

IFPAC SUMMIT with INDUNIV

August 26-27, 2025

Royal Sonesta San Juan | Carolina, PR



View the Program

**A collaborative meeting
designed for the
Pharmaceutical &
Biopharmaceutical
Industries**

Topics Include:

Advanced Manufacturing Strategies for:

- **Artificial Intelligence & Continuous Manufacturing - Regulatory Considerations**
- **PAT & Analytics**
- **Biologics & Therapeutics**
- **A.I. and Industry 4.0**



View the Program

Meet with new & existing colleagues for networking and in-depth discussions at this forward-looking event! The program will address the latest challenges & solutions in advanced quality & control, to improve your manufacturing processes.

LEARN MORE - www.IFPACsummit.org

IFPAC SUMMIT WITH INDUNIV

PROGRAM

DAY 1 – AUGUST 26, 2025

QUADRANT I

Continuous Manufacturing, Artificial Intelligence, and Regulatory Considerations
9:00 AM - 12:30 PM

Chairs: Sonia Aviles Eli Lilly & Carlos Tollinche, INDUNIV

Continental Breakfast & Networking: 8:00-8:45 AM

Welcome to the Conference (8:45 AM)

Implementing strategies for a more stable and efficient pharmaceutical supply chain: from understanding supply chain challenges to employing continuous flow, Gabriela Grasa Mannino, Programs Director, US Pharmacopeia

Enhancing an Existing Continuous Manufacturing Platform by Implementation of an Automatic Dispensing/Refill System, Jason Melnick and Sonia Aviles, Eli Lilly

Continuous Manufacturing reinvented by QBD and PAT, Ulrik Frodermann, Fette Compacting America

Embedding FDA's Risk-Based Credibility Framework into a Six-Phase AI Development Lifecycle, Angel Benitez, ProQuality Network

Optimization / Automation of Intensified Processes, Christopher McCready, Sartorius

Q&A / Discussion

Vendor Spotlight - Introduction of Exhibitors

Lunch Break & Networking

QUADRANT II

PAT, Analytics, and Smart Manufacturing
1:30 PM - 5:15 PM

Chair: Rodolfo Romañach, University of Puerto Rico - Mayaguez

Tailored Generation of Metastable Polymorph During Formulation, Suresh Manivel, University of Puerto Rico, Molecular Science Research Center

Additive Manufacturing for Personalized Solid Dosage Formulation of Warfarin Sodium, Aliou Mbodji, MSRC, Medical Sciences Campus, UPR

An Update: USP General Chapter <1037> Process Analytical Technology – Theory and Practice, Yang Liu (USP), and Rodolfo J Romañach, UPR-M

Integrating representative sampling in PAT to ensure process control in continuous manufacturing, Dhavalkumar Patel, UPRM, UPR-Mayaguez

Model Updates, Eduardo Hernandez, Eli Lilly

Ultra-Fast Raman Imaging (RAMANtouch) with Laser Line Scanning Technology, Mark Kemper, Bruker Optics

State of Control, PAT, Significant Phases and CFR 211.110, Rodolfo Romanach, UPR-M and Considerations for Complying With 21 CFR 211.110 Guidance for Industry Panel Discussion: Elizabeth Plaza, Eric Sanchez, Leonel Maisonet, Rodolfo Romanach, Sonia Avilés, Vanessa Avilés, et al.

DAY 1 - Wrap Up

Networking Reception

View the latest program details online at:
www.IFPACsummit.org/program

**ADVANCED MANUFACTURING
SOLUTIONS FOR THE
BIOPHARMACEUTICAL &
PHARMACEUTICAL INDUSTRIES**



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LATEST INFORMATION!**

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DAY 2 – AUGUST 27 , 2025

QUADRANT III

Biologics, Therapeutics, and Artificial Intelligence

9:00 AM - 12:30 PM

Chair: Hermes Puig, AbbVie

Introduction & Overview

Technology as an Ally of Speed and Efficiency,
Mike Rigau, Amgen

Effective Spray Drying Process for Biologics,
Andrew Birkmire, GEA Process Engineering, Inc.

Risk Mitigation in Bioprocesses through Multi-
Modal PAT Integration for Real-Time Monitoring,
Dmitriy Kogan, Amgen

“We can help you design something better” -
Innovation through PAT & the Artificial
Intelligence driven RNA BioFoundry
(AIRFoundry). Rodolfo Romañach, UPR,
Mayagüez, PR

Online Multiplexing for PAT: A Novel Approach
to Biopharmaceutical Quality Control, Dan Hasle,
FIALab

Enhancing Biotech Process Control with AI
Ricardo Valdes, TriNova

Q&A / Discussion

Lunch Break & Networking



QUADRANT IV

Engineering & Drug Manufacturing - Industry 4.0, Modeling, A.I.

1:30 PM - 5:15 PM

Chair: Pablo Rosado, Amgen

Virtual Reality Use in Pharmaceutical Training,
Sheila Medina, Yolando Ramos, BMS, Drug
Product

Five Ways to Organize and Make Better
Decisions in Manufacturing, Wuxiang Shen,
Rovisys

AI-Empowered Process Analytical Technology:
Adaptive Monitoring for Biopharmaceutical
Quality Control, Dan Hasle, FIALab

Autonomous AI – Building AI for control and
advisory, Chris Conry, RoviSys

Accelerating Workforce Training in High-Risk
Industrial Operations with AI, Gabriel
Goncalves, SmartHow

An Approach to Machine Learning Model
Validation for GxP Compliance, Bryan Looze,
Sartorius

Breakouts & Discussion - The Factory of the
Future: Artificial Intelligence in Drug
Manufacturing

DAY 2 Wrap Up / Close / Networking Reception

**REGISTER
TODAY!**

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GROUP RATES**