 **Novel PAT tools in the GMP Space for Biologics in Continuous Manufacturing**
Marco Bieri, Merck Sharpe Dohme, (MSD), Luzern, Schachen, Switzerland

5:00 p.m.	**Panel Discussion – All Speakers**
	Student Posters: Introductions and Discussions
5:45 p.m.	**Close**
6:45 p.m.	**Gala Dinner - Town Centre**

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

Wednesday, 11 October 2023

DAY THREE – 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. **Challenges of Raw Materials & Excipients Used in the Manufacture of Pharmaceutical Products**
Brian Carlin, Consultant, Lawrenceville, NJ, USA & IPEC

10:00 a.m. **PAT Approaches using NMR Analytical Techniques (TBA)**
Michael Hammer, Bruker BioSpin GmbH, Etingen, Germany

10:30 a.m. **Break**

11:00 a.m. **Blend monitoring of a Low Dose formulation Using Sam-Spec Spectroscopy**
fabien Chauchard, INDATECH, clapiers, HERAULT, France
Topic: Case Examples of PAT - Real Time Release in Production & Rapid Testing

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 a.m. **Panel Discussion**
All Speakers

12:30 a.m. **Poster Session**
Poster Chair: Mel Koch, CPAC, Seattle, WA, USA

1:00 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, Consultant, CPAC

2:00 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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