IFPAC® - 2015
TWENTY-NINTH INTERNATIONAL FORUM & EXHIBITION
QUALITY BY DESIGN...QbD
PROCESS ANALYTICAL TECHNOLOGY
Crystal Gateway Marriott, Arlington, Virginia (Washington, D.C.) U.S.A.
January 25-28, 2015
www.ifpacpat.org

ADVANCE WITH IFPAC
…Pathway to Quality Manufacturing

SHOW PREVIEW
Conference Overview
IFPAC is the essential meeting place for the latest developments in Process Analytical Technology...PAT and Quality by Design...QbD within the Pharmaceutical, Biotechnology, Chemical, Petrochemical & 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, as well as International and U.S. Regulatory Agencies to discuss the latest trends in technologies, standards and controls.

IFPAC-2015 HAS IT ALL!

• PROCESS CONTROL & MONITORING
• QUALITY BY DESIGN (QbD)
• CONTINUOUS MANUFACTURING
• REAL TIME RELEASE TESTING
• LIFECYCLE MANAGEMENT
• RISK MANAGEMENT
• ANALYTICAL QbD
• INTERNATIONAL HARMONIZATION
• QUALITY METRICS
• POST-APPROVAL MANUFACTURING
• ENABLING TECHNOLOGIES
• GENERIC INDUSTRY APPLICATIONS
• BIOPHARMACEUTICALS/BIOPROCESSING
• CONTINUOUS EMISSIONS MONITORING
• ADVANCED INSTRUMENTS CONCEPTS
• ADVANCED SEPARATIONS
• CHEMOMETRICS
• NESSI
• VARIOUS ANALYTICAL TECHNIQUES
• PLUS… PRECON EVENTS, THREE DAY EXHIBITION AND NUMEROUS NETWORKING OPPORTUNITIES

The Program
IFPAC-2015 will feature comprehensive tracks covering multiple areas of interest including Quality by Design-QbD, Continuous Manufacturing, Real-Time Release Testing, Risk Management, Lifecycle Management, Post-Approval Manufacturing, Analytical QbD, International Harmonization, Enabling
Technologies, Biotechnology, Process Monitoring & Control, Imaging, Process Analysis/Spectroscopy, Separations, and Food Quality, Safety & Analysis. An expanded program has been developed for the chemical and petrochemical industries with current and important topics including Advanced Instrument Concepts, Continuous Emissions Monitoring, Sample Handling…NeSSI, chemometrics…COPA and improvements in process analysis. IFPAC-2015 will also be held in conjunction with a Symposium for the Generic Industry. The extensive program will bring in leading experts from across the globe covering important research, trends, technological advances, case studies and the latest in regulatory guidance.

This conference is forward thinking with high profile speakers from International and U.S. Regulatory Agencies, NIST, CPAC, MIT, Duquesne, Rutgers, and global representatives from numerous Pharmaceutical & Biotechnology corporations.

- Meet with new and existing colleagues to discuss solutions to common problems
- Network with Regulatory, Academia, Students & Industry Leaders
- See the Latest Trends & Technologies in the Exhibition Hall
- More Q&A during the Expanded Poster Session
- Panel Discussions, Roundtables, and Evening Dinners

A comprehensive exhibition of PAT equipment and services, poster sessions, and social events will be available throughout the conference to provide numerous opportunities for networking and informal meetings. ...see our web pages www.ifpacpat.org for more information www.ifpacpat.org

IFPAC provides a unique opportunity to interact with other industries that have been using PAT for nearly 60 years!

IFPAC-2015: SCHEDULE OF EVENTS

Sunday, January 25, 2015 - AM
Pre-Conference Short Courses:
SHORT COURSE I: 8:30 AM - 12:00 PM
QbD – Manufacturing Sciences & Technologies
Prof Jose C Menezes, Technical University of Lisbon
Dr Pedro G Felizardo, 4Tune Engineering Ltd

SHORT COURSE II: 8:30 AM – 12:00 PM
Root Cause Analysis / Problem Solving
Juergen von Frese, Ph.D., Data Analysis Solutions, Germany, www.da-sol.com and Walter Henslee, Dow Chemical Lead PAT Scientist, retired

Please visit www.ifpacpat.org for more details.

Sunday, January 25, 2015 – PM
Pre-Conference Regulatory Workshop
Post Approval Change Management for PAT and RTRT-Scientific & Regulatory Considerations
Chairs: Christine Moore, FDA and Theodora Kourti, GSK

HPLC Workshop

Monday, January 26, 2015 – AM
IFPAC PLENARY
Chairs: Scott Armstrong, John Kauffman, G.K. Raju and Martin Warman

Keynote Speakers Including…

Lawrence Yu, Director of OPS, FDA, Silver Spring, MD
Monday, January 26, 2015 - PM

International Harmonization for Implementation of Risk Based Review and Inspection
Sharmista Chatterjee, FDA and Dolores Hernan, EMA

Risk Management Over Product Life Cycle – I (Brand)
Chairs: G. K. Raju, Light Pharma and Rick Friedman, FDA

Chairs: Jun Huang and Mojgan Moshgbar

Chairs: Gretchen Allison and Vibhakar Shah

Implementation of QbD for Analytical Methods
Chairs: John Kauffman, FDA and Sonja Sekulic, Pfizer

Biotech – I: Small Molecule Manufacturing & the Application of PAT & QbD
Chairs: Antonio Moreira, University of Maryland-Baltimore County and John Higgins, Merck

QbD – Applications and Tools – I
Chairs: Scott Furness, FDA, Theodora Kourtì, GSK, Manoharan Ramasamy, Merck, and Lorenz Liesum, Novartis

Process Raman
Chair: Brian Marquardt, CPAC, APL, University of Washington

Chemometrics (COPA) – I
Chairs: Juergen von Frese, Data Analysis Solutions DA-SOL GmbH, Christian Airiau, GSK and Brian Rohrback, Infometrix

Microscopy/Spectroscopy/Sensors
Chair: Jason Dickens, GSK (TBC)

Monday Evening, January 26, 2015

Discussion Session I - NIRS Guideline by EMA – What are the Implications for Industry?
Panel: Theodora Kourtì, GSK, Lorenz Liesum, Novartis and Sonja Sekulic, Pfizer

Special Evening Session- Training the Next Generation: Process Analyzer Technicians
Chairs: Scott Armstrong, ExxonMobil and J.D. Tate, Dow Chemical

Tuesday, January 27, 2015 – AM

QbD – Applications and Tools – II
Chairs: Scott Furness, FDA, Theodora Kourtì, GSK, Manoharan Ramasamy, Merck and Lorenz Liesum, Novartis
Risk Management Over Product Life Cycle – II (Generics)
Chairs: G. K. Raju, Light Pharma and Daniel Peng, FDA

Process Monitoring & Control - II: PAT Implementation for Drug Product Development and Manufacturing
Chairs: Tim Stevens, BMS and Ajit S. Narang, BMS

Lifecycle Management of Analyzer and Method Robustness
Chairs: Gert Thurau, Roche and John Kauffman, FDA

BioTech – II: MSAT in Biologics Manufacturing
Chairs: Jose C. Menezes, IST, UTL, Portugal and Ranjit R. Deshmukh, MedImmune

Imaging
Chairs: Steve Hammond, Pfizer and Carl Anderson, Duquesne University

NeSSI
Chair: Mel Koch, APL, University of Washington

Advanced Separations – I: Technology & Applications (FastGC, HPLC, Data Systems)
Chair: John Crandall, Falcon Analytical

Food-I: Emerging Technologies with Focus on Traceability and Contamination
Chairs: Michael McCarthy, Ph.D., University of California Davis, Davis, CA and Carol Zrybko, Ph.D., Mondelez International, East Hanover, NJ

Tuesday, January 27, 2015 – PM

QbD – Applications and Tools – III
Chairs: Scott Furness, FDA, Theodora Kourti, GSK, Manoharan Ramasamy, Merck and Lorenz Liesum, Novartis

Product Lifecycle and QA
Chairs: Tara Gooen Bizjak, FDA and Ravi Tejwani, BMS

Using Process Capability to Ensure Pharmaceutical Product Quality – Industry and Regulatory Perspective (Brand and Generics)
Chair: Daniel Peng, FDA, Alex Viehmann, FDA and George Millili, Genentech – ISPE

Enabling Technologies to Continuous Manufacturing
International Consortium for Innovation and Quality in Pharmaceutical Development - IQ
Chairs: Doug Both, BMS and Sonja Sekulic, Pfizer

BioTech - III: Process Control for Biotechnology/Pharmaceutical
Chairs: Cenk Undey, Amgen and Jose C. Menezes, IST, UTL, Portugal

Particle Characterization
Chairs: Ewa Marszal, FDA and Zhigang Sun, FDA

Mass Spectroscopy/Process Spectroscopy
Chairs: Bob Bear, Ametek and John Coates, Coates Consulting

Advanced Separations – II: Technology & Applications (FastGC, HPLC, Data Systems)
Chair: John Crandall, Falcon Analytical
**Food-II: Food Safety**  
Chairs: Luis E. Rodriguez-Saona, Ph.D., The Ohio State University, Columbus, OH and Bei Ma, M.S., United States Pharmacopeial Convention, Rockville, MD

**IFPAC Poster Session**  
Chairs: Antonio Moreira, University of Maryland, Baltimore County and Walter Henslee, Dow Chemical Lead PAT Scientist, retired

**Tuesday Evening, January 27, 2015**

**Discussion Session II: A Proposal for a Drug Product Manufacturing Classification System (MCS) for Oral Solid Dosage Forms**  
Chair: Theodora Kourti, GSK

**Wednesday, January 28, 2015 – AM**

**QbD and PAT in the Generic Industry**  
Chair: Dr. Geoffrey Wu, FDA and Inna Ben Anat, Teva Pharmaceuticals

**Continuous Manufacturing - I**  
Chairs: Rapti Madurawe, FDA and Theodora Kourti, GSK

**Fundamental University Research and its Industrial Applications**  
Chairs: Kevin Macias, BMS and James Drennen, Duquesne University

**Blend Uniformity/Content Uniformity**  
Alex Viehmann, FDA and Tom Garcia, Pfizer - ISPE

**BioTech – IV: Real Time Monitoring of Bio-Reactors and Bio-Processing**  
Chairs: Kurt Brorson, FDA and Michael Tarlov, NIST

**Advanced Instruments Concepts**  
Darren P. Hydutsky, DuPont, J.D. Tate, Dow Chemical, Jason Dickens, GSK and Troy Francisco, DuPont

**Chemometrics (COPA) – II**  
Chairs: Christian Airiau, GSK, Juergen von Frese, Data Analysis Solutions DA-SOL GmbH and Brian Rohrback, Infometrix

**Screening/Surveillance/Handheld (IFPAC/OnSite Joint Session)**  
Chairs: Paul DeRose, NIST and Paul Vahey, The Boeing Company

**Food-III: PAT for the Dairy Industry**  
Chairs: Colm O’Donnell, Ph.D., University College, UCD-Dublin Institute of Food & Health, Dublin, Ireland, Brent R. Young, Professor and Head Chemical and Materials Engineering, The University of Auckland, New Zealand and Steve Holroyd, Ph.D., Fonterra Research Centre, New Zealand

**Wednesday, January 28, 2015**

**IFPAC Poster Session / Student Poster Day**  
Chairs: Antonio Moreira, University of Maryland Baltimore County and Walter Henslee, Dow Chemical Lead PAT Scientist, retired

**Wednesday, January 28, 2015 – PM**
Continuous Process Verification (CPV) – the Ultimate PV Frontier and Continual Improvement Enabler: Practices, Challenges and Opportunities
Chairs: Vibhakar Shah, FDA and Ranjit Deshmukh, MedImmune

Continuous Manufacturing – II
Fundamentals of Manufacturing Science
Chairs: Fernando Muzzio, Rutgers University and Eric Jayjock, J&J

Quality Metrics
Russell Wesdyk, FDA and Stephen Tyler, AbbVie - ISPE

Process Control and Quality
Chair: Walter Henslee, Dow Chemical Lead PAT Scientist, retired

CEMS Technology and Emerging Regulatory Requirements
Chair: Matthew MacConnell, Air Products

PAT Implementation
Chairs: James Cheney, Celgene and Martin Warman, Vertex Pharmaceuticals

Food-IV: PAT As A Quality Control Tool
Chairs: P. J. Cullen, Ph.D., Dublin Institute of Technology, School of Food Science and Environmental Health, Dublin, Ireland

See our website for additional details and continuous updates: www.ifpacpat.org

IFPAC Posters: Located in the Exhibit Hall

Chairs: Antonio Moreira, University of Maryland-Baltimore County and Walter Henslee, Dow Chemical Lead PAT Scientist, retired

Poster Session will run Tuesday PM through Wednesday including a Special Student Poster Session on Wednesday

Exhibition Schedule:
Monday, January 26th ..........2:00 - 7:00 PM
Grand Opening ..................2:00 PM
Tuesday, January 27th ..............10:00-4:00 PM
Wednesday, January 28th ....................9:00-12:00 Noon

Join Your Fellow Exhibitors at IFPAC-2015: Don’t miss this opportunity. Full exhibition services will be provided during the three day exhibit. Companies interested in exhibiting are invited to contact exhibition management as soon as possible. Email: info@ifpacnet.org Tel: 847-543-6800.

To Register:
Please contact IFPAC at:
Tel: 847-543-6800; Fax: 847-548-1811
Email: info@ifpacnet.org
Register Online at Web Page: www.ifpacpat.org

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