

# Seventh Annual IFPAC®/PAT/QbD Summit

## PROCESS ANALYTICAL TECHNOLOGY

Pharmaceutical & Biopharmaceutical Manufacturing

June 22-23, 2010

Isla Verde Beach Resort, Marriott Courtyard, Carolina, 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 the IFPAC®/PAT/QbD Summit...  
the Essential Meeting for Furthering your Expertise in Quality by Design - QbD  
and Process Analytical Technology-PAT...in a major pharmaceutical/biopharmaceutical center  
of new initiatives, Puerto Rico”

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

#### Organization Representatives

Dr. Rodolfo Romañach, UPR, Mayaguez, PR (Co-Chairman)  
Dr. Carlos Tollinche, INDUNIV  
Manuel Hormaza, IBS Caribe  
Robert S. Zutkis, IFPAC

#### Organization Representatives

Dr. Carlos Conde-Reyes, Pfizer, Guayama, PR  
Eric Sanchez, Johnson & Johnson  
Angel R. Martinez, Pfizer  
Zainette Ramos Rivera, Eli Lilly

**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 June 18, 2010). This includes the two day conference, program portfolio, access to the 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/QbDSUMMIT 2010** will be held in Carolina, Puerto Rico...at the Isla Verde Beach Resort, Marriott Courtyard, 7012 Boca de Cangrejos Ave., Carolina, 00979 Puerto Rico, Tel: 787-791-0404; Direct Reservations: Tel: 787-999-6500 or 1-800-791 2553 (Mention IFPAC® Summit 2010 while making your hotel reservation.) Or register on the web at: [www.sjcourtyard.com](http://www.sjcourtyard.com). Isla Verde Beach Resort, Courtyard by Marriott is majestically located on the best beachfront in San Juan. Check-in to our Puerto Rican oasis and enjoy modern, high-tech accommodations that envelope you in comfort. With over one mile of pure white sand beach, you're destined to find the perfect spot to relax.



## 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 22-23, 2010, Carolina, Puerto Rico

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

June 22 and June 23 - Two (2) Day Registration  
(Does not include lodging)

\$695.00 U.S. (Before June 18, 2010) \$ \_\_\_\_\_  
\$795.00 U.S. (After June 18, 2010) \$ \_\_\_\_\_

One (1) Day Registration (DOES NOT INCLUDE Lodging)  
June 22 - \$375.00 U.S. (Before June 18, 2010) \$ \_\_\_\_\_  
June 22 - \$475.00 U.S. (After June 18, 2010) \$ \_\_\_\_\_  
June 23 - \$375.00 U.S. (Before June 18, 2010) \$ \_\_\_\_\_  
June 23 - \$475.00 U.S. (After June 18, 2010) \$ \_\_\_\_\_

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 2010.

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### OPTIONAL

IFPAC Membership (New or Renewal for 2010) \$ \_\_\_\_\_  
\$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:

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253 Commerce Dr. Suite 103  
P.O. Box 7100  
Grayslake, IL 60030 USA  
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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 2010

## 22-23 June 2010 Carolina, Puerto Rico

### PRELIMINARY PROGRAM

**June 22, 2010**

**Day 1:**

#### **Regulatory**

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

Introduction and Opening Remarks

Rodolfo Romañach, Ph.D., UPR, Mayaguez, PR

PAT and Human Resources

Rodolfo Romañach, Ph.D., UPR, Mayaguez, PR

Presenting PAT & QbD to FDA

Thirunellai Venkateshwaran, Pfizer

Pfizer Experience with Real Time Release Applications

Tom Garcia, Pfizer, Inc., Groton, CT

QbD/PAT: Update and Regulatory Perspective

Vibhakar Shah, Ph.D., Senior Policy Advisor, Division of Manufacturing and Product Quality, Office of Compliance, CDER, FDA, Silver Spring, MD

Lunch

Afternoon Session

#### **Process Knowledge and Process Monitoring Methods**

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

Process Monitoring and Control: Particle Characterization

Angel Martinez, Pfizer

NIR & NIR-CI for Evaluation of Gel Strips and Polymeric Drug Delivery Systems

Rodolfo Romañach, Ph.D., UPR, Mayaguez, PR

Next Generation HPLC: Novel Process Applications

Rick Cooley, Dionex, Martinsville, IN

Approval of Real Time Release

Carlos Conde-Reyes, Ph.D., Pfizer, Guayama, PR

In-Process Particle Characterization-FBRM and PVM: Current

State of the Art and Recent PAT Case Studies

Des O'Grady, Mettler Toledo, Columbia, MD

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

**June 23, 2010**

**Day 2:**

#### **PAT & QbD Implementation**

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

Expanding your Process Knowledge: Applying Databases and informational procedures within your processes

Marc Champagne, Eli Lilly, Indianapolis, IN

Role of Models in Implementing the QbD Paradigm: A Regulatory Perspective

Sharmista Chatterjee, Ph.D., Office of New Drug Quality Assessment, OPS, CDER, FDA, Silver Spring, MD

Multivariate Batch Analysis, a Powerful Tool for Bioprocess Materials

Chris McCready, Umetrics

Transmission Raman for Tablet Analysis

David Strachen, Kaiser Optical

Cell Culture and Bioprocess Analysis by Near Infrared Spectroscopy

Todd Strother, Thermo Fisher Scientific, Lanham, MD

Lunch

Afternoon Session

#### **Pharmaceutical Engineering and Control for PAT and QbD**

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

Engineering and Control for PAT and QbD (TBA)

Salvador Garcia Muñoz, Ph.D., Pfizer

Modeling and Engineering in Continuous Pharmaceutical Manufacturing

Carlos Velázquez, Ph.D., Department of Chemical Engineering, UPR-Mayagüez

The potential of Continuous Manufacturing: Continuous Oral Solid Dosage Tablet making.

Rebecca Vangenechten, Siemens AG

Increasing Process Understanding: The Role of Feed-Frames in Tablet Compression

Rafael Mendez, Ph.D., Department of Chemical Engineering, UPR-Mayagüez

#### **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.

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

**or visit our web pages:**

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

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

Exhibits (Table Tops) Tuesday June 22  
and Wednesday June 23, 2010

**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

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JPAC

UPR-M

IBS - Caribe

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

June 22-23, 2010, Isla Verde Beach Resort, Marriott Courtyard,  
Carolina, Puerto Rico