

IFPAC® /PAT/QbD Summit 2011
21-22 June 2011 Carolina, Puerto Rico
PRELIMINARY PROGRAM

Tuesday - June 21, 2011

Day 1:

Progress in PAT & QbD - Regulatory Aspects

Chair: Dr. Carlos Tollinche, INDUNIV

Introduction and Opening Remarks
Dr. Carlos Tollinche, INDUNIV

A View of This Year's Conference
Rodolfo Romañach, Ph.D., UPR, Mayagüez, PR

Transforming QC & QA in Light of QbD & PAT
Eric Sanchez, Janssen-Ortho, Global Technical Services-Solids Platform

Manufacturing Perspective on the Implementation of a QbD/PAT New Product Regulatory Submission
Frances Montes, Euripides Guillen, Angel Vega, Carmen Lopez, Bristol-Myers Squibb Manufacturing, Humacao, PR

QbD/PAT: Update and Regulatory Perspective
Vibhakar Shah, Ph.D., FDA, CDER, DMPQ, Silver Springs, MD

Lunch

Implementation of Process Analytical Technology in a Bulk API Process in Merck, Barceloneta, PR
Dr. K. Ganeshwar Prasad, Dr. Zhihao Lin, Dr. George Zhou, Dr. Tseng-En Hu, Dr. John Higgins and Paul Fernandez, Merck Sharp & Dohme PR, Inc., Barceloneta, PR

The Business Case for PAT & QbD

Chair: Manuel Hormaza, IBS Caribe

Elements to Building a Tangible Business Case for PAT & QbD
Jose Montenegro, Pfizer, Vega Baja, PR

The Financial Returns on Investments in PAT and Lean Manufacturing: Benchmarks and Case Study
Manuel Hormaza, IBS Caribe

The Business Case for Real Time Release
Carlos Conde-Reyes, Ph.D.

The Business Case for PAT & QbD Panel Discussion
Manuel Hormaza, IBS Caribe, Carlos Conde-Reyes, Eric Sanchez, Janssen-Ortho, Nelson Rivera, J&J and Jose Montenegro, Pfizer

... **Additional Presentations to follow.**

Wednesday - June 22, 2011

Day 2:

QbD/PAT in Pharmaceutical Manufacturing

Chair: Rodolfo Romañach, Ph.D., UPR, Mayagüez, PR

Raman PAT Application for Monitoring Cell Culture Seed Expansion and Production Processes
Danais Carrion, Amgen Manufacturing, Juncos, PR

Enhanced Process Understanding using QbD Approaches during Earlier Stages of Biopharmaceutical Process Development

Antonio Moreira, Ph.D., Vice Provost for Academic Affairs, UMBC, Baltimore, MD

Multivariate Batch Analysis for Process Characterization, Monitoring and Optimization
Chris McCready, Umetrics

Better Process Understanding with Combined Spectral Information from PAT Analyzers Based on Molecular Spectroscopy
Yan Wang, Ph.D. and John Richmond, Ph.D., Bruker Optics, Inc., Billerica, MA

Lunch

Continuous Manufacturing - Pharmaceutical Engineering & Control for PAT and QbD

Chair: Carlos Conde-Reyes, Ph.D.

NIR Monitoring of Continuous Blending Process
Yieana Colon, UPR, Mayagüez, PR

Mastering Continuous Manufacturing: Current Technology and the Regulatory Environment
Rebecca Vangenechten, Siemens AG, Antwerp, Belgium

Understanding Continuous (Open) Processes: Control Advantages
Carlos Velazquez, Ph.D., UPR, Mayagüez, PR

Continuous Manufacturing of Polymeric Gel Strips for Pharmaceutical Formulations
Lucas Sievens Figueroa, Ph.D., NSF-ERC Structure Organic Particulate Systems, Rutgers/NJIT

Near Infrared Analysis of Polymeric Gel Strips
Rodolfo Romañach, Ph.D., UPR, Mayagüez, PR

Operational Excellence Panel Discussion
Details include: QbD/PAT initiatives being worked on from an operational excellence perspective. Specific projects to be discussed include: PR PAT Forum coordination towards optimizing processes, reducing variability and overall process control.

EXHIBITION

Join your fellow exhibitors at IFPAC®/PAT/QbD Summit. Table top displays and sponsorship opportunities are yours for demonstrating your product or services before a specialized audience. It's an opportunity to see and be seen by old and new colleagues and customers. Those companies who are interested in exhibiting or sponsorship are invited to contact exhibition management as soon as possible.

Email: info@IFPACnet.org; Tel: 847-543-6800; Fax: 847-548-1811.

To Register - Please contact IFPAC at:

Tel: 847-543-6800; Fax: 847-548-1811

Email: info@IFPACnet.org

or visit our web pages:

Web Page: www.IFPACSummit.org

**Additional Presentations to follow...see our web pages for continuous updates:
www.IFPACSummit.org**

Exhibits (Table Tops) Tuesday June 21 and Wednesday June 22, 2011