The IFPAC Cortona Conference:

Manufacturing Innovation

PRELIMINARY PROGRAM & SCHEDULE

The scientific program as outlined in the program will be adhered to as much as possible.

October 5 - 8, 2025

Centro Convegni Sant'Agostino

Cortona, Italy

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

SESSION I - MONDAY - AM

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.	**Advancing Process Analytics: Connecting QbD, PAT, and Automation for Smarter Drug Manufacturing** Ernie Hillier, EJH Consulting
11:30 a.m.	**Custom Design of Materials and Biomaterials: from Precision Recovery to Therapeutics** Alessandra Bossi, University of Verona
12:00 PM	**Update on the Regulatory Framework** Ali Afnan, Step Change Pharma, Inc.
12:20 p.m.	**Sponsor/Exhibitor Introductions,** Approx 5 min. per sponsor
12:40 p.m.	**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 – MONDAY PM
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.

2:00 p.m. **Manufacturing Opportunities of the Future**
Ali Afnan, Step Change Pharma, Inc.

2:30 p.m. **Fifth-Order Pharmaceutical Manufacturing: Aligning Evidence, AI, and Empathy in Pharma (DOUBLE TIME SLOT - ?)**
Ajaz Hussein, NIPTE

3:00 p.m. **Effective removal of immunogenic dsRNA byproducts from ssRNA based vaccines and therapeutics**
Thomas Scanlon, Repligen

3:30 p.m. **BREAK – Exhibits / Posters**

4:00 p.m. **Process Control & State of Control**
Ian Flawn Orpana, Verto Pharma

4:25 p.m. **Biomarkers - Challenges and Opportunities in Manufacturing: Industry Perspective**
Dr. Ralf Hess

4:55 p.m. **Challenges and Opportunities in Manufacturing**
Jae (Mike) Lee (Professor, Formerly FDA)

5:20 p.m. **CDMO Talk, TBC**

5:45 p.m. **TBA**
Fabrica Italiana Sintetice, CDMO, Italy

6:15 p.m. **Q&A / Panel Discussion: All Present**

6:30 p.m. **End**

6:30 p.m. – 8:00 p.m. Evening Cocktail Event / Light Dinner

Table Top Exhibits – 10:00 a.m. – 4:30 p.m. / Posters 2:00 p.m. – 4:00 p.m.

SESSION III – TUESDAY AM
The Future of PAT and Analytics
Artificial Intelligence / Industry 5.0 / Machine Learning / Modeling
Digital Technologies & Data Information Management

Session Chairs: Philip Deamer, GlaxoSmithKline, Ware, Hertfordshire, UK
Filipe Gaspar, Hovione FarmaCiencia SA
and Pierantonio Facco, University of Padova, Padova, Italy

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.

This session will also cover 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.

9:00 a.m. **HIGH SHEAR WET GRANULATION MONITORING WITH PROCESS ANALYTICAL TECHNOLOGIES (PAT), IMAGE ANALYSIS FOR GRANULATION AND MOISTURE SENSOR FOR FLUID BED DRYING (FBD)**
Philip Deamer, GSK

9:30 a.m. **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

10:00 a.m. **Advances in process control utilizing magnetic resonance spectroscopy**
Michael Hammer, Bruker BioSpin GmbH & Co. KG

10:30 a.m. **BREAK**

11:00 a.m. **Holistic Approach to Optimize Raman PAT Implementation in the Lab & Facility**
Fabrice Thomas, Merck KGaA, Darmstadt, Germany

11:30 a.m. **Digital Technologies & the Latest Applications (TBA)**
Jan Verelst et al., Siemens

12:00 p.m. **PAT & Analytics (TBA)**
Andrew Anderson, Consultant (Previously at J&J) - TBC

12:30 p.m. **PAT & Analytics (TBA)**
Louis Bouckaert, Ghent University (TBC)

Q&A / Panel Discussion

1:00 p.m. **Lunch**

Table Top Exhibits – 10:00 a.m. – 4:30 p.m. / Posters 2:00 p.m. – 4:00 p.m.

SESSION IV – TUESDAY PM
Developments in Continuous Manufacturing

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

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.

2:00 p.m.	**Continuous Manufacturing of Oral Dosage Forms: Quality and Regulatory Perspectives from a CDMO Standpoint** Nuno Matos, Hovione
2:30 p.m.	**A Strategy for Digital Real-Time Release Testing (RTRT) in Continuous Tablet Production** Selma Celikovic, Senior Scientist, Research Center Pharmaceutical Engineering GmbH
3:00 p.m.	**Predictive platforms for continuous manufacturing of oral solid dosage forms** Prof. Thomas De Beer, Ghent University, Ghent, BE
3:30 p.m.	**Break / Group Photo**
4:00 p.m.	**Industry Insights from Innovators – Part I** Cristina Ruiz Samblás, Makosfield, AstraZeneca
4:30 p.m.	**Industry Insights from Innovators – Part II** Andrew Shier, GSK
5:00 p.m.	**Enabling Technologies – Solutions from a Technology Provider** James Holman, GEA
5:30 p.m.	**A View from the CMO** Filipe Gaspar, Hovione FarmaCiencia SA
6:00 p.m.	**Q&A / Panel Discussion**
6:30 p.m.	**End**
6:45-8:30 p.m.	Gala Dinner – Towne Center

SESSION VI – WEDNESDAY AM

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.

9:00 a.m. **An Update: BioProcessing Engineering**
Colm O'Donnell, UCD School of Biosystems and Food Engineering, University College Dublin, Belfield, Dublin, Ireland

9:30 a.m. **Growth & Development in the Biopharma Manufacturing Industry**
NIBRT - The National Institute for Bioprocessing Research and Training (NIBRT), Ireland – Invited (TBC)

10:00 a.m. **PAT driven continuous and controlled freeze-drying for biopharmaceuticals according to GMP**
Prof. Thomas De Beer, Ghent University, Ghent, BE

10:30 a.m. **BREAK**

11:00 a.m. **Advancing Early AAV Development with TrueMass CDMS: Bridging Analytical Gaps in Preclinical Manufacturing and Enabling Safer Gene Therapy**
Ernie Hillier, EJH Consulting

11:30 a.m. **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)

12:00 p.m. **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)

Q&A / Panel Discussion

12:30 p.m. **LUNCH**

Table Top Exhibits – 10:00 a.m. – 1:00 p.m. / Posters 10:00 a.m. – 1:00 p.m.

WEDNESDAY – PM

1:30 – 3:00 P.M.

Wrap-Up Session/Action Planning 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. 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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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

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