



Monday, 6 October 2008

Welcome

Prof. Silvano Focardi, Rector of Università di Siena

Introduction/Overview

Challenges and Opportunities for Product and Process Optimization

Mel Koch (CPAC, Università di Washington)

Plenary Sessions - Chair: Mel Koch

QbD: A Global Implementation Perspective, Moheb M. Nasr (FDA) and Riccardo Luigetti (EMEA)

Food Safety and Security, Nelson Marmiroli (Università di Parma)

Bio-Energy: Critical Issues and Challenges, Michelle Cohn (Honeywell - UOP)

Hazard Evaluation by PAT Approach, Marino Nebuloni (Redox, Monza, Italy)

Green Chemistry, Attilio Citterio (Milan Polytechnical Università)

Welcome/Introduction - Afternoon

Prof. Luigi Campanella, President of Italian Chemical Society (SCI)

Case Studies: Quality by Design – QbD - Chair: Graham Cook

Using PAT to Complement QbD at Wyeth, Graham Cook (Wyeth, UK)

Integrating PAT to Support API Development at GSK, Vern de Biasi (GSK R&D, Stevenage, UK)

Quality by Design: The New Paradigm of ICH Q8, Q9 and Q10 – An Industry View

Fritz Erni, (Novartis Pharma, Switzerland)

QbD Panel Discussion

Vern de Biasi (GSK, UK), Graham Cook (Wyeth, UK), Fritz Erni (Novartis, Switzerland), Moheb M. Nasr, (FDA) and Riccardo Luigetti, (EMEA)

Evening Event at Enoteca Italiana

Tuesday, 7 October, 2008

Plenary Presentations: Chair: Mel Koch

Micro-Reactors, Mr. Philippe Caze (Corning, France)

Nanotechnology: from technological processes to applications, Ross Rinaldi, National Nanotechnology Laboratory, CNR INFM (Istituto Nazionale di Fisica della Materia ISUFI-Distretto Tecnologico Università degli Studi di Lecce via Arnesano, Lecce, Italy)

Parallel Session - I

Advances in Tools for PAT - Session Chair – Brian Marquardt

- Implementation of Advanced Gas Chromatography: from the Discovery Stage to Real-Time On Line Analysis, Robert Synovec, (CPAC, Università di Washington)
- Choice of Fiber Spectroscopy Systems for Effective PAT, V. Artyushenko and G. Colquhoun, (Fibre Photonics Ltd., West Lothian, Scotland) and V. Lobachov, T. Sakharova, and D. Savitskij (General Physics Institute of RAS, Moscow, Russia)
- PAT- Driven Developments in Process Mass Spectrometry, Graham Lewis, Tony Slapikas and Nosa Agbonkonkon (Ametek Process & Analytical Instruments, Meerbusch, Germany) and Rafael Arguelles and Joseph Ocando (Pfizer, Inc.)
- Dynamic Surface Tension Detection: Advances in PAT, Kristen Skogerboe (Seattle Università)
- Raman Spectroscopy, A Useful Tool for Process Analytical Technology (PAT), Dr. Hervé Lucas (Kaiser Optical Europe, Lyon, France)
- Visual Creation and Exploration of Design Space, Control Space and Operating Space Unifies QBD and PAT, Robin Brooks BSc, PhD, John Wilson BSc, PhD, CENG, Na Zhao BSc, PhD, (Curvaceous Software Limited, Cross, Buckinghamshire, United Kingdom)

Parallel Session – II - Session Chair: Ross Rinaldi

Nano-Technology

- Integration of Silicon Nanowires in Digital Microfluidic Devices: Lab-on-Chip for Direct Mass Spectrometry Analysis, Florian Lapierre, Yannick Coffinier, Gaëlle Piret, Vincent Thomy and Rabah Boukherroub, Institut de Recherche Interdisciplinaire (IRI, USR 3078) and Institut d'Electronique, de Microélectronique et de Nanotechnologie (IEMN, UMR 8520), Cité Scientifique, Villeneuve d'Ascq, France.
- Integration of Molecular Structures in Electrode Gaps by Dielectrophoresis, Andrea Csaki, Christian Leiterer, Andreas Wolff, Robert Kretschmer, & Wolfgang Fritzsche (Institute of Photonic Technology, Jena, Germany)
- Molecular Nanotechnologies for Photonic Devices, Michele Manca (NNL-Lecce)
- Total Reflection X-ray Fluorescence (TXRF) Analysis and how it will support Process Control in Pharmaceutical Production and Nano Technology, Armin Gross and Hagen Stosnach (Bruker AXS Microanalysis GmbH, Berlin, Germany)

Hazard Evaluation - Chair: Marino Nebuloni

- Real-Time in Situ FTIR for the Safe and Efficient Scale Up of Chemical Processes, Jeff Sherman, Paul Scholl and Dr. Wes Walker (Mettler –Toledo, Columbia, MD USA)

Tuesday, 7 October, 2008 (Continued)

Parallel Session –I

Micro-Reactors – Session Chair – Phillippe Caze

- Micro-Reactors (TBA), Volker Hessel (IMM, Germany & Università di Einhoven, Netherlands)
- Chemical Synthesis in Flow Reactors, Paul Watts (Department of Chemistry, Università di Hull, UK)
- Combining Analytical Sensors and NeSSI to Improve Process Understanding, Brian J. Marquardt, Senior Engineer Applied Physics Laboratory and Center for Process Analytical Chemistry, (Università di Washington, Seattle, WA USA)
- C2V 200: A Nessi Compatible Fast MicroGC, Elders, J., Enschede, NL, Burger, G.J., Enschede, NL, Spiering, V., Enschede, NL, van Weerden, H., Enschede, NL, C2V, Concept to Volume BV, Enschede, The Netherlands
- Miniaturized Wireless Sensing for Process Analysis, Prof. Brian Otis (Università di Washington, Seattle, WA USA)

Parallel Session - II

Environmental - Session Chairs - Marco Benedetti and Maurizio Anzini

- The Social Needs of Product and Process Optimization for a Better Environmental Legacy, Marco Benedetti (CINSA Venezia)
- Quantification of Road Transport Emissions for a Better Environmental Legacy, Seref Soyly, SAU. – Sakarya Università Department of Environmental Engineering, Sakarya, Turkey)
- Megacities for Soil and Groundwater Contamination (Ludo Diels, VITO – Flemish Institute for Technological Research, Mol, Belgium)
- Rapid Microbiological Methods (RMM) for Optimization Process in Pharmaceutical Environmental Monitoring, Dr. Silvia Conti and Dr. Luca Moriani (CTP System, Poggibonsi, Siena, Italy)
- Pharmaceutical Manufacturing Process Optimization Using PAT, Lean Six Sigma and Simulations, Barry Gujral, Process Analytical Technology Coordinator, Freeman Stanfield, Manager Analytical Development and Peter Amantides, Senior Director Quality Operations, DSM Pharmaceuticals Inc., Greenville, NC (USA)

Gala Dinner - Siena Town Centre

Wednesday, 8 October, 2008

Parallel Session -I

Bio-Energy/Green Chemistry/Process Control - Session Chair - Michelle Cohn

- The Italian Biochar Initiative (ITABI), S. Baronti (CNR, Institute for Biometrology, Italy)
- Green Chemistry: More Aspirational Transformations, More Advanced Methods, Angelo Albini and Maurizio Fagnoni, (Università di Pavia, Italy)
- PAT - Turning Data into Knowledge, Thomas L Buijs, (ABB, Quebec, Canada), Daniel Keogh, (ABB, Ireland) and Marco Banti, (ABB, Milan, Italy)
- Bioprocesses, from Trial and Error to Smart Design, Renger H. Jellema¹, Carina Rubingh¹, Sabina Bijlsma¹, Age K. Smilde², Karin Overkamp¹, Bas Muilwijk¹, Leon Coulier¹ and Mariët van der Werf¹ (TNO Quality of Life AJ Zeist, The Netherlands) 2 (Swammerdam Institute for Life Sciences, Università of Amsterdam, Amsterdam, The Netherlands)

Parallel Session –II

Food Safety and Security – Session Chair - Nelson Marmiroli

- EFSA and its Role in Food Safety, Lesley Koschel, (EFSA, Parma, Italy)
- Food Safety and Security, Nelson Marmiroli (Università di Parma)
- Magnetic Resonance-based Systems for Food Quality and Safety for Fresh Products, M. McCarthy, (Università di California at Davis)
- Online Measurements of Quality, Martin Høy and Jens Petter Wold (Norwegian Food Research Institute, Matforsk AS, Nofima Food, Norway)
- NATO - SPS Pilot Study on Food Chain Security: Preliminary results to reduce risk and threats to the food system for managing food chain security, Beyazit Cirakoglu (Marmara Università - School of Medicine – TR) and Hami Alpas Middle East Technical Università - Engineering Faculty – TR

Plenary Approach to Round Table Discussions - Session Chair - Mel Koch

Topics will be on how the advances in Measurement Sciences can be applied to the areas of QbD, Food Safety and Security, Environmental topics, Bio- topics, and Green Chemistry

Lunch

Summary of Round Table Discussions

Develop 2-3 Action Plans for implementation during the next year.

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