

PAT

Process Analytical Technology

IFPAC®

253 Commerce Dr. Suite 103
Grayslake, IL 60030

IFPAC®/PAT Summit with INDUNIV

PROCESS ANALYTICAL TECHNOLOGY Pharmaceutical/BioPharmaceutical Manufacturing

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American Pharmaceutical Review

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

June 14-15, 2007, Condado Plaza Hotel, San Juan, Puerto Rico

Fourth Annual IFPAC®/PAT Summit with INDUNIV

PROCESS ANALYTICAL TECHNOLOGY
Pharmaceutical & Biopharmaceutical Manufacturing
June 14-15, 2007, Condado Plaza Hotel, San Juan, Puerto Rico

PAT - Process Analytical Technology: The Implementation - Strategies and Control

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. Successful Case Studies or Real Applications will be used to clearly illustrate the key components and the benefits of PAT - Process Analytical Technology.

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

.... A look at the Framework of PAT, Process Analytical Technology: A Systems Approach
.....PAT: Knowledge Management/Continuous Improvement, Process Understanding & Quality by Design
.....PAT: Regulatory and Compliance Issues - QUALITY SYSTEMS GUIDANCE
.....An overview of Pharmaceutical/Biopharm Manufacturing using PAT
.....PAT Tools: Process Analyzers, Chemometrics, Multivariate Analysis, Process Control
.....A Comprehensive table-top exhibit display: PAT Tools from Leading Vendors will be on display.

Break-outs and Networking groups

to be utilized so one can become directly involved along with your colleagues; and to discuss established & emerging PAT applications/technologies for the Pharmaceutical / Biopharmaceutical Industry.

ProActive Involvement with Illustrated Case Studies

defining the impact of PAT on Pharmaceutical/BioPharm Manufacturing.

- Quality by Design (QbD) , Design Space, QUALITY SYSTEMS
- Discussions on Analytical Methods to be Utilized.
- PROCESS ANALYZERS
- Controlling the application.
- PROCESS CONTROL
- PAT APPROVALS
- The Necessary Steps to Submit PAT Applications (to discuss during the Summit) to FDA.

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 Summit...

the Essential Meeting in Puerto Rico for Process Analytical Technology...PAT.
For updated Registration/information see our web page at: 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)

IFPAC®

253 Commerce Dr. Suite 103 • Grayslake, IL 60030 USA
Tel: 847-543-6800 • Fax: 847-548-1811
email: ifpac@IFPACnet.org
www.IFPACSummit.org

EXHIBITION

Join your fellow exhibitors at IFPAC®/PAT 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: ifpac@ais.net; Tel: 847-543-6800; Fax: 847-548-1811.

REGISTRATION INFORMATION

A two day registration is available for \$595.00 U.S (Before May 31, 2007). This includes 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

LOCATION

IFPAC®/PAT SUMMIT 2007 will be held in San Juan, Puerto Rico...at the Condado Plaza Hotel, 999 Ashford Avenue, San Juan, Puerto Rico, 00907. Tel: 800-468-0389 Direct Reservations. (Mention IFPAC® while making your hotel reservation.) 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.

REGISTRATION FORM

(photocopy for multiple applications)

IFPAC®/PAT Summit with INDUNIV

June 14-15, 2007, San Juan, Puerto Rico

Name/Title _____
Organization _____
Address _____
City/State/Zip _____
Telephone _____
Fax _____
email _____

2 Day Registration (DOES NOT INCLUDE Lodging)

\$595.00 U.S. (Before May 31, 2007) \$ _____
\$695.00 U.S. (After May 31, 2007) \$ _____

1 Day Registration (DOES NOT INCLUDE Lodging)

June 14 - \$350.00 U.S. (Before May 31, 2007) \$ _____
June 14 - \$450.00 U.S. (After May 31, 2007) \$ _____
June 15 - \$350.00 U.S. (Before May 31, 2007) \$ _____
June 15 - \$450.00 U.S. (After May 31, 2007) \$ _____

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

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 31 May 2007.

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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.

OPTIONAL
IFPAC Membership (New or Renewal for 2007) \$ _____
\$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: ifpac@ais.net 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 Summit 2007 14-15 June 2007 San Juan, Puerto Rico PRELIMINARY PROGRAM

Dr. Rodolfo J. Romañach, University of Puerto Rico

Session Chair

DAY ONE

AM - Introduction

Dr. Rodolfo J. Romañach

FDA's Quality Systems Guidance

FDA Representative (TBC)

David Gonzalez and Dr. Rodolfo J. Romañach, UPRM

FDA Update - QbD, Quality Assessment and PAT

Rebeca Rodriguez, FDA, San Juan, PR

Break

PAT Implementation: Risk Management and Process

Analytical Technology

Stephen M. Taylor, Abbott Laboratory, North Chicago, IL

Implementation of PAT in Pharmaceutical Manufacturing
Dimithu A. Jayawickrama, Engineering Technology Group,
Bristol Myers Squibb (Pedro Hernandez, Ph.D., Wyeth
Guayama, PR)

Lunch

PM - Session Chair: Dr. Rodolfo J. Romañach

Process Analytical Technology Implementation: A Project
Management Approach

Dave Johnson & Paul Davies, Expo Tech., Columbia, MD

PAT for Fermentation Applications (TBA)

Cap Munday, Hamilton Sundstrand

Chemometrics for PAT

L. Scott Ramos and Brian G. Rohrback, Infometrix, Inc.,
Bothell, WA

Break

Networking Extravaganza

Manuel Hormaza, IBS Caribe, San Juan, PR

Concurrent Focus Group (Breakout) Discussions:

(1) - Regulatory Concerns and Issues

(2) Analytical Methods: including Chemometrics for PAT

Discussion Leaders Include: Rebeca Rodrigues, FDA,
Rebecca Parrilla, FDA, Manuel L. Hormaza, IBS, Caribe,
Rodolfo J. Romañach & David Gonzalez, UPRM, Industrial
Engineering, and Carlos Conde, Ph.D. Wyeth, Guayama, PR

Close/Reception

Dr. Rodolfo J. Romañach, University of Puerto Rico

Session Chair

DAY TWO

AM - Introduction

Dr. Rodolfo J. Romañach

Particle Engineering for Flow Improvement

(Pharmaceutical Engineering)

Rajesh N. Dave (Raj), Ph.D., NJIT, Newark, NJ

Break

NIR Spectroscopy to Ensure a Robust Process (TBA)

George X. Zhou, Merck Research Laboratories, Rahway, NJ,
(Dr. Rodolfo J. Romañach)

QbD - Use of NIR at the Blending Stage to Support QbD
Carlos Conde, Ph.D., Wyeth Guayama, PR

Lunch

PM - Session Chair: Dr. Rodolfo J. Romañach

PAT Tools: Raman Analysis (TBD)

Quality by Design: PAT Implementation
TBD

Break

Case studies: Applications

Discussion Leaders (Case Study Participants Include)

Rebeca Rodrigues, FDA, Rebecca Parrilla, FDA, L.Scott
Ramos, Infometrix, Manuel L. Hormaza, IBS, Caribe, Rodolfo
J. Romañach & David Gonzalez, UPRM, Industrial
Engineering, and Carlos Conde, Ph.D. Wyeth, Guayama, PR

Report on Discussions

Finalize- Meet to summarize

Take Home Messages - Rodolfo J. Romañach, David
Gonzalez, Carlos Conde, Ph.D. Wyeth, Guayama, PR, and
Rebeca Rodriguez, FDA

Close/Reception

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

Exhibits (Table Tops) Thursday June 14
and Friday June 15, 2007