

QbD/PAT: Advanced Technological and Regulatory Developments Impacting Pharmaceutical Manufacturing and Control

September 19-22, 2010

Centro Convegni Sant'Agostino, Cortona, Italy

...an International meeting on Process Optimization, Quality by Design, and Regulatory Harmonization within the Pharmaceutical, BioTechnology and related Manufacturing Industries

An encounter with Cortona is an encounter with art, history and spirituality. Making oneself acquainted with this timeless town leads to an authentic discovery of the past. Cortona offers testimony to its history, as well as an enchanting view of the landscape between Lake Trasimeno and the Appenines. Cortona, this ancient land of the Etruscans. Please enjoy your stay.

Cortona is 500 metres above sea level. It is situated at the heart of a vast unspoiled district which enjoys artistic, historic and scenic distinction. Cortona still holds on to the values of its surroundings, of life "at a human pace". Within its Etruscan walls it proudly preserves the evidence of a truly noble civilization.



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Michael McCarthy, Ph.D., Food Science, UC Davis
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EXHIBITION AND SPONSORSHIP

Join your fellow exhibitors at IFPAC® Cortona Conference and Exhibition. 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.

REGISTRATION INFORMATION

A three day registration is available for €1375.00 Euro (EUR) (Before September 17, 2010). This includes, the three day conference, program portfolio, access-table top exhibition, Gala dinner, 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: <http://ifpaccortona.org>

LOCATION

IFPAC®- 10 CORTONA will be held at The Centro Convegni Sant'Agostino, located in the Citta Di Cortona, Italy.
<http://www.cortonasviluppo.it>

REGISTRATION FORM

(photocopy for multiple applications)

IFPAC® - Cortona Conference

September 19-22, 2010, Cortona, Italy

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

September 19-22, 2010 Registration
(Does not include lodging)

€1375.00 Euro (EUR) (Before September 17, 2010) € _____
€1675.00 Euro (EUR) (After September 17, 2010) € _____

Registration includes conference, access to table top exhibits, welcome reception, Evening Event, Gala dinner, refreshments, and lunch each day. Lodging is separate.

SUBTOTAL Payment € _____
(continue on next column)

Group registration packages are available.

Academia and government rates are also available.

Please contact IFPAC at info@ifpacnet.org

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 19 August, 2010.

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AIRLINES

Numerous airlines have direct flights into Florence Airport (closest) as well as Milan, and Rome. Call your preferred airline or Travel Agent for further information.

GROUND TRANSPORTATION

If arriving via Florence or Roma, the Florence to Rome Railway line is most convenient. Train Station for Cortona is Camucia. A bus or taxi will take you to Cortona.

OPTIONAL

IFPAC Membership (New or Renewal for 2010) € _____
€140.00 Euro (EUR)
(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 Discover

Card No. _____

Exp. date _____ 3-4 Digit Code _____

Signature: _____

Please return this registration form to:

IFPAC®
253 Commerce Dr. Suite 103
Grayslake, IL 60030 USA
Tel: 847-543-6800 Fax: 847-548-1811
email: info@ifpacnet.org <http://ifpaccortona.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.

20-22 September 2010 Cortona, Italy

Preliminary Sessions and Program Topics

Monday, 20 September 2010

DAY ONE -AM Session Chair: Mel Koch
Plenary Session

Welcome/Introduction: Challenges and Needs in the Pharmaceutical, Biotechnology, and Food Industries - Quality and Regulatory Harmonization
Mel Koch (Univ.of Washington) and Attilio Citterio (Politecnico di Milano)

Opportunities and Challenges to the Implementation of New Technologies and Innovation into Pharmaceutical Manufacturing
Ferdinando Aspesi (Novartis)

FDA Perspective: Regulatory Aspects of Pharmaceutical Development and Manufacturing in the 21st Century
Moheb M. Nasr (Food and Drug Administration - FDA)

European Perspective: Regulatory Aspects of Pharmaceutical Development and Manufacturing in the 21st Century
Riccardo Luigetti (European Medicines Agency-EMA)

Green Processing (TBA)
Attilio Citterio (Politecnico di Milano)

PAT Implementation: Process Control & Instrumentation
TBA

Lunch

Table Top Exhibit/Posters each day - 11:00a.m. - 4:30p.m.

DAY ONE - PM Session Chair: Robert Baum
Pharmaceutical Quality and Manufacturing: Implementation of Modern QbD & PAT Concepts

Session Introduction: The technological and regulatory aspects of QbD and PAT.

Implementation of PAT for Real Time Release Testing
Mark R. Smith (Pfizer)

Project Management on API Manufacturing: Develop an Efficient Control Strategy and Implementation
Andrea Castellin and Marco Galvagni (FIS Fabbrica Italiana Sintetici S.p.A.)

How can the Pharmacopoeia Support the Implementation of QbD/PAT?

Michael Wierer (Deputy Head, European Pharmacopoeia Department, European Directorate for the Quality of Medicines & Healthcare- EDQM)

Adapting the Pharmacopeial UDU Test Standard for Larger Sample Sizes
Mark Berry (Pfizer)

Panel Discussion - All Speakers- Day One

Special Exhibitor Presentations

Departure for evening Event/Evening Cocktail Event
Hosted by the University of Georgia, College of Arts and Sciences, School of Art, and the UGA Cortona Program

Tuesday, 21 September 2010

DAY TWO - AM Session Chairs: Moheb Nasr and Mel Koch
Continuous Processing (including Micro-Reactors and Advances in Micro-Instrumentation) - Session Introduction and Overview

Novartis Approach to Continuous Manufacturing (API and Drug Products)
Walter Bisson (Novartis Pharma AG)

Drug Product Continuous Manufacturing
Gordon Muirhead (GSK)

Continuous Processing (TBA)
Christine Seymour (Pfizer)

Continuous Manufacturing of API
Darren Caine (GSK)

Use of Micro Reactors: Improvements in Chemistry

Advance Flow Reactors
Pierre Woehl (Corning)

Micro-Reactors and Continuous Processing
Paul Watts (Hull University)

Continuous Manufacturing; Challenges and Opportunities
Mel Koch et al. (CPAC, University of Washington)

Session Wrap-Up with Q&D - Continuous Processing/Micro-Reactors
Moheb Nasr (FDA), Mel Koch (CPAC, University of Washington), et al.

Lunch

Table Top Exhibit/Posters each day - 11:00a.m. - 4:30p.m.

DAY TWO-PM Session Chairs: Marino Nebuloni and Ferdinando Aspesi
Pharmaceutical Process Improvements and Analytical Technology

Standard Solutions for Quality by Design Productions and Realtime Release in the Pharmaceutical Industry
D. Keogh, T. Buijs, M. Banti (ABB)

From Early Start to Operational Excellence in Generic Analytical Development
Bianca Avramovitch (Teva Pharmaceuticals, Global Generic R&D)

Application to Drug Substance Crystallization
Marino Nebuloni (Redox and Università di Parma)

Improvements in Bio-Processing

Session Chair: Martin Warman
Bio-Processing (TBA)
Martin Warman (Vertex Pharmaceutical)

Implementation of the QbD Principles to a Biopharmaceutical Operation: A Novartis Example
Marianna Machin and Lorenz Liesum (Novartis Pharma AG)

Towards Online Control of Glycosylation in MAbs
M.M. St. Amand, M.M. McCabe, A.S. Robinson, B.A. Ogunnaike (University of Delaware)

Gala Dinner - Town Centre

DAY THREE - AM Session Chair: Brian Rohrbach
Session Introduction and Overview - Technical Presentations on Selected Topics in PAT for achieving QbD.

Advances in Separations Science (Alignments etc.)
Brian Rohrbach (Infometrix)

Multivariate Methods in Food Authenticity Studies: Classical and Recent Applications within Italian Food Products
Giuliana Drava, (Di.C.T.F.A. Department of Pharmaceutical and Food Chemistry and Technologies - University of Genova - Italy)

Novel & Usable Technologies within the Food Industry
Saskia van Ruth (RIKLT - Institute of Food Safety)

On-Line Spectral Imaging being Applied to Food Process Control
Jens Petter Wold (Nofima - Norwegian Food Research Institute)

Advances in Process Spectroscopy: Jeffrey Sherman
Advances in Process Spectroscopy: Mid-Infrared In-Situ Reaction Monitoring - Case Studies in Acylation, Reductive Amination/Hydrogenation, and Sandmeyer Reactions
Jeffrey Sherman (Mettler Toledo)

Process Fiber Optics (TBA)
Viacheslav Artyushenko (Fibre Photonics Ltd.)

Raman Spectroscopy for Chemical Development, Formulation Development, and Fermentation Applications
Harry Owen (Kaiser Optical Systems, Inc)

Lunch

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PAT

Process Analytical Technology

QbD

Quality by Design

CALL FOR PAPERS

The Cortona conference invites you to submit an abstract for the forum. Posters and limited verbal presentations are still being accepted.

..see our web pages for continuous updates:

<http://IFPACcortona.org>

Exhibits (Table Tops)
20-22 September 2010

Sponsor Packages are also available.

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: <http://IFPACcortona.org>

“Designed by Industry, Academia, and the Regulators”

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DAY THREE - PM Session Chair: Jeffrey Sherman
Applications of QbD/PAT

In-Situ Particle Characterization: Applications in Formulations Development and Manufacturing - Disintegration/Dissolution, Fluid Bed Layering, and High Shear Wet Granulation
Jeffrey Sherman (Mettler Toledo)

Process Spectroscopy (TBD)

Use of OPC for Data Handling Connectivity to Process Control
Daniel Keogh (ABB)

MATRIC Europa Process Optimization Center Concept Solution Providers; Giorgio Borghi (MATRIC Europa)

Wrap-Up Panel Discussion - Audience-wide Discussion on the possibilities to establish Collaborations and develop Action Plans based on the topics presented during the conference.

Moderators: Mel Koch, Moheb Nasr
Marino Nebuloni, Robert Baum, Paul Watts, Ferdinando Aspesi, et al.

Close

Table Top Exhibits - 11:00a.m. - 1:00p.m.

Tear down - 1:00p.m. - 4:00p.m.