

# 20-22 September 2010 Cortona, Italy

## Preliminary Sessions and Program Topics

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### Monday, 20 September 2010

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DAY ONE -AM Session Chair: Mel Koch

Welcome/Introduction/Overview

Mel Koch (University of Washington) and Attilio Citterio (Politecnico di Milano)

Challenges and Needs in the Pharmaceutical, Biotechnology, and Food Industries - Quality and Regulatory Harmonization  
Mel Koch (University of Washington)

Plenary Sessions

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

Regulatory Aspects of Pharmaceutical Development and Manufacturing in the 21st Century

European Medical Authority (EMA) and/or Moheb M. Nasr (FDA)

Green Processing (TBA)

Attilio Citterio (Politecnico di Milano)

Open

Food Quality and Safety

TBC European Food Safety Authority, TBD (EFSA)

TBC US FDA, Center for Food, Safety, and Nutrition (CFSAN)

Lunch

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. Topics to include: case studies, modeling, PAT implementation, sampling, role of public standards. Presentations will be followed by a Panel Discussion.

Case Study - PAT Implementation (TBA)  
(Graham Cook; Pfizer) TBC

Case Study II - QbD/PAT  
Andrea Castalini (FIS)

Modeling and/or Sampling  
Pharma industry representative

Role of Public Standards (TBC)

Panel Discussion

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

Table Top Exhibit and Posters - 11:00a.m. - 4:30p.m.

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### Tuesday, 21 September 2010

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DAY TWO - AM Session Chairs: Brian Marquardt and Moheb Nasr

Continuous Processing (including Micro-Reactors and Advances in Micro-Instrumentation) - Session Introduction and Overview

Continuous Manufacturing; Challenges and Opportunities  
Brian Marquardt, (APL, University of Washington)

Advance Flow Reactors  
Sergio Pissavini (Corning)

Continuous Manufacturing of API  
Darren Caine (GSK), TBD (GSK)

Drug Product Continuous Manufacturing  
Gordon Muirhead (GSK), TBD (GSK)

Novartis Approach to Continuous Manufacturing  
Walter Bisson (Novartis)

Continuous Processing or Micro Reactors for Organic Reactors  
Pfizer or Hans-Rene Bjorsvik, MSc, Ph.D., (University of Bergen)

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

Continuous Processing Discussions  
Brian Marquardt, (APL, University of Washington) et al.

Lunch

DAY TWO-PM Session Chairs: Marino Nebuloni and Ferdinando Aspesi

Pharmaceutical Process Improvements and Analytical Technology

QbD/PAT - Pharmaceutical Applications

Teva Pharmaceuticals (TBC) or other Generic Pharma

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

Improvements in Bio-Processing  
Session Chair: Martin Warman, Vertex Pharmaceutical (TBC)

Bio-Processing (TBA)  
Martin Warman, Vertex Pharmaceutical (TBC)

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

Table Top Exhibit and Posters - 11:00a.m. - 4:30p.m.

Wednesday, 22 September 2010

DAY THREE - AM Session Chair: Robert Synovec  
Technical Presentations on Selected Topics in PAT for achieving QbD.

Session Introduction and Overview

Advances in Separations Science (Alignments etc.)  
Robert Synovec (University of Washington)

Advanced Separations Technology  
Hernan Cortes (TBC) or other

Advances in Process Spectroscopy  
Jeffrey Sherman

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

Process Spectroscopy (TBD)

Particle Characterization (TBD)

Open

Lunch

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

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

Use of OPC for Data Handling Connectivity to Process Control  
TBA

MATRIC Europa Process Optimization Center Concept  
Solution Providers; Keith Pauley (MATRIC)

Audience-wide Discussion on the possibilities to establish  
Collaborations and develop Action Plans based on the topics pre-  
sented during the conference.  
Mel Koch (University of Washington) et al.

Close

Table Top Exhibits - 11:00a.m. - 1:00p.m. Tear down - 1:00p.m. -  
4:00p.m.

## 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: [ifpac@IFPACnet.org](mailto:ifpac@IFPACnet.org); Tel: 847-543-6800; Fax: 847-548-1811.

# PAT

*Process Analytical Technology*

# QbD

*Quality by Design*

## CALL FOR PAPERS

The Cortona conference cordially invites you to submit an abstract for the forum. Posters and limited verbal presentations will be accepted through 30 July, 2010.

..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:**

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