IFPAC Annual Meeting 2026

March 1-4, 2026 Washington, D.C., USA

Preliminary Program Overview

International Conference & Exhibition

Navigating the Future of

Advanced Manufacturing Science

www.IFPACglobal.org

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IFPAC® - 2026

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ADVANCED MANUFACUTINRG SCIENCE & INNOVATION

PROGRAM PREVIEW

A leading conference in Process Analytical Technology…PAT, Process Analysis & Control, Continuous Manufacturing, and Advanced Manufacturing Science; IFPAC has earned a reputation for being a forum for insightful discussions bringing you the latest trends and real-life applications in the field of process analytical chemistry for the pharmaceutical, biotechnology, generic, chemical, petrochemical, food, and related industries.

Throughout the IFPAC event, explore emerging trends and innovative strategies that will equip you with the knowledge and insights to stay ahead of the curve.

The IFPAC program includes updates on important mainstay topics, coverage of new critical areas & technologies, new innovative solutions on the horizon, as well as planning for potential challenges.

The event includes powerful sessions, expert speakers, exhibition, and numerous networking opportunities. Leaders from across the globe will present important research, technological advances, case studies, and the latest in regulatory guidance, standards & controls.

The IFPAC-2026 program is relevant and forward-thinking, bringing together experienced professionals and the next generation of leaders. Meet with colleagues, renew acquaintances, and build key relationships.

IFPAC has been leading the way in Advanced Manufacturing for over 35 years.

REGISTER FOR IFPAC-2026 TODAY!

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PRE-CONFERENCE WORKSHOP
AI in Pharma/Bio Manufacturing
Aspects of Regulatory Harmonization, Supply Chain Integrity, and Increasing Digitalization

Chairs: Michael Tarlov, NIST, Kevin Macias, Eli Lilly, Ganeshkumar Subramanian, BMS

A special pre-conference workshop will kick off the event the afternoon of March 1st: AI in Pharma: Aspects of Regulatory Harmonization, Supply Chain Integrity, and Increasing Digitalization. This theme will explore how artificial intelligence is transforming pharmaceutical manufacturing, driving regulatory harmonization across global markets, strengthening supply chain integrity, and accelerating the digitalization of processes. Experts will share research, technological advances, case studies, and the latest regulatory guidance, standards, and controls, with a particular emphasis on the integration of AI and digital technologies. Presentations will including regulatory insights from regulatory organizations and industry leaders will be followed by a Panel Discussion (All Speakers) & Questions from the Audience.

Speakers Announcements Coming Soon!

PLENARY SESSION
From Insight to Impact: Accelerating Innovation Through Smart Manufacturing Systems

Chairs: Michael Tarlov, NIST, Kevin Macias, Eli Lilly, Ganeshkumar Subramanian, BMS

The Plenary Session will set the stage with presentations from industry, government, and innovative leaders on “From Insight to Impact: Accelerating Innovation Through Smart Manufacturing Systems”.

Conference tracks will cover QbD/PAT/RtRT, Continuous Manufacturing & Risk Management, Industry 4.0, Control Strategy & Implementation, Process Monitoring with a focus on Automation, Life Cycle Management and Emerging Regulatory Expectations, Bio-Technology, Emerging Technologies, Analytical Technologies & Applications, Chemometrics & Advanced Separations, Sampling & Process Spectroscopy, and more.

Check back soon for Speaker Announcements!

IFPAC-2026
PRELIMINARY OVERVIEW OF TRACKS
The below order does not reflect days and times. Schedule is to be Announced.

Real Time Analytics (RTRT/PAT/QbD) Track

This Track is a long standing, important series of sessions for IFPAC. As QbD, PAT and RTRT have evolved over the last decade, so has this track to bring you new updates and developments.

Case Examples of PAT - Real Time Release in Production & Rapid Testing

Chairs: Manoharan Ramasamy, Merck and Lorenz Liesum, Roche

Presentations will cover rapid testing (including real time release), clinical or commercial, and both small and large molecules.

Control Strategy and Technology Development for Oligonucleotide and RNAi Therapeutics

Chairs: Zhenqi (Pete) Shi, Genentech and Mohan Sapru, FDA

The session is intended to showcase the wide array of analytical technologies used for process development and manufacturing of oligonucleotide therapies. The analytical technology could be as straightforward as online UV monitoring and as complicated as offline mass spec characterization of the oligo sequence and impurities. The roles played by the analytical technology vary from providing process understanding to real-time process monitoring, and from offline characterization of impurity formation to real-time release testing on oligo sequence. It is the intention of the session to identify potential gaps in the field and look for future opportunities to collaborate.

Peptides / Complex API – Manufacturing & Regulatory Considerations

Chair: Katherine Windsor, FDA and Pinky (Paresma) Patel, Gilead Sciences

This session will have presentations from both industry and regulatory agencies with a focus on chemistry, manufacturing, and controls for peptide drug substances and drug products. Peptides are complex drug substances with unique considerations from manufacturing and regulatory perspectives.

Excipients

Chairs: Brian Carlin, Consultant and Chris Moreton, FinnBrit

A panel of speakers will review the impact of excipient variability, the role of excipients in advanced technologies (CM, 3D printing) and implications on quality risk management.

Innovative High Resolution Imaging

Chairs: Steve Hammond, ExpoPharma and
Jeff Hall, Mecuriale

This session will share the latest imaging techniques and technologies from across the globe.

CONTINUOUS MANUFACTURING TRACK

The successful implementation of Continuous Manufacturing processes in facilities has continued to increase over the last several years, and is being applied not only in the area of small molecules, but large molecules as well. This multi-track topic will include a series of interactive sessions presenting the latest developments, case studies and technologies.

Continuous Manufacturing: Latest Developments Towards Industrializing CM in Pharma (Presented by the IQ CM Working Group)
Chairs: Manel Bautista, Roche, Matthew Kiesz and Greg Connelly, Vertex

Presentations will dive into CM applications in the commercial manufacturing landscape, as well as the implementation of RTRT control strategies. The session will have as well an FDA representative to update on Agency interactions on CM. Challenges and opportunities will be part of the discussion.

Recent Developments to Realizing Continuous Manufacturing
Chair: David Acevedo, FDA and Doug Hausner, Thermo Fisher

This session will include recent developments as building blocks to realizing continuous manufacturing. It will cover developments in equipment and unit operations to facilitate implementation of CM, as well recent developments from Regulatory Perspective. Topics will include a mix of solid dose and continuous bio.

Agile PAT Development for Continuous Manufacturing – from Drug Product to Drug Substance and Beyond
Chairs: David Wilsdon, Pfizer, Zhenqi (Pete) Shi, Genentech, and Massoud Ghasemzadeh-Barvarz, Vertex

As more and more experience accumulated on the use of continuous manufacturing of drug products, the value of PAT has been well demonstrated from development to commercialization stage. In early development, the benefit of agile/lean PAT approaches has been proven valuable on improving process understanding and preparing for its readiness for GMP decision making. In late stage, the value of PAT is manifested on its critical roles played in the control strategy to assure product quality. The common use of PAT methods often ranges from monitoring, IPC, to RTRt. The session aims to survey the industrial practice on the different roles of PAT methods played in the control strategy, discussing the comprehensive considerations and challenges from technical, regulatory and quality aspects. Presentations will look into how batch PAT is doing given the success of CM in the field, and how companies are pursuing PAT on both sides.

Drug Substance Continuous Manufacturing
Chairs: Adil Mohammed, FDA and Tom Roper, VCU

Continuous manufacturing (CM) is an emerging technology can help address some of inherent challenges of the pharmaceutical batch manufacturing such as reliance on global supply chain for drug substance and drug products which lead to drug shortages and product recalls. CM consist of ‘continuous’ non-stop flow of materials and ‘continuous’ removal of product. Since the first drug product approval of Orkambi in 2015, there have been eight more drug product approvals of NDAs using this technology. However, the manufacture of drug substance (DS) using CM is still in its initial stages. The goal of this symposium is to bring together different aspects of DS-CM on to the same forum. This will include talks on using different platforms to synthesize DS such as continuous flow reactors (classically known as flow chemistry), continuous stirred tank reactors (CSTRs), continuous oscillatory baffled reactors (COBR) and other related platforms. The session will also

include talks on continuous crystallization and its integration with continuous DS synthesis. Another focus of the session will be process control strategy to monitor the progress of the continuous synthesis process with focus on process analytical technologies (PAT) tools and product quality. Lastly, the session will also include talks on digital twin models for DS-CM, use of kinetic modelling, simulation and machine learning which can play a critical role in continuous process development.

Continuous Manufacturing in Pharma & Biologics
Chairs: Gulsad Kucuk, BMS, Caitlin Schram, Vertex, and Tomas Vermeire, BMS

Regulatory agencies are driving the transformation from batch to continuous processing in biologics. The batch process involves multiple stages, and materials need to be held and transferred at certain points. In contrast, continuous manufacturing is a non-stop process in which the raw materials are constantly introduced into the production line. The drug product travels through the sequential processing steps without a holding time. It requires better understanding of the process and well-defined control strategy using process analytical technology (PAT) to ensure the critical material attributes, critical process attributes and critical quality attributes are well-controlled. In this session we will focus on how continuous manufacturing can increase manufacturing efficiency, reduce production cost, improve product quality and provide more production flexibility.

Check back soon for the latest updates on the program at www.IFPACglobal.org.

CONTROL STRATEGY & VALIDATION TRACK

This Track was created to include both long-time sessions and new sessions based on the increasing attention to and availability of solutions for end-to-end quality assurance & control. This session will include FDA perspectives on Quality Risk Management, new tools, and new technologies.

Quality Risk Management (QRM)
Chairs: G.K. Raju, Light Pharma, Rick Friedman, FDA, Andre Raw, FDA and Alex Viehman, FDA

This session will bring the latest updates for this important mainstay session at IFPAC, addressing risk management for both small & large molecules and the generic industry.

Knowledge Management as an Enabler to Pharmaceutical Lifecycle Management
Chairs: Theodore (Ted) Carver, FDA and Massoud Ghasemzadeh-Barvarz, Vertex

Since 2015 Knowledge Management has been re-emerging as a topic in pharmaceutical manufacturing. With continued discussion within industry and through organizations such as ISPE and PDA, industry and regulatory continue to use the KM discipline to improve the flow of knowledge around patient safety, products, and processes. With a year of rapid product development to address the global pandemic, harnessing knowledge from patients, products, and processes has never been more important to advancing the science of medicine. This session will address the use and advances of knowledge management as an enabler to product acceleration and the impact on lifecycle management. In the afternoon, the FDA will present on FDA's strategies and tools for knowledge management throughout product lifecycle to ensure

consistent regulatory decision-making and product quality.

Inspection & Surveillance of Facilities with Advanced Manufacturing Techniques: Technological Advances and Regulatory Challenges
Chairs: Hossein Birjandi Nejad, FDA, ORA

This session will provide an update on recent progress on advanced manufacturing technologies and use of novel solutions to implement, qualify and inspect pharmaceutical manufacturing. Though regulatory agencies have long recognized the value of advanced manufacturing technologies to product high quality medical products, advanced manufacturing processes present unique regulatory challenges. Updates on regulatory framework on regulation of advanced manufacturing including specific case studies will be presented. Lastly, recent advances on training techniques to effectively develop a nimble taskforce capable of operating or inspecting advanced manufacturing processes are presented.

Integration of PAT within Control Strategies for Drug Product Continuous Manufacturing
Chairs: Rodolfo Romañach, University of Puerto Rico - Mayaguez and Anthony Tantuccio, Hovione

This session evolves each year. This year it will focus more on the integration of PAT within control strategies. The decision making for CM & PAT is often related to the drug product or substance being developed. However, in manufacturing, we often hear that it "depends on the business case". This business case includes a balance of benefits, costs, and risk management; and many PAT projects depend on this decision-making progress. This session will highlight the grey areas and understand technical & business reasons why CM was/was not the right fit.

LIFECYCLE MANAGEMENT & EMERGING REGULATORY EXPECTATIONS TRACK

Regulatory Guidance continues to change and evolve as we see more case studies to learn from and grow, and as tools and technologies evolve. This important track continues to share perspectives and keep IFPAC attendees up to date on emerging expectations and how industry can fine-tune their processes and to adjust and maintain quality & control.

Portable & Point of Care and Distributed Manufacturing
Chairs: Andrew Dell, KeyPlants and Celeste Frankenfeld Lamm, Merck

Topics will include regulatory considerations, pod manufacturing with portability to manufacturing unit, and manufacturing direct to patient. Speakers from industry will share their perspectives, and end with a panel discussion.

Continuous Process Verification (CPV) & Validation – Practices, Challenges and Opportunities
Chairs: Ranjit Deshmukh, Ocugen and Vibhakar Shah, FDA

The theme for this session will also include a focus on global rapid process validation approaches. This is a topic of interest and mutual benefit to both industry and regulators to overcome the challenges being faced under the circumstances. The Chairs will continue to chair this important session covering regulatory expectations of and industry perspective on implementing Continued Process Verification (CPV) for new and legacy products, representing both small molecules and biologicals. With some real-life examples and case studies, the session will seek to highlight best

industry practices in implementing the CPV program within Firm's Quality system, and leveraging the knowledge gained through CPV program for improvement opportunities under proactive rather than reactive change control management. The session will also discuss some creative approaches in overcoming CPV implementation challenges and advances in Informatics for CPV programs.

The Challenges and Opportunities in the Use of AI/ML, PAT, Soft Sensor, Modeling, and MSPC for Process Monitoring and Control

Chairs: Michael Tian, FDA, Sandra Silva, ValGenesis, and TBA

Emerging tools, such as AI/ML, Multivariate Statistical Process Control (MSPC), Process Analytical Technology (PAT), Soft Sensor, and Modeling methodologies provide valuable means for on-line monitoring, establishing a solid diagnostic mean for early detection of process faults for both continuous and batch manufacturing. This type of monitoring approach for assessing the operational performance of the process is a strategically valuable, as it allows to look at the process variables both individually and multi-dimensionally via its correlation within complete design space. This session aims to cover from classical approaches to the state-of-the-art ideas and implementation in these technologies usability and encourages a robust discussion between industry and regulators on how we can go further in using this framework for assessing the state of control of a process in real time

Using PAT and Data Automation Systems to Enable a Proactive CPV Program

Chairs: Ganeshkumar Subramanian and June Axelson, BMS

Continuous process verification (CPV Stage 3) is a regulatory expectation and crucial to ensuring the quality of pharmaceutical products. Process analytical technology (PAT) is an important tool to measure, monitor, and provide data to drive the CPV program. Data automation is another key aspect of the CPV program that enables the real-time collection, analysis, and prediction of process trends. This session will focus on commercial manufacturing with case studies leveraging PAT and data automation systems to identify shifts or trends and take a proactive approach toward product robustness and continuous improvement.

Emerging Technologies and Regulatory Challenges to Sterile Product Manufacturing

Chairs: Maxwell Korang-Yeboah, FDA, Serguei Tchessalov, Pfizer, and Steve Rhieu, FDA

This session will highlight recent advances and regulatory considerations in freeze thaw, fill finish, aseptic drying techniques. Specifically, case studies on the application of emerging techniques for process monitoring and real time control, digital twins, robotics, and AI for sterile manufacturing will be presented. Further, the session will include presentations on alternates to traditional vial freeze drying such as aseptic spray freeze drying, spray-drying and continuous lyophilization.

BIOTECHNOLOGY TRACK

Bio-Manufacturing & Bio-Processes continues to expand and draw more attention at IFPAC both in the number of attendees and speakers from this industry. Make sure to check out additional sessions on continuous manufacturing and emerging technologies covering large molecule applications.

MSAT & Biologics

Chairs: Tony Wang, Amgen, Angela Martinho, ValGenesis Company, Ranjit Deshmukh, Ocugen

Manufacturing Sciences & Technologies relate to science-based process and product understanding. It spans all stages from late stage development, through industrialisation and commercialization, of biologics. This session covers all aspects of Quality as a Manufacturing Science, as indicated in ICH Q8 through Q12 guidelines. Applications of QbD elements of biologics manufacturing, such as risk-assessments, PAT, DoE, control-strategy and lifecycle management initiatives, will be explored.

New Modalities for Biological Products

Chairs: Kelley Burridge Tillinghast, FDA, Colm O'Donnell, UCD, and Angela Martinho, ValGenesis

This session is an expansion of the historical biosimilars session, and will discuss new modalities that are emerging as of significant importance in the overall biopharmaceutical products landscape. These include viral vector technologies, mRNA products, antisense oligonucleotides, antibody-drug conjugates, and biosimilars to name a few. The session will present current advances with these new product areas as well as outline the challenges that lie ahead with them.

Advanced Biomanufacturing Technology & Innovation

Chairs: Seongkyu Yoon, University of Massachusetts – Lowell and Nicholas Trunfio, FDA

Biomanufacturing is one of the key technology areas identified by the US Advanced Manufacturing Partnership (AMP) as an appropriate target for public-private investment to support advances in manufacturing and U.S. competitiveness. The development of advanced biomanufacturing technologies consortium will support the quickly-growing biomanufacturing industry and will establish sustained leadership of the U.S. in the field. Regional meetings will be organized by the consortium in order to consult with experts from government, academia and industry and seek to: 1) discuss the challenges and drivers of biomanufacturing in upstream, downstream and drug product processing, 2) identify the major scientific/technological, operational and regulatory barriers to the adoption biomanufacturing in the biopharmaceutical industry and 3) define a pre-collaborative work space for companies, academia and regulatory authorities.

Manufacturing Technologies for Cell & Gene Therapies

Chairs: Laura DeMaster, FDA, Colm O'Donnell, UCD, and Seongkyu Yoon, University of Massachusetts-Lowell

This half-full day session will look at cell therapy, gene therapy, and COVID-19 response. Presentations will cover the technological challenges and engineering solutions for the advanced biomanufacturing of cell and gene therapies. Challenges requiring new paradigms in the manufacturing of the cell therapy products, recent advances in viral vector production, and emerging gene-editing tools and their deployment in human clinical trials are the main focus of the session.

Automation Upstream (New Title TBA)

Chairs: Dan Kopec, Cell Culture Technology, Sartorius, Helena Ohrvik & Kristen Manchester, Cytiva

The use of single use systems is an increasingly important area to discuss and a full session will be dedicated to this topic. The first part of this session will cover PAT & Continuous Manufacturing with SUS including SU sensors, online monitoring, CQAs & CPPs, QbD vs. QbT and data analytics. The second part of this session will focus on SUS - Key Challenges for Implementation in DS & DP Process Steps including

regulatory challenges, integrity, particles, E&L, security of supply, standards in SUS (PDA, ASTM…), aseptic processing/closed systems and aseptic vs. sterile connection.

Smart Sensors for Bio-Processing
Chairs: Jagdish Tewari, Syros Pharmaceuticals Inc. Cenk Undey, Amgen, and Colm O'Donnell, UCD

Smart sensor applications in bio-processing are becoming increasingly essential and advanced. Real-time information from process sensors supports decision making and process control. Recent dramatic improvements in sensor technology including compactness and advanced microprocessor integration, particularly in wireless and microcontroller sensors, broaden the range of sensor applications in any field. Smart sensors are used for analog to digital conversion, digital processing, decision making, and two-way communications. This session will cover ways these smart sensors can benefit bio-processing.

Check out several additional Sessions on Biotechnology/BioManufacturing including Quality Risk Management, Particles in Biologic Drug Products, Case Examples of PAT - Real Time Release in Production & Rapid Testing and more!

INDUSTRY 4.0 & DIGITAL MANUFACTURING TRACK

Industry 4.0 and Digital Manufacturing are the future of this industry. Manufacturing Intelligence is providing new and quicker pathways to knowledge management. This Track will focus on the latest developments, applications and regulatory implications. Each session will focus on a stage in the product lifecycle.

Industry 4.0 - Strategies
Chairs: Kaschif Ahmed, ReciBio Pharm, Dan Hill, Thermo Fisher, Rob Guenard, Pfizer

Industry 4.0 is reshaping our industry to approach data exchange and automation in a new light. This session will cover strategies on implementation, program & framewords in smart manufacturing. And a vision for Industry 4.0 and digital manufacturing.

Industry 4.0 – Digital R&D
Chairs: Jayanti Das, FDA and Shyam Mudiraj, Regeneron

To further drive scientific and operational excellence in R&D, pharmaceutical companies are increasingly harnessing the power of digital transformation. Digital capabilities make it possible to empower R&D to generate data-driven insights and decision making, and are already impacting how the pharmaceutical products are discovered, designed and developed. This session, as part of the Industry 4.0 track, offers a thought-provoking knowledge exchange forum on the development and implementation of digital technologies across R&D value chain, including, but not limited to, Industry 4.0 IT/OT infrastructure, data management, data engineering, data science, advanced analytics, AI, ML, mechanistic/hybrid modeling, digital twin, advanced process control, cloud computing, IIoT, lab automation, robotics and AR/VR etc. The topics may cover business cases, technical approaches, digital platforms and tools, practical considerations in development and implementation, qualification and validation, business processes, resourcing, and workforce training using case studies in drug discovery, product design, process development and technology transfer.

Industry 4.0 - Delivering the Vision of Industry 4.0: Technological Advancements in Manufacturing for Building Smart Factories

Chairs: Ahmed Zidan, FDA and Ricardo J Leandro, ValGenesis

Digitalization has launched a new era of pharmaceutical drug manufacturing through the vision of smart factories with characteristics of data visibility, ubiquitous connectivity and automation autonomy. These enhancements are driven by the business goals of improving operational excellence, improved drug Quality and stable production of medicines for patients. Advanced Process Controls, Process Analytics, cloud based IT and OT infrastructures, Artificial intelligence, Digital Twins and the Industrial Internet of Things are few of the enabling technologies to deliver the vision of Industry 4.0. While Industry 4.0 has transformational potential, the journey is a major shift from established approaches to drug manufacturing leading to an unclear path for many manufacturers. This session will focus on various technological advancements in manufacturing for building smart factories of future.

Information Architecture

Chairs: Rachelle Howard, Vertex and Boonserm Kulvatunyou

Industry 4.0 requires that we share massive amounts of data in any manufacturing or research environment. The structure through which we communicate, contextualize and store data impacts the quality and integrity of system interfaces and depth of information that can be gained from the data. The data management at all levels is critical, from each instrument's measurement capabilities to how that information is relayed for process control and product control strategy to how CQAs in batch records and lab results link to product release. This session contains topics on the requirements and design for infrastructure for the data handling across all levels.

Stability Modeling for Small and Large Molecule Drug Substance and Drug Product

Chairs: Sithamalli Chandramouli (Mouli), FDA, Dan Skomski, Merck and Matthew Scholfield, AstraZeneca

Completion of stability data requirements is one of the most observed challenges during the submission of marketing applications to the FDA. Modeling Approaches to Reimagining Stability (MARS) has been proposed to support tentative retest date of a drug substance and expiration date of a drug product. MARS incorporate statistical tools and other available options as a part of developing predictive models. There is a widespread recognition for stability modeling internationally. The ICH has also initiated efforts to make targeted revisions of the ICH stability guideline series (Guidelines ICH Q1A-F, ICH Q5C). In its concept paper and business plan for this project the ICH expert working group states that the revised guidance will address the use of stability modelling for small and large molecules. In this session, experts from the FDA and industry will provide their perspectives on this topic. The discussion will include hyper accelerated stability testing and statistical evaluation of available long term and accelerated stability data to extrapolate and predict shelf life or retest date.

PAT & Advanced Manufacturing, A.I.

Chair: Greg Doddridge, AbbVie

EMERGING TECHNOLOGIES TRACK

Emerging Technologies are bringing new innovative solutions to the manufacturing plant and processes benefitting all industries. This series of session will share the latest developments and applications.

Particles in Biologic Drug Products
Chair: Ashwinkumar Bhirde, FDA

The presence of particles in parenteral drug products is a critical quality attribute that directly impacts the quality, efficacy, and safety of the product. Particles in drug products can be unintentional effects of product, process, packaging, or contamination. Particles are found in all classes of drugs, including biotechnology products, and biologics. This session will 1) discuss analytical methods to detect, identify, characterize, and classify particles in biologic drug products; 2) discuss the regulatory considerations in conducting product quality review with regard to particles; and 3) discuss common concerns regarding particles in biologic drug products regulated by FDA.

Drug Product Formulation, Fill-Finish, Delivery
Chairs: Stanley Kwok and Markela Murphy, AstraZeneca

The Drug Product Formulation/Fill-Finish/Delivery track focuses on the challenges during CMC development of biologics. The speakers from both public and private institutions will discuss breakthrough research, novel technologies, case studies and strategies to overcome both technical and regulatory challenges. The goal for this track is to provide a platform for discussion of innovative solutions for a holistic patient centric drug product development.

Modular Design of Advanced Manufacturing Systems
Chairs: Fernando Muzzio and Ravendra Singh, Rutgers University

This session will continue at IFPAC 2025 with more new approaches to modular design in manufacturing.

Modelling, control, and digital transformation of advanced drug substance and drug product manufacturing processes
Chair: Ravendra Singh, C-SOPS, Department of Chemical and Biochemical Engineering, Rutgers University

Advanced manufacturing (CM) is emerging as a preferred platform to produce active pharmaceutical ingredients (APIs) as well as full finished drug product. A digital twin is critical for quick design, adaptation, optimization, scale up, and control of manufacturing process, allowing for virtual modeling of operations without extensive process development. This session accepts the papers related to flowsheet modelling, digital twin modelling, mechanistic modelling, CFD modelling, control system design, control system implementation, digital scale-up and cyber-physical security of advanced drug substance manufacturing processes, injectable drug product manufacturing, solid dose manufacturing, and end to end manufacturing.

Statistical process control, and the application of modeling techniques to develop inhalation products.
Chair: Ali Afnan

More Details Coming Soon!

Lean Chemometrics
Chairs: Steve Hammond and O. Rehrauer

New Session at IFPAC 2026 – more details coming soon!

ANALYTICAL TECHNOLOGIES & APPLICATIONS TRACK

Technology advances in this industry have improved to not only include PAT (Process Analytical Technology), but numerous other analytical methods as well. This session will share different applications and approaches.

Data-Driven Solutions and Modeling-based Analytics for Small and Large Molecules
Chairs: Chikkathur Madhavarao, FDA and TBA

This session looks to share knowledge between and increase cross-industry discussions.

Emerging Key Concepts in Continuous Solid Dose Manufacturing
Chairs: Doug Hausner, Thermo Fisher Scientific and Fernando Muzzio, Rutgers University

This session continues to evolve each year with new research projects that are being done. The session will include a mix of academic researchers and the adoption of previous research from companies. They will share a mix of work being done in support of the FDA as well as industrial sponsored research, and a new program on Industry 4.0 about to be launched. There will also be talks on industrial sponsored research from different major companies.

Enhanced Analytical Approaches
Chairs: Shujun Chen, FDA and Nina Cauchon, Amgen

This session has been an important topic at IFPAC and will include a series of forward-looking presentations.

Enhanced Product and Process Robustness via PAT & Modeling
Chairs: Kevin Macias, Eli Lilly and Sonja S. Sekulic, Pfizer

This session focuses on approaches and case studies that demonstrate how robustness can be ensured via design and/or control. Approaches on measuring and assessing robustness will be discussed as an important part to process development and a lifecycle approach to product quality. This session will cover drug substance, drug product, excipients, container closure system and process variations and how robustness can be approached via an integrated approach.

PAT Implementation for Process Understanding to Small Molecule Drug Substance (SMDS)
Chairs: Archana Kumar, ORIC Pharmaceuticals, Zachary Dance, Merck and Brad Greiner, AbbVie

This session received a great response last year in its first year at IFPAC, and will provide a cross-industry opportunity to share knowledge about new techniques, new analyses, and best practices in addition to being an important networking opportunity.

CHEMOMETRICS & ADVANCED SEPARATIONS TRACK

This Track covers numerous analytical technologies that can benefit not only the petrochemical and chemical industries, but pharma, biotechnology, and more… IFPAC creates a unique opportunity to learn about successful applications and how technologies can be applied across all industries. There will be numerous opportunities for discussion.

Advanced Separations: FASTGC, HPLC & DATA Systems
Chair: Ernie Hillier, EJH Consulting and Bill Foley, Waters

Separations technology has been the go-to laboratory tool for quantitative analysis information regarding both the process and the product/sample of interest. The critical pieces of information that are needed regarding critical process parameters (CPP) and critical quality attributes (CQA) to assure the process and product are under control provides the analysis a snapshot in time as to the status of the reaction and product as well as the level of impurities. In that moment it is known with a high degree of confidence if the process and product are under control or if intervention is required.

This session will discuss the latest advances in analytical chromatography separations technology instrumentation/chemistry/informatics/sample prep/automation and new sensor technology that allows for this near real time quantitative information whether in the lab the process or in the field.

Spectroscopic Solutions for Complex Systems/Portable, Handheld & Small Footprint Instrumentation
Chair: Huzeyfe Yilmaz, FDA

Small-footprint, portable spectrometers are transforming the way screening and testing are performed. This session examines the way these miniaturized field-deployable technologies are applied to real world settings to solve complex problems.

Chemometrics - COPA (Chemometrics for Online Process Analysis)
Chairs: Brian Rohrback, Infometrix, Antonio Benedetti, Polymodels Hub, Hossein Hamedi, ReciBioPharm

The IFPAC Chemometrics session is focusing on the organization of analytical libraries (primarily optical spectroscopy) and the efficient use and integration of chemometric principles in support of an industry initiative by US Pharmacopeia to establish guidelines and standards for calibration. Participation by industry leaders, instrument company scientists, and chemometrics experts is on the schedule.

Information Architecture (Under the Industry 4.0 Track!)
Chairs: Rachelle Howard, Vertex and Boonserm Kulvatunyou

Industry 4.0 requires that we share massive amounts of data in any manufacturing or research environment. The structure through which we communicate, contextualize and store data impacts the quality and integrity of system interfaces and depth of information that can be gained from the data. The data management at all levels is critical, from each instrument's measurement capabilities to how that information is relayed for process control and product control strategy to how CQAs in batch records and lab results link to product release. This session contains topics on the requirements and design for infrastructure for the data handling across all levels.

Advanced Technologies from Concept to Reality – Problem(s) Solved Implementation and Integration
Chair: Ernie Hillier, Consultant, EJH Consulting and Oscar Navarro, Repligen

This session will include a diverse group of technologies used in PAT including instrumentation, software, etc. Session Overview: Journey of this equipment: new technology - how it is used in PAT and manufacturing - impact on business.

SAMPLING & PROCESS SPECTROSCOPY TRACK

This Track covers numerous technologies that benefit all industries in the area of process understanding and control. There will be numerous opportunities for cross-industry dialogue to learn more about successful applications and approaches.

Process Raman Symposium
Chair: Brian Marquardt, Thermo Fisher Scientific/MarqMetrix

Raman spectroscopy has been applied for process monitoring and control applications in a wide range of application fields, including bioprocessing, pharmaceuticals, petrochemicals, and food. This session will highlight the successful application of Raman for process analysis across those and other industries.

1. Highlight advancements in Raman instrumentation and sampling technology
2. Describe data analysis and pretreatment advances
3. Demonstrate effective applications of Raman spectroscopy for process monitoring

Sampling and Process Sensor Developments to Incorporate PAT and QbD in Process Optimization
Chair: Mel Koch, CPAC

This session has evolved from the development of new sampling approaches (NeSSI, New Sampling and Sensor Initiative) – for positioning of sampling and sensors – to an approach to achieve process optimization with unique approaches to advances in measurement systems. The data from these innovative measurement tools contributes to developing more effective process control strategies.

Mass Spec/Process Spectroscopy
Chair: Bill Foley

The session covers application of spectroscopic technologies to process monitoring applications, including the measurement of component concentrations and critical process parameters. Presentations will include the underlying spectroscopic techniques, interfaces to the process, and applications for process monitoring & control.

Emerging Technology for Spectroscopic PAT Applications
Chairs: Daniel Willett, FDA and Andrew Anderson, GSK

This session focuses on novel methodologies built around spectroscopic approaches that are or could be used in PAT applications or laboratories to support PAT. This encompasses emerging spectroscopic techniques with the potential to be applied in a PAT environment as well as innovative ways to apply more traditional and routine spectroscopic tools to further advance PAT science.

Implementing Spectroscopy Globally
Chair: David Ejeh

New session for IFPAC-2026 - More details coming soon!

Process Analysis and Control
Chairs: TBA

The Process Analysis and Control session will showcase novel online process analytical technologies and their applications in the petrochemical manufacturing space. Emphasis will be placed on technologies and applications that advance safety, profitability, and/or reliability. Sample conditioning systems requirements for successful online analytical measurements will also be discussed.

PAT Implementation & Advanced Manufacturing
Chairs: Walter Henslee, JPAC, Mel Koch, CPAC

This session will include analytical techniques and applications across all industries.

POSTERS

Poster Session

Chairs: Walter Henslee and Colm O'Donnell

Student Poster Session & Student Poster Competition
Chairs: Walter Henslee and Colm O'Donnell

The Student Poster Session will take place on Wednesday, March 4th.

Visit www.IFPACglobal.org/authors for details on the student poster competition.

EXHIBITION

Exhibitor booth spaces are available for demonstrating your product or services before a specialized audience. www.IFPACglobal.org/exhibitors

SHORT COURSES
Sunday, March 1, 2026

Short Course I:
PAT from Development to Real Time Release Testing
Instructor: Rodolfo J Romañach, Ph.D.
Professor of Chemistry, University of Puerto Rico at Mayagüez

Please visit www.IFPACglobal.org/attendee-registration for more details and to register.

NETWORKING EVENTS

Networking Events will be held throughout the event in the Exhibit Hall.

All Inclusive Registrations with Lodging Include:

Welcome Reception – All-Inclusive Registrations Only

Monday Gala Dinner – All Inclusive Registration Only

Visit www.IFPACglobal.org/attendee-registration Registration for more information.

All Registrations (Local & All-Inclusive) Include

Continental Breakfasts – Monday, March 2 – Wednesday, March 4, 2026

Lunch – Monday, March 2 – Wednesday, March 4, 2026

Visit www.IFPACglobal.org to register and for continuous program updates.

***** This program is preliminary. Some changes may occur. *****

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