

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
Gordon Muirhead (GSK)

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)

Chemical Synthesis and Efficient Scale-Up in Flow Reactors
Paul Watts (Hull University)

Continuous Manufacturing; Challenges and Opportunities
Melvin V. Koch (CPAC, University of Washington) and Brian Marquardt (APL/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. Ogunnaiké (University of Delaware)

Gala Dinner - Town Centre

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

Advances in Separations Science (Alignments etc.)
Brian Rohrback (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)

Signals for Economic Adulteration: Novel Approaches
Saskia van Ruth, Hans Marvin, Martin Alewijn, Monique Bremer, Esther Kok (RIKLT - Institute of Food Safety, Wageningen University and Research Centre)

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)

Fibre Spectroscopy with Clear Process Vision
Viacheslav Artyushenko, G. Colquhoun and J. Mannhardt (Fibre Photonics Ltd.)
Raman Spectroscopy for Chemical Development, Formulation Development, and Fermentation Applications
Harry Owen (Kaiser Optical Systems, Inc)

Lunch

EXHIBITION AND SPONSORSHIP

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PAT

Process Analytical Technology

QbD

Quality by Design

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Exhibits (Table Tops)
20-22 September 2010

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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, Fernando Aspesi, et al.

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

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