

# 20-22 September 2010 Cortona, Italy

## Preliminary Sessions and Program Topics

### Monday, 20 September 2010

DAY ONE -AM Session Chair: Mel Koch  
Plenary

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 Pharmacopoeial 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 & 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

### EXHIBITION AND SPONSORSHIP

Join your fellow exhibitors at IFPAC<sup>®</sup> 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](mailto:info@IFPACnet.org); Tel: 847-543-6800; Fax: 847-548-1811.

DAY THREE - PM Session Chair: Jeffrey Sherman  
Applicatoins 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, Ferninando Aspesi, et al.

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

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

# 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.

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