

IFPAC[®]-2013

The Twenty-Seventh International Forum and Exhibition Quality by Design...QbD Process Analytical Technology... PAT

**January 22-25, 2013
Baltimore Marriott Waterfront
Baltimore, Maryland, U.S.A.**

IFPAC-2013: The Premier International Event on QbD and PAT

Multiple sessions/tracks on QbD, PAT, Continuous Manufacturing, Real-Time Release and more for the Pharmaceutical, Biotechnology, Generic, Imaging, Food and other related industries.

ISPE will also be presenting a special session on its PQLI Initiative: Process Validation Lifecycle Approaches and Experiences during IFPAC, plus IFPAC-2013 will include a high profile plenary, QbD Evening Discussion Session, numerous networking opportunities and several tracks that will be of interest to ISPE members.

The Event:

IFPAC is the essential meeting place for the latest developments in Process Analytical Technology...PAT and Quality by Design...QbD within the Pharmaceutical, Biotechnology, Generic, Food & related industries. IFPAC is known for being a collaborative forum to exchange ideas and network through panel discussions, evening sessions, poster sessions, and the exhibition. For over 25 years IFPAC has brought together industry, academia, research institutions, manufacturers/suppliers, and government to discuss trends in technology, standards, and controls.

IFPAC attendees come to learn more about how they can boost productivity, streamline implementation processes, enhance operational efficiency, and maximize their resources.

IFPAC-2013 continues to attract high profile speakers with scheduled representatives from International and U.S. Regulatory Agencies, CPAC, CFACT, MIT, Duquesne, Rutgers and numerous Biotechnology, Pharmaceutical, Generic, Chemical/Petrochemical corporations...

IFPAC-2013 will have representatives from Belgium, Canada, China, France, Germany, India, Ireland, Italy, Japan, New Zealand, Portugal, Sweden, Switzerland, The Netherlands, United Kingdom, United States and more...a truly International event.

Program Overview:

IFPAC-2013 will feature comprehensive Pharmaceutical/Biotechnology tracks including the topics: Continuous Manufacturing, Real-Time Release, Risk Management, Biotechnology & BioProcessing, Bioreactors, PAT Applied for Biologics Manufacturing, Lifecycle Management of Analyzer & Method Reliability, Handheld Instrumentation/Screening & Surveillance, Particle Characterization, and various analytical techniques,

Plus New Topics including:

- Rapid Microbiological Methods (RMM) for Manufacturing Roles
- Linking PAT to PV and Continuous Process Verification

- Experience with QbD Submissions Internationally: Future Steps with QbD & PAT
- QbD/PAT in Generics
- Particle Identification in Pharmaceuticals
- Intelligence Based Manufacturing (IbM)
- PAT/QbD in CMO/CRO

Other topics to include the latest information on advanced instrumental concepts for process analysis, new sensor technology, imaging techniques, manufacturing, control strategies, Process Raman, Near Infrared Spectroscopy, LIF, Mass Spec, and data management.

A precon workshop on the Statistical Process Control (SPC) and RTRT will be held Tuesday afternoon, January 22nd.

Program Highlights:

Several sessions related to instrumentation, techniques, case studies, and data management will be at IFPAC-2013. Following the Plenary Monday morning, attendees will have several sessions to choose from:

- **Wednesday Afternoon** – ISPE Sponsored Session, The Technical, Regulatory & Business Case for PAT Implementation, Risk Management, Sampling/Content Uniformity, Process Raman, Advanced Instrument Concepts, Mass Spec, Particle Identification in Pharma
- **Thursday Morning** – QbD/PAT, Real Time Monitoring of BioReactors & BioProcessing, PAT Implementation for Drug Product Development & Manufacturing, QbD/PAT in the Generic Industry Symposium, Advanced Separations, NeSSI, Chemical Imaging
- **Thursday Afternoon** – QbD/PAT-II, PAT Applied for Biologics Manufacturing, PAT Approaches to Continuous Manufacturing, Intelligence Based Manufacturing – I, QbD/PAT in the Generic Industry, Question Based Review System, Rapid Microbiological Methods for Manufacturing Roles, Chemometrics (COPA) - I, Process Analysis/Spectroscopy
- **Friday Morning** - Continuous Manufacturing, BioProcessing & Biosensing, PAT/QbD in CMO/CRO, Intelligence Based Manufacturing – II, Screening & Surveillance/Handheld Instrumentation, Particle Characterization, Taking Advantage of PAT for Lifecycle Quality Assurance, Real-Time Light Induced Fluorescence (LIF), Chemometrics (COPA) - II
- **Friday Afternoon** - Experience with QbD Submissions Internationally: Future Steps with QbD & PAT, Process Control for Biotechnology/Pharmaceutical, Life Cycle Management and Analyzer Reliability with Model Maintenance, Linking PAT to PV and Continuous Process Verification, Tools & Case Studies for Process Understanding and Control, Sustainability, Process Analysis/Spectroscopy

ISPE Sponsored Session - Topics to include Process Validation Concept Papers and Status & PQLI Progress and Future, Stephen Tyler, AbbVie, & Joanne Barrick, Eli Lilly; Expectations/Deliverables from PV Stage 1 (Process Development), Criticality, Design Space and Control Strategy, as a Foundation for PPQ/PV, John Lepore, Merck, & Bruce Davis; Design Space Verification, Tim Watson, Pfizer; Process Performance Qualification: How Many Batches?, Line Lundsberg, NNE Pharmaplan; Continuous Process Verification Drug Substance Pilot/Case Study, Jay Buffi, Pfizer; Stage 3 of the Process Validation Lifecycle: Goals, Expectations and Technical and Regulatory Considerations, Dave Dolgin, AbbVie; plus a Round Table Q&A.

PAT Implementation for Drug Product Development and Manufacturing - This year we will focus more on the end-use, implementation and what is needed in manufacturing to support PAT as part of the process. Topics will include; changes to manufacturing quality systems to accept in-process control as part of release, integration and automation challenges, and instrumentation

examples that have been implemented in manufacturing. We are also looking for examples of how PAT software (SynTQ, SiPAT, etc...) have been used both in development and in manufacturing to integrate data acquisition, data archiving, instrument control, and process control.

QbD and PAT in the Generic Industry Symposium - Co-Chaired by representatives from OGD/FDA and a leading Generic Industry Corporation this session will highlight real case studies from industry, setting the stage for the final afternoon Event: The Detailed Report on OGD's Question Based Review (QbR) System.

Intelligence Based Manufacturing (IBM) - Intelligent/Smart Manufacturing harnesses the complementary power of data, models, engineering and IT infrastructure to create a game changing paradigm based on: transformation of data into knowledge and intelligence; moving from reactive actions to proactive and preventative strategies; and shifting from stand-alone and isolated unit operations towards integrated infrastructure at process, plant, and enterprise level. Data can be the output of sensors designed to provide real-time insight into a process

Continuous Processing Evening Session - There will be discussion on some hot issues in Continuous Processing like the batch definition, representative sampling, traceability of raw materials, start-ups / shut downs. Regulators, Industrial Practitioners and Academics are expected to participate at an open discussion.

And More...

Pre-Meeting Short Courses will also be available.

Plus Posters Sessions... An excellent opportunity for one on one discussions and networking.

With over 30 topics covering all industry segments – IFPAC provides an opportunity to interact with industries that have been using Process Analytical Technology for nearly 60 years!

Visit www.ifpacpat.org for program details.

IFPAC-2013 EXHIBITION

A comprehensive exhibition showcasing the latest instrumentation and services will also be available.

For more information, contact conference management.

Wednesday, January 23rd.....2:00 - 7:00 PM

Grand Opening.....2:00 PM

Thursday, January 24th.....10:00-4:00 PM

Friday, January 25th.....9:00-12:00 Noon

Join your fellow exhibitors at IFPAC-2013:

- ABB
- Aber Instruments
- Advantest Corporation
- American Pharmaceutical Review
- Applied Instrument Technologies
- Art Photonics GmbH
- ASTM
- Axiom Analytical, Inc.
- Azbil BioVigilant, Inc.
- Bend Research
- Bioresearch Online, Pharmaceutical Online, Food Online
- Brabender Pharma, USA

- Bruker Optics Inc.
- Buchi Corporation
- CAMO Software
- Canty
- COSA Instrument
- CPAC, Center for Process Analysis & Control
- Emerson Process Management
- European Pharmaceutical Review
- Excellims Corporation
- Extrel CMS
- Flownamics Analytical Instruments
- Food Processing
- FOSS NirSystems, Inc.
- Freeman Technology, Inc.
- FTRX LLC
- 4TUNE Engineering, Ltd.
- GEA Pharma Systems
- Innopharma Labs
- InnovaPrep, Inc.
- ISPE
- JDSU
- Kaiser Optical Systems, Inc.
- New Food
- Nova Biomedical
- Parker Hannifin Corporation
- Pharmaceutical Manufacturing
- PharmaQbD.com
- Polytec
- Precise
- Prozess Technologie
- Real-Time Analyzers
- Rigaku Raman Technologies
- Rimbach
- Sartorius Stedim Biotech
- Sentronic GmbH
- Siemens Industry, Inc.
- Stratophase Ltd.
- Swagelok
- Thermo Fisher Scientific
- TSI, Inc.
- Uhlmann VisioTech GmbH
- Umetrics
- Waters Corporation
- WILCO AG
- Yokogawa

Exhibit Hall Traffic Boosters - There will be multiple social functions within the exhibit hall providing our exhibitors numerous opportunities for networking. Full exhibition services will be provided during the three day exhibit. Sponsorship opportunities are also available. Those companies who are interested in exhibiting at IFPAC®-2013 are invited to contact exhibition management as soon as possible.

Contact Conference Management: Email: info@ifpacnet.org; Phone:847-543-6800; Web: www.ifpacpat.org

It's an opportunity to see and be seen by old and new colleagues and customers. Those companies interested in exhibiting at IFPAC-2013 are invited to contact conference management as soon as possible.

Please visit www.ifpacpat.org for details on registration and the most up to date information on the program.

For more information on this event contact conference management:

Tel: 847-543-6800

Email: info@ifpacnet.org

Registration Information

This premier event is being held January 22-25, 2013 at the Baltimore Marriott Waterfront Hotel, located within Baltimore's Inner Harbor.

Local and All Inclusive Registration is Available... www.ifpacpat.org.

For more information contact: 847-543-6800; info@ifpacnet.org; www.ifpacpat.org

IFPAC®... First Name in PAT... the Essential Meeting Place for PAT