

# *Sixth Annual*

# **IFPAC®/PAT/QbD Summit**

## **PROCESS ANALYTICAL TECHNOLOGY**

**Pharmaceutical & Biopharmaceutical Manufacturing**

**June 23-24, 2009, Condado Plaza Hotel, San Juan, Puerto Rico**

### **Advances in PAT and QbD- Process Analytical Technology and Quality by Design: Understanding and Monitoring the Process**

Learn from key experts the practical aspects of PAT, Process Analytical Technology as it is applied to the Pharmaceutical & BioPharmaceutical Manufacturing Environment. PAT is understanding the Process for innovative pharmaceutical & biopharmaceutical manufacturing and continuous quality assurance.

**Broaden your knowledge about PAT, and how industry is responding to the PAT opportunity.**

### **Organizations**

INDUNIV is an organization promoting and providing the catalyst for effective collaboration amongst industry, academia and government within Puerto Rico. IFPAC is an international organization dedicated to the advancement and implementation of PAT.



So join us at IFPAC®/PAT/QbD Summit...  
the Essential Meeting in Puerto Rico for Quality by Design - QbD  
and Process Analytical Technology...PAT.

For updated Registration/information see our web page at: [www.IFPACSummit.org](http://www.IFPACSummit.org)

#### **Organization Representatives**

Dr. Carlos Tollinche, INDUNIV  
Manuel Hormaza, IBS Caribe  
Robert S. Zutkis, IFPAC

#### **Organization Representatives**

Dr. Carlos Conde-Reyes, Wyeth, Guayama, PR  
Dr. Rodolfo Romañach, UPR, Mayaguez, PR (Co-Chairman)  
Dr. Dominic Ventura, Wyeth (Co-Chairman)

**IFPAC®**

253 Commerce Dr. Suite 103 • Grayslake, IL 60030 USA

Tel: 847-543-6800 • Fax: 847-548-1811

email: [info@IFPACnet.org](mailto:info@IFPACnet.org)

[www.IFPACSummit.org](http://www.IFPACSummit.org)

## REGISTRATION INFORMATION

A two day registration is available for \$695.00 U.S (Before May 30, 2009). This includes the dinner and Forward Looking lecture on Tuesday night, the two day conference, program portfolio, access- table top exhibition, refreshments, and lunch each day.

To register, complete and return the registration form, along with payment or billing instructions to IFPAC®. You may also pre-register by telephone: 847-543-6800; Register by FAX: 847-548-1811, or the web [www.IFPACSummit.org](http://www.IFPACSummit.org)

## LOCATION

**IFPAC®/PAT/QbD SUMMIT 2009** will be held in San Juan, Puerto Rico...at the Condado Plaza Hotel, 999 Ashford Avenue, San Juan, Puerto Rico, 00907. Telephone for reservations: 800-266-7232. (Mention IFPAC® while making your hotel reservation.) [www.condadoplaza.com](http://www.condadoplaza.com).

Stay at the four-diamond Condado Plaza Hotel and experience the magic of Puerto Rico at this elegant urban resort. From the luxury hotel itself to the attractions of San Juan and the Condado strip, you'll have the best the island offers. From the hotel's central location overlooking the Atlantic and the Condado Lagoon, you can take in sea breezes and watch the sun slowly set.

## AIRLINES

Numerous airlines have direct flights into San Juan, Puerto Rico, Luis Munoz Int'l. Airport (SFU). Call your preferred airline or Travel Agent for further information.

## SHUTTLE

A commercial taxi service is easily available to/from the airport.

## REGISTRATION FORM

(photocopy for multiple applications)

### IFPAC®/PAT/QbD Summit with INDUNIV

June 23-24, 2009, San Juan, Puerto Rico

Name/Title \_\_\_\_\_  
Organization \_\_\_\_\_  
Address \_\_\_\_\_  
City/State/Zip \_\_\_\_\_  
Telephone \_\_\_\_\_  
Fax \_\_\_\_\_  
email \_\_\_\_\_

June 23 and June 24 - Two (2) Day Registration  
(Does not include lodging)

\$695.00 U.S. (Before May 30, 2009) \$ \_\_\_\_\_  
\$795.00 U.S. (After May 30, 2009) \$ \_\_\_\_\_

One (1) Day Registration (DOES NOT INCLUDE Lodging)  
June 23 - \$375.00 U.S. (Before May 30, 2009) \$ \_\_\_\_\_  
June 23 - \$475.00 U.S. (After May 30, 2009) \$ \_\_\_\_\_  
June 24 - \$375.00 U.S. (Before May 30, 2009) \$ \_\_\_\_\_  
June 24 - \$475.00 U.S. (After May 30, 2009) \$ \_\_\_\_\_

Registration includes conference (one or two days), access to table top exhibits, refreshments, and lunch each day. (2 Day Registration includes Dinner/Lecture)

SUBTOTAL Payment \$ \_\_\_\_\_  
(continue on next column)

### Cancellations

If you are unable to attend, another person can be substituted, or your registration may be credited to a future symposium. Notification to be received in writing by 30 May 2009.

© Copyright 2009 IFPAC®, Grayslake, IL 60030

### OPTIONAL

IFPAC Membership (New or Renewal for 2009) \$ \_\_\_\_\_  
\$175.00 U.S.

(includes discounts to future IFPAC® events; subscription to the Journal JPAC; IFPAC® Newsletter; and IFPAC® membership card.)

TOTAL Payment Enclosed: \$ \_\_\_\_\_

Please check appropriate box:

Payment Enclosed (Check payable to: IFPAC®)

Please bill my company P.O. \_\_\_\_\_

(Payment due prior to symposia.)

American Express  Visa  Mastercard

Card No. \_\_\_\_\_

Exp. date \_\_\_\_\_ 3-4 Digit Code \_\_\_\_\_

Signature: \_\_\_\_\_

Please return this registration form to:

IFPAC®  
253 Commerce Dr. Suite 103  
P.O. Box 7100  
Grayslake, IL 60030 USA  
Tel: 847-543-6800 Fax: 847-548-1811  
email: [info@ifpacnet.org](mailto:info@ifpacnet.org) [www.IFPACSummit.org](http://www.IFPACSummit.org)

### Disclaimer

For unforeseen circumstances, whereby meeting facility is not operating for business, due to acts of God, government authority, disaster, strikes, construction, remodeling or other reasons outside our control, an alternative venue and dates of comparable quality will be confirmed.

# IFPAC® /PAT/QbD Summit 2009

## 23-24 June 2009 San Juan, Puerto Rico

### PRELIMINARY PROGRAM

**June 23, 2009**

**Day 1:**

**Regulatory - QbD Interaction with the FDA**

Chair: Dominic Ventura

Introduction and Opening Remarks

Dominic Ventura, Ph.D., Vice President Process Excellence, Wyeth Pharmaceuticals

Improved Process Understanding for Late-Stage Drug Product Development using QbD/PAT Principles and Tools.

Jun Huang, Saly Romero-Torres and Pedro Hernandez, Principal Scientist II-PAT, Wyeth Pharmaceuticals, Pearl River, NJ

What might QbD look like in Bio Manufacturing

Vincent L. Vilker, Director, OTR, OPS, CDER, FDA, Silver Spring, MD

Routine LC analysis on the Manufacturing Floor: New Technology for Real-Time Process Reaction Monitoring, Process Chromatography Analysis, and Cleaning Validation

Craig Dobbs, Waters Corporation, Milford, MA

Deliverables:

1. Learn about QbD in Bio Manufacturing.
2. Examples of successful application of QbD and PAT Principles for Late Stage Product Development.
3. Opportunities for Using Liquid Chromatography in PAT.

Lunch

**PAT & QbD Implementation**

Chair: Dominic Ventura

Transforming Pharmaceutical Manufacturing with PAT & QbD

Carlos Conde-Reyes, PAT Director, Wyeth, Guayama, PR

Chemometrics in PAT: A Six Sigma Perspective

Charles E. Miller, Ph.D., Eigenvector Research

PAT in Bio-Manufacturing (TBC)

Panel - Progress in PAT in Puerto Rico's Pharmaceutical Industry  
Manuel Hormaza, PR PAT Service Provider, Carlos Conde, PAT Implementation in Pharma, Rodolfo Romañach, PAT Developer in Academia, Dominic Ventura, Long Time PAT Leader and Charles E. Miller, Eigenvector Research

Deliverables:

1. How to structure pharmaceutical manufacturing in support of PAT & QbD initiatives.
2. Understand the relationship between PAT and Lean Six Sigma Manufacturing.
3. Implementing QbD principles in the biotechnology industry.
4. How to progress towards real time release.

#### 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](mailto:info@ifpacnet.org); Tel: 847-543-6800; Fax: 847-548-1811.

**June 24, 2009**

**Day 2:**

**Engineering based on Quality by Design**

Chair: Carlos Velázquez, Ph.D.

A Quality by Design Approach to Continuous Manufacturing of Tablets

Fernando Muzzio, Professor II, Department of Chemical and Biochemical Engineering, Rutgers University & NSF-Engineering Research Center for Structured Organic Particulate Systems, New Brunswick, NJ

Development, Implementation and Validation of PAT for the Pharmaceutical Manufacturing Community:

What is the role of the vendor?

Paul Davies, Expo Technologies, Columbia, MD

A Quality by Design Approach to Control Systems

Carlos Velázquez, Ph.D., Department of Chemical Engineering & NSF Engineering Research Center for Structured Organic Particulate Systems, UPR-Mayagüez

Deliverables:

1. Advantages of continuous manufacturing, and control strategies.
2. Learn strategies for control systems for QbD manufacturing processes.

Lunch

**Implementing Spectroscopic Methods in Industry**

Chair: Manuel Hormaza, IBS Caribe

Implementation of NIR Methods in a Pharmaceutical Environment.

Angel R. Martinez, Scientist IV, Wyeth Consumer Products

PAT Data Management: Now that We Have PAT-What do we Do with the Information, ABB Presentation (TBC)

Raman Methods for Bio-processes

Manuel Hormaza, IBS Caribe

A Procedure for Development of Quantitative NIR Methods and its Application to a Potent Drug Formulation

Joshua León Ricardo, Rodolfo J Romañach, Department of Chemistry & NSF Engineering Research Center for Structured Organic Particulate Systems, UPR-Mayagüez

Deliverables:

1. Procedure for implementing quantitative NIR methods.
2. Learn about industries' experience in implementing NIR methods. Opportunities for reducing implementation time.
3. NIR, Raman for process monitoring
4. Going beyond process monitoring: PAT data management systems, and how to use them to improve processes.

Additional Presentations to follow...see our web pages for continuous updates:  
[www.IFPACSummit.org](http://www.IFPACSummit.org)

Exhibits (Table Tops) Tuesday June 23  
and Wednesday June 24, 2009

**To Register - Please contact IFPAC at:**

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

**Email: [info@ifpacnet.org](mailto:info@ifpacnet.org)**

**or visit our web pages:**

**Web Page: [www.IFPACSummit.org](http://www.IFPACSummit.org)**

**QbD**  
Quality by Design

**PAT**

Process Analytical Technology

**IFPAC®**

253 Commerce Dr. Suite 103  
Grayslake, IL 60030

# ***IFPAC®/PAT/QbD Summit*** **with INDUNIV**

## **PROCESS ANALYTICAL TECHNOLOGY** **Pharmaceutical/BioPharmaceutical Manufacturing**

**COSPONSORS/Media Partners**

(contributing organizations include:)

American Pharmaceutical Review

INDUNIV

JPAC

UPR-M

IBS - Caribe

Advanced Registration Announcement  
(Process Analysis & Control) - IFPAC®

June 23-24, 2009, Condado Plaza Hotel, San Juan, Puerto Rico