

**The IFPAC Cortona Conference:
Manufacturing Innovation**

PRELIMINARY PROGRAM



October 5 - 8, 2025

Centro Convegni Sant'Agostino

Cortona, Italy

Register and View the Latest Program Details at www.IFPACcortona.org

SESSION I
Plenary Session: Pharmaceutical/Bio Manufacturing Innovation
Session Chair: Mel Koch, 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.	Overview (Past & Present) and Introduction to the Plenary Talks Mel Koch, Seattle, WA, USA
9:30 a.m.	An Update - The Role of Innovative Engineering, Systems Thinking and New Unit Operations in the Circular Bioeconomy (Title TBA) Harald U. Sverdrup, Professor of System Dynamics, Game Development & Interactive Simulations, Norwegian Inland University, Hamar, Norway
10:00 a.m.	What is Needed in the Pharma / Biotech Industries – Advances in Providing Medicines for All. (Title TBA) B. Frank Gupton, Department Chair, Chemical & Life Science Engineering, Virginia Commonwealth University, Richmond, VA
10:30 a.m.	Break
11:00 a.m.	Advances in Micro Extrusion Technology Simone Maccagnan, GiMAc, Italy
11:30 a.m.	Microbiome Advances CTO, SeqBiome (TBC)
12:00 PM	The Use of Molecular Imprint Polymers to Facilitate More Efficient Separation of Component from Complex Process Streams - A New Area Technology Alessandra Bossi, University of Verona
12:30 p.m.	Sponsor/Exhibitor Introductions , Approx 5 min. per sponsor Short History on Etruscan Culture Harald U. Sverdrup, Norwegian Inland University, Hamar, Norway
1:00 p.m.	Lunch
Table Top Exhibits – 10:00 a.m. – 4:30 p.m. / Set up 8:00-10:00 a.m.	

SESSION II
Pharmaceuticals - Challenges & Opportunities
Chair: Ali Afnan, StepChange Pharma

The pharmaceutical industry finds itself at a critical juncture, confronted with regulatory requirements, scientific challenges, financial and cost-reduction pressures, and the perpetual imperative to uphold quality and patient safety. From the initial stages of drug development to the meticulous control of manufacturing processes to guarantee quality, globalization, digital innovation, regulatory and cost-reduction measures present both challenges and innovative opportunities that must be strategically harnessed to fulfill business objectives.

This conference will explore opportunities and challenges from the perspective of researchers, regulators, technology suppliers and manufacturers.

Manufacturing Opportunities of the Future

Ali Afnan, StepPharma

Effective removal of immunogenic dsRNA byproducts from ssRNA based vaccines and therapeutics

Thomas Scanlon, Repligen

Process Control & State of Control

Ian Flawn Orpana, Verto Pharma

Biomarkers - Challenges and Opportunities in Manufacturing: Industry Perspective

Dr. Ralf Hess

Challenges and Opportunities in Manufacturing

Jae (Mike) Lee (Formerly FDA)

Fifth-Order Pharmaceutical Manufacturing: Aligning Evidence, AI, and Empathy in Pharma

Ajaz Hussein, NIPTE

Q&A / Panel Discussion: All Present

SESSION III

Artificial Intelligence / Industry 5.0 / Machine Learning / Modeling Digital Technologies & Data Information Management

Session Chairs: Pierantonio Facco, University of Padova, Padova, Italy and TBA

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.

Digital Technologies & the Latest Applications (TBA)

Jan Verelst et al., Siemens

PAT driven continuous and controlled freeze-drying for biopharmaceuticals according to GMP

Prof. Thomas De Beer, Ghent University, Ghent, BE

Advance in Process Control Utilizing Magnetic Resonance Spectroscopy

Michael Hammer, Bruker BioSpin GmbH & Co. KG (Abstract Received) – Requested for IVA

Holistic Approach to Optimize Raman PAT Implementation in the Lab & Facility of the Future

Fabrice Thomas, Merck KGaA, Darmstadt, Germany (Abstract Received) – Requested for IVA

AI & Digital Technologies, TBA

Q&A / Panel Discussion

SESSION IV - A

PAT and Analytics

Session Chairs: Philip Deamer, GlaxoSmithKline, Ware, Hertfordshire, UK and Filipe Gaspar, Hovione FarmaCiencia SA

Full Day Session with Developments in Continuous Manufacturing (See IV-B)

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.

Comparison of Instant Moisture Content Measurement of Tablets by Near Infrared Spatially Resolved Spectroscopy and 3-D Microwave Resonance Technology

Sven Borchert, Product Specialist, Pharma Technology (Abstract Received)

PAT & Analytics (TBA)

TBA, Sensum (Sanofi) – TBC

PAT & Analytics– New Concepts - Development to Manufacturing (TBA)

Philip Deamer et al., GSK

Industry Implementations – Innovator Insights

Cristina Ruiz Samblás, Makosfield, AstraZeneca

Advancing Process Analytics: Connecting QbD, PAT, and Automation for Smarter Drug Manufacturing

Ernie Hillier, EJM Consulting

Advanced Analytics (TBA)

Andrew Anderson, Consultant, TBC

Advanced Analytics (TBA)

TBC, J&J et al.

PAT Solutions

TBA, Solution Provider

Q&A / Panel Discussion

SESSION IV – B

Developments in Continuous Manufacturing

Session Chairs: Filipe Gaspar, Hovione FarmaCiencia SA and Philip Deamer, GlaxoSmithKline, Ware, Hertfordshire, UK

Full Day Session with PAT & Analytics (See IV-A)

This conference session will explore the exciting potential of continuous manufacturing for oral dosage forms - an emerging technology poised to transform pharmaceutical production. By shifting from traditional batch processes to continuous tableting, the industry can achieve real-time quality monitoring, faster drug development, greater supply chain flexibility, improved sustainability, and more cost-effective manufacturing. A diverse panel of stakeholders will share their perspectives, including regulators discussing evolving guidelines and quality expectations, academic researchers presenting advances in process modeling and control, and technology providers showcasing the latest equipment and digital tools enabling continuous production. Innovators and Contract Manufacturing Organizations (CMOs) will highlight how they are adopting this approach to offer flexible, scalable manufacturing solutions that meet the demands of a dynamic market. Overall, attendees will gain a comprehensive view of the opportunities, challenges, and collaborative efforts needed to drive the widespread adoption of continuous tableting across the industry.

Continuous Manufacturing of Oral Dosage Forms: Quality and Regulatory Perspectives from a CDMO Standpoint

Nuno Matos, Hovione

News from Academia and Research Institutions – Advancing Science & Technology – Part I

Selma Celikovic, Senior Scientist, Research Center Pharmaceutical Engineering GmbH

Predictive platforms for continuous manufacturing of oral solid dosage forms

Prof. Thomas De Beer, Ghent University, Ghent, BE

Industry Insights from Innovators – Part I

Eleonora De Giorgi, AstraZeneca (TBC)

Industry Insights from Innovators – Part II

TBA, GSK

Enabling Technologies – Solutions from a Technology Provider

James Holman, GEA

A view from the CMO

Filipe Gaspar, Hovione FarmaCiencia SA

Q&A / Panel Discussion

SESSION VI

BioProcessing – Cell and Gene Therapy: A.I. and New Innovations

Session Chair: 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.

An Update: BioProcessing Engineering

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

Growth & Development in the Biopharma Manufacturing Industry

NIBRT - The National Institute for Bioprocessing Research and Training (NIBRT), Ireland – Invited (TBC)

Potential from previous speakers in 2023 session:

An Update from 2023 Cortona Meeting - PAT of the Future: Spectroscopy and Chemometrics for vaccine drug product development

Angelo Palmese et al., GSK Vaccines (TBC)

Update - A RISK-BASED SCIENTIFIC APPROACH TO QUALIFY REPLENISHMENT WORKING CELL BANKS - AN INDUSTRY VIEW

Scott Wensel Director, et. al., Cell Banking Janssen R&D LLC (TBC)

Innovative Technologies

TBA

Cell & Gene AI and Innovation – TBA

Ernie Hillier, EJH Consulting

Q&A / Panel Discussion

Wrap-Up Session/Action Planning Meetings – TBC

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

CALL FOR STUDENT POSTERS!

Students are the future of this industry and encouraged to attend!

EXHIBITOR SPONSORSHIP OPPORTUNITIES ARE AVAILABLE!

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Contact info@ifpamet.org for more details or with recommendations.
www.IFPACcortona.org

Active Participants/Session Leaders

Ali Afnan, StepChange Pharma, USA

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 USA

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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