

**Global Challenges for Investigational Medicinal Products:
Good Practices from Research Lab to Commercial Scale
28-29 January 2009**

Venue:

Hotel Quirinale:

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A PDA Europe Inter-Chapter Conference

Wednesday, 28 January 2008

8:30 **Purpose and Format of the Conference**
Stefano Maccio, President, PDA Italy Chapter
Alessandro Rigamonti, President AFI

Keynote Session: The Regulatory Framework

Chair: Luciano Gambini, PDA-Italy

EU Regulations and Guidance for IMPs

Carlo Pini, Head Biotechnology, Istituto Superiore della Sanità, Italy

Carlo Tomino, Head Clinical Trials, AIFA, Italy

US Regulations and Guidance for IMPs

FDA Representative, CDER/OBP (invited)

10.30 Break

11:00 Session 1: Quality Issues Related to API's

Chair: Philippe Gomez, Sartorius-Stedim, France

Reduced Virus Safety Package for IMPs for Enhanced Speed to Clinic - a Case Study

Hannelore Willkommen, Regulatory Affairs & Biological Safety Consulting, Germany

Path from Biological Drug Substance Development through to Commercialization

Spencer Fisk, Organon, The Netherlands

Maintaining Quality throughout the Development - a Small Molecule Case Study

Paul Madeley, Synthisis, UK

Discussion

All Speakers of this morning

13:00 Lunch

14:00 Session 2: Process Development, Changes and Control

Chair: Jean-Louis Saubion, PDA France Chapter

Transferring Embryonic Stem Cell Substrate from Research into a Development and Clinical Manufacturing Setting

Stephen Brown, Vivalis, France

Change Management in Development on Both Sides of the Ocean – a Case Study

Ruhi Ahmed, Biomarin, USA

Quality by Design for a Real-Time-Release Approved Product – a Case Study

Paul Dickinson, AstraZeneca, UK

Discussion

All Speakers of this morning

15:30 Break

16:00 Session 3: Certification –The Role of the QP

Chair: Desirée Vendrig, Teva, The Netherlands

Being an In-House QP of a Virtual Company: a Case Study

Peter Mayne, Osi Pharmaceuticals, UK

In-House big Pharma QP Case Study

Industry Speaker invited

CRO/CMO QP Case Study

Industry Speaker invited

Discussion

All Speakers of this Session

18:00 Close of day

20:00 **Networking Event**

Walking tour to dinner

Thursday, 29 January 2008

**8:00 Breakfast Session: moderated by Georg Roessling (*Continental Breakfast served*)
Issues sourcing from India and China**

Geographical areas like India and China are becoming more frequent part of the supply chain in commercial manufacturing. This is now expanding to investigational medicinal products.

The consequences are a more complex situation with regards to

- What is the best regulatory approach?
- What qualification / certification is typically required?
- How to resolve GMP compliance?
- How to achieve oversight and lean development for Phase I/II on a remote site?

Speakers:

Pharmaceutical Raw Materials: Quality, Safety, Speed and Cost - the Challenge in Development

Frédéric Thomas, Arthur D Little, France (invited)

Sourcing from China: Opportunities and Pitfalls in Development - a Case Study

Charles Hu, BIMSIFRAMGROUP, France (invited)

09:00 Session 4: Supply Chain Issues

Chair: Joachim Leube, Bayer Healthcare, Italy

EU Labelling of Clinical Trial Material: Omitting Retest Date - a Case Study

Gary Cunningham, Wyeth, UK

Managing Hospital Pharmacy Activities; Case Study

Armelle Mijonnet, Merck&Co, France

Supply Chain Issues for Investigational Medicinal Products – an Inspector's View

Lorella Chiappinelli, Inspector, AIFA, Italy (invited)

Discussion

All Speakers of this Session

11:00 Coffee Break

11:15 Session 5: Practical Issues with Regulatory Filings for IMPD's

Chair: Hiltrud Horn, Horn Pharmaceutical Consulting

Assessor's Experiences on IMPDs Quality

Antoine Sawaya, Head of Assessors, AFSSAPS, France; (invited)

Biotech Dossier Quality (CMC): Pitfalls and How to Avoid Them - Case Study

Carina Sonnega, Biotechnology Consultant, Regulatory and Quality Affairs, France

Small Molecule Dossier Quality (CMC): the Dos and Don'ts - Case Study

Hiltrud Horn, Horn Pharmaceutical Consulting, Germany

Discussion
All Speakers of this Session

13:00 Lunch

14:00 Q&A - Panel Session: How to Assure Quality for Investigational Products
Chair: Karen Ginsbury, *Pharmaceutical Consulting Israel*

Pharma

Paul Dickinson, *AstraZeneca, UK*
Ruhi Ahmed, *Biomarin, USA*
Peter Mayne, *Osi Pharmaceuticals, UK*
Armelle Mijonnet, *Merck&Co, France*

Regulators

Antoine Sawaya, *Head of Assessors, AFSSAPS, France; (invited)*
Carlo Pini, *Head Biotechnology, Istituto Superiore della Sanità, Italy*
Carlo Tomino, *Head Clinical Trials, AIFA, Italy*
Lorella Chiappinelli, *Inspector, AIFA, Italy (invited)*
FDA Representative, *CDER/OBP (invited)*

Issues and Comments on Recent EMEA and FDA Guidelines on IMPs
Karen Ginsbury, *Pharmaceutical Consulting Israel*

15:45 **Closing comments and adjournment**
Claudio Puglisi, *Co-Chair, SIFI*
Georg Roessling, *Senior Vice President PDA-Europe*

Organizing Committee:

Volker Eck, *PDA Europe*
Luciano Gambini, *Consulting, Italy*
Karen Ginsbury, *Pharmaceutical Consulting, Israel*
Philippe Gomez, *Sartorius-Stedim, France*
Hiltrud Horn, *Horn Pharmaceutical Consulting, Germany*
Joachim Leube, *BayerHealthCare, Italy*
Peter Mayne, *OSI Pharmaceuticals, UK*

Armelle Mijonnet, *Merck Sharp & Dome, France*
Stefano Macciò, *CTP, Italy*
Claudio Puglisi, *SIFI, Italy*
Jean-Louis Saubion, *PDA France Chapter*
Carina Sonnega, *Biotechnology Consulting, France*
Desirée Vendrig, *Teva Europe, The Netherlands*