Updated Programme

ISPE

Vienna congress

18-22 September 2006 InterContinental Vienna, Austria

Science-Based Manufacturing for the Next Decade

September

18 September

- Plenary Day: Science-Based Manufacturing for the Next Decade

19-20 September

- PAT - The Science, Its Applications and Regulatory Implications
- Lyophilisation - Technologies and Practice
- Barrier Isolation Technology Forum

21-22 September

- Developing Investigational Medicinal Product (IMP) Supply Strategies and Working Practices to Meet Future Trends in Clinical Research
- Quality Risk Management - Guidance and Case Studies
- Continuous Processing in the Real World

22 September

- GAMP® Part 11: Update on 21 CFR Part 11 with a Focus on Manufacturing Execution Systems (MES)

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ISPE®

2006 Vienna Congress

Science-Based Manufacturing for the Next Decade

Content

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About the Event

The 2006 ISPE Vienna Congress is your opportunity to stay abreast of the pharmaceutical industry's most current trends and challenges. The event includes:

- Plenary Day
- Seven leading-edge conferences
- Some 70 conference leaders and speakers
- ISPE Table Top exhibition including some 45 different companies
- An Opening Reception hosted by the Germany/Austria/Switzerland Affiliate
- Two Networking Receptions
- Site Visits

Over 400 delegates are expected!

Join us in VIENNA

Register today!

Programme at-a-Glance

Monday, 18 September	Tuesday, 19 September	Wednesday, 20 September	Thursday, 21 September	Friday, 22 September
Plenary Day Science-Based Manufacturing for the Next Decade	PAT - The Science, Its Applications and Regulatory Implications	Site Visits*	Developing Investigational Medicinal Product Supply Strategies and Working Practices to Meet Future Trends in Clinical Research	
	Lyophilisation - Technologies and Practice	Site Visits*	Quality Risk Management - Guidance and Case Studies	
	Barrier Isolation Technology Forum	Site Visits*	Continuous Processing in the Real World	
				GAMP® Part 11: Update on 21 CFR Part 11 with a Focus on Manufacturing Execution Systems (MES)
	ISPE Table Top Exhibition	ISPE Table Top Exhibition	ISPE Table Top Exhibition	ISPE Table Top Exhibition
Opening Reception hosted by the Germany/ Austria/Switzerland Affiliate	Networking Reception		Networking Reception IMP COP Dinner	

5-Day Package

3-Day Package 1

3-Day Package 2

5-Day Package

includes
- Plenary Day and Opening Reception
- 2 Conference Sets (19-22 September)
- 2 Networking Receptions
- ISPE Table Top Exhibition

3-Day Package 1

includes
- Plenary Day and Opening Reception
- 1 Conference Set (19-20 September)
- 1 Networking Reception
- ISPE Table Top Exhibition

3-Day Package 2

includes
- Plenary Day and Opening Reception
- 1 Conference Set (21 -22 September)
- 1 Networking Reception
- ISPE Table Top Exhibition

* Site visits are not included in packages. Please select an option on the registration form.

Plenary Day: Science-Based Manufacturing for the Next Decade
18 September 2006

Senior executives from the global pharmaceutical industry and regulatory agencies will provide major insights into the challenges facing the industry with science-based manufacturing over the next ten years.

In the morning session, the importance and opportunities for science-based manufacturing will be addressed, a European regulatory perspective will be given and global trends in the industry will be detailed. In the afternoon, an academic viewpoint on science-based manufacturing will be given, a presentation on PAT and a comprehensive review and update on ICH initiatives. ICH has developed a series of documents which change the direction from 'blind compliance' to science-based approach, these include pharmaceutical development (Q8), the use of risk management in the pharmaceutical industry (Q9) and facilitating the changes by applying quality systems (Q10).

The Plenary Day will conclude with a presentation on the pharmaceutical manufacturing professional of the future project, the vision of which is that future professionals supporting manufacturing will require new applied scientific process and engineering knowledge.

Conference Leaders

Charles Hoiberg, Pfizer, USA
Gert Moelgaard, NNE A/S, Denmark

Who Should Attend

- Development personnel
- Regulatory affairs executives
- Manufacturing personnel
- Production staff
- Engineers
- Quality operations executives

Agenda

Monday, 18 September

10.00 - 10.15 Welcome and Introduction
***Gert Moelgaard,* NNE A/S, Denmark**

10.15 - 11.00 Meeting the Challenges of the Next Decade – Key Role for Science-Based Manufacturing
***Trevor Jones,* Allergan Inc., USA and NextPharma Technologies EU**

- Are scientific advances outpacing regulation? What effect could this have on manufacture?
- Delivering the potential of genomics and proteomics and the biological revolution: Will this require a sea change in manufacture?
- Purchasing power, affordability and rationing of medicines: What will these factors mean for product costs/prices?
- Is pharmaceutical production technology keeping pace with other industries?
- "In-house" or "Out-sourcing". Have we got the balance right?

11.00 - 11.45 Science-Based Manufacturing: The EMEA Regulatory Perspectives
***Riccardo Luigetti,* EMEA, UK**

- EMEA position in the global regulatory environment
- EMEA road map to 2010
- New legislation: Current status of implementation (GMP topics)
- ICH guidelines Q8, Q9 and Q10
- European PAT team

11.45 - 12.30 Global Perspectives for the Pharmaceutical Industry
***Allister Clark,* IMS Consulting, UK**

- Worldwide statistics and trends
- R&D expenditure and pipeline sizes
- Strategies for success in the global environment
- Outlook for the pharmaceutical industry

12.30 - 12.45 Questions and Answers

12.45 - 14.00 Lunch

14.00 - 14.45 Opportunities and Challenges Associated with an Improved Science Base for API Manufacture

Kevin Roberts, **Leeds University, UK**

- 4Ms – Modelling, measurement, manipulation and manufacturing for pharmaceutical development
- Design space (ICHQ8) and improving current API manufacturing science
- Molecular and particulate modelling for materials process design
- PAT for improved control of particulate processes
- Impact of improved API quality on secondary processing

14.45 - 15.30 PAT – A Model for Science-Based Manufacturing

Chris Watts, **FDA, USA**

- Background and history of PAT
- Regulatory expectations for PAT
- Impact of PAT for the pharmaceutical industry
- Future challenges and opportunities for PAT in science-based manufacturing

15.30 - 16.00 Coffee Break

16.00 - 16.45 A Review and Update on ICH Quality Initiatives

John Berridge, **Pfizer, UK**

- ICH Q8, design space and regulatory flexibility
- ICH Q9 and utilisation of quality risk management
- ICH Q10, latest news from the EWG
- Quality guidelines under revision, potential new quality topics and why they are being proposed

16.45 - 17.30 Pharmaceutical Manufacturing Professional of the Future

Shawn Whitfield, **GlaxoSmithKline, UK**

- The nature of our business is changing – The regulatory and economic drivers
- Pharmaceutical manufacturing technology is advancing – Traditional to future state
- Greater level of emphasis now on fundamental process understanding – The PAT philosophy
- New skill sets and experience required to achieve new business model goals – The gap
- How GlaxoSmithKline and the industry can fill the skills gap

17.30 - 17.45 Review of the Day

Charles Hoiberg, **Pfizer, USA**

18.30 - 20.00 Opening Reception

Enjoy food, drinks and music at the Konzerthaus, located in the heart of Vienna. For more information see page 22.

PAT – The Science, Its Applications and Regulatory Implications

19-20 September 2006

Conference Description

PAT is pivotal to any company striving to achieve manufacturing operational excellence. PAT needs management awareness from R&D to manufacturing. Important benefits are achieved by PAT projects and examples will be presented. PAT has an ongoing impact on quality systems and plays a key role in process development and the management of data. Key aspects of PAT include identifying critical process control parameters and enabling effective process control to be used during manufacture. PAT starts in R&D and needs strong collaboration of R&D and manufacturing in the future. Understanding this will provide the delegate understanding of how this relates to increasing yield, reducing waste, shortening cycle times and ultimately delivering continuous improvement in quality consistency and cost reduction including effective product lifecycle management.

Conference Leaders

Jan Gustafsson, Novo Nordisk A/S, Denmark
Christian Wölbeling, Werum Software & Systems AG, Germany

Learning Objectives

- Gain insight into FDA and European regulatory views
- Learn about the standards used with PAT (e.g. ASTM E55)
- Learn about new technologies for monitoring the process
- Understand how the QA concepts will have to adapt
- Hear current case study feedback on the application of PAT
- Discuss with peer groups the benefits of PAT
- Learn how to manage the step change technology

Who Should Attend

- Executives involved in operational excellence
- Production managers and personnel
- Responsible R&D managers
- QA and QC executives
- Project and process engineers
- Regulatory affairs executives
- Qualified persons
- Facility design engineers
- Any professional involved in the area of PAT
- Equipment and systems suppliers

Agenda

Tuesday, 19 September

09.00 - 09.15 Welcome and Introduction
Jan Gustafsson, **Novo Nordisk A/S, Denmark**
Christian Wölbeling, **Werum Software & Systems AG, Germany**

09.15 - 10.00 Current FDA/EMEA Status and Industrial Application of PAT
Gabriele Reich, **University of Heidelberg, Germany**
- PAT – A key element of modern GMP
- The regulatory framework and its opportunities
- Challenges and drivers for industrial PAT application
- Industrial strategies to address the challenges

10.00 - 10.30 Coffee Break

10.30 - 11.15 Impact of PAT
Chris Watts, **FDA, USA**
- Background and history of PAT
- Regulatory expectations for PAT
- Impact of PAT for the pharmaceutical industry
- Future challenges and opportunities for PAT in science-based manufacturing

11.15 - 12.00 Current Experiences in the European Union Regulatory System
Christina Graffner, **Medical Products Agency, Sweden**
- Pharmaceutical development and design space
- Real-time quality assurance
- Understanding and its possible implications on post approval variations

12.00 - 12.30 Panel Discussion – Regulatory Implications in the Market
Chris Watts, **FDA, USA**
Christina Graffner, **Medical Products Agency, Sweden**

12.30 - 14.00 Lunch

14.00 - 14.45 PAT During the Development Phase – Does it Make Sense?

***Thomas Fürst,* Schering AG, Germany**

- Process understanding
- The PAT toolbox
  Feasibility studies in early development
  - What data should we collect?
  - How to calibrate and validate your methods/models?
- Feedback of information from production to development

14.45 - 15.30 PAT Project Experiences in API and Drug Product Manufacturing

***Lars Sukowski,* F. Hoffmann - La Roche, Switzerland**

- PAT implementation – The drivers and benefits
- Validation strategy
- Experiences in R&D
- Experiences in manufacturing

15.30 - 16.00 Coffee Break

16.00 - 16.45 Impact of PAT on the Automation of Production Processes and its System Validation

***Hartmut Hensel,* Hochschule Harz, Germany**

- PAT basic principles, PAT process structuring
- Impact of PAT on automation structures and automatic control systems
- Impact of PAT on computer system validation

16.45 - 17.00 The Global PAT COP Initiative

***Jan Gustafsson,* Novo Nordisk A/S, Denmark**

- The PAT COP in the ISPE Organisation
- Vision and mission of the PAT COP: Steering Committee
- Current and scheduled activities

17.00 - 17.30 The ISPE PAT SIG D/A/CH – Creating PAT Management Awareness

***Christian Wölbeling,* Werum Software & Systems AG, Germany**

- Results out of the PAT SIG COP D/A/CH
- Drivers and benefits for PAT projects
- Implications on the organisation
- Generation of PAT management awareness

17.30 - 17.45 Questions and Answers Session – Chairman's Day 1 Close

***Jan Gustafsson,* Novo Nordisk A/S, Denmark**

***Christian Wölbeling,* Werum Software & Systems AG, Germany**

17.45 - 19.00 Networking Reception

Wednesday, 20 September

09.00 - 09.15 Recap of Day 1 – Introduction of Day 2

***Jan Gustafsson,* Novo Nordisk A/S, Denmark**

***Christian Wölbeling,* Werum Software & Systems AG, Germany**

09.15 - 10.00 Utilisation of Data-based Process Understanding in the Manufacturing of a Medical Device

***Per Vase,* NNE A/S, Denmark**

- Need for critical to quality (CTQ) process control barriers identified from risk analysis (FMECA)
- Machines optimised by design of experiments (DoE) to improve yield
- On-line SPC on measurable parameters with shop floor screens for immediate control feedback to operators
- Six sigma quality obtained with low cost of poor quality (CoPQ)

10.00 - 10.30 Coffee Break

10.30 - 11.15 PAT in Wyeth – Accelerating Towards the Desired State

***Graham Cook,* Wyeth, UK**

- Examples of PAT projects in Wyeth
- PAT integration into the new Wyeth Pharmaceutical Development Centers
- Reflections on progress and remaining challenges

11.15 - 12.00 Application of PAT from the Chemical Reaction to the Tablet

***Hedinn Valporsson,* Novartis, USA**

- Utilisation of MVDA for PAT
- Identification of critical process parameters
- Controlling CPP's within the design space

12.00 - 12.15 Questions and Answers Session – Chairman's Conference Close

***Jan Gustafsson,* Novo Nordisk A/S, Denmark**

***Christian Wölbeling,* Werum Software & Systems AG, Germany**

12.15 - 13.45 Lunch

Lyophilisation – Technologies and Practice

19-20 September 2006

Conference Description

Developments in the field of lyophilisation and subsequent impact on production operations present professionals with a myriad of challenges. Process technology transfers and continual GMP impacts create additional focus in this area of technology. This conference will focus on formulation, cycle development, scale-up, PAT and new process control technologies, as well as qualification and regulatory issues to provide the delegate with new and improved tools to deal with the challenges of lyophilisation operations.

Conference Leaders

Miquel Galán, IMA – Telstar sl., Spain
Kyran Johnson, Centocor Biologics, Ireland

Learning Objectives

- Hear about new and developing technologies
- Understand the commissioning, qualification and validation challenges of new equipment designs
- Learn about the regulatory expectations
- Learn about the latest technology of process controls
- Understand product consistency control from the laboratory to full scale production
- Discover areas for potential process and operational optimisation

Who Should Attend

- All professionals working, operating/maintaining a facility, designing, commissioning and validating lyophilisation lines and fully-automated systems
- QA and QC professionals
- R&D and process development
- Project managers
- Facility design engineers

Agenda

Tuesday, 19 September

09.00 - 09.15 Welcome and Introduction
Kyran Johnson, **Centocor Biologics, Ireland**

09.15 - 10.15 Impact of Physical Properties of Bioproducts on Formulation and on Freeze-drying Cycle Development
Fernanda Fonseca**, UMR GMPA/I.N.R.A/INAP-G, France**
- Identifying stresses encountered during freezing, drying and storage. How to limit them?
- Determining the physical properties allowing the identification of critical events and temperatures, affecting product stability
- Analysing the relevance of these physical properties for predicting product structure and activity
- Trying to get general rules for formulation and cycle development
- Exploring the most widely used excipients

10.15 - 10.45 Coffee Break

10.45 - 11.45 Technology Transfer and Scale-Up: Process Equivalence and Product Assessment for Lyophilised Biopharmaceuticals
Dina Patel, **Global Biologics Supply Chain (J&J), Switzerland**
- Strategy for transferring process to the multiple lyophilisers
- Establishment of reproducibility within a lyophiliser and equivalency between multiple lyophilisers
- Scale-up of freeze-drying process: Watch out for instrument-to-instrument variability
- Process equivalence: Against what? How do you measure it?
- Product assessment: Sampling and testing strategy
- Opportunity to improve process: Minor vs. major changes and regulatory impact

11.45 - 12.45 Development and Scale-up of a Freeze-drying Cycle with a Cold Plasma System
Yves Mayeresse, **GlaxoSmithKline Biologicals, Belgium**
- Presentation of cold plasma system
- Comparison with other development method
- End of primary drying determination
- Scale-up of a product inside freeze-dryer of different size with cold plasma system

12.45 - 14.15 Lunch

14.15 - 15.15 Regulatory Requirements for Lyophilisation Processes and Lyophilised Products
***Stan O'Neill,* Irish Medicines Board, Ireland**
- Inspection practices
- Inspection experiences
- Potential areas of concern

15.15 - 15.45 Coffee Break

15.45 - 16.30 Lyophilisation, an Operational Perspective
***Barry Mulcahy,* Schering-Plough (Brinny) Co., Ireland**
- Use of product probes for development and alternate approaches for manufacturing
- Moisture mapping development of a 3D model
- Sticking stoppers and mitigation strategies
- Raised stoppers and approaches to address through capping in a grade A environment

16.30 - 17.15 Case Study: Product and Process Transfer from Vial to Syringe
***Jörg Zimmermann,* Vetter Pharma Fertigung GmbH & Co. KG, Germany**
- Major differences between vial and double chamber system syringe
- Considerations on residual moisture
- Development approach for transfer: Lab scale clinical/up-scaling commercial process
- Process comparability and process robustness test
- Development strategy and project management

17.15 - 17.30 Questions and Answers Session – Chairman's Day 1 Close
***Miquel Galán,* IMA – Telstar sl., Spain**
***Kyran Johnson,* Centocor Biologics, Ireland**

17.45 - 19.00 Networking Reception

Wednesday, 20 September

09.00 - 09.15 Recap of Day 1 – Introduction of Day 2
***Miquel Galán,* IMA – Telstar sl., Spain**

09.15 - 10.15 Advancement in Freeze Drying Manufacturing and Design
***Ernesto Renzi,* BOC Edwards, USA**
- PAT applied to freeze drying using laser spectroscopy
- New non flammable heat transfer fluids
- Latest refrigeration and freeze drying design improvements

10.15 - 10.45 Coffee Break

10.45 - 11.45 Some (timid) Approaches to PAT in Lyophilisation
***Miquel Galán,* IMA –Telstar sl., Spain**
- Some PAT review: A matter of process knowledge
- First approach: Detailed calculation process to predict product interface temperature according to shelf temperature and chamber pressure (maximising efficiency while maintaining product temperature below the collapse conditions)
- Second approach: On-line probe-less measurements of soft variables
- Third approach: Closing the loop. Controlling the cycle through scalable variables
- Immediate applications: Cycle development and robust production monitoring

11.45 - 12.30 Lyophilisation Technologies
***Franz Bosshammer,* Klee GmbH, Germany**
- Product loading and unloading systems
- Isolator technology interactions
- Product temperature measurement systems

12.30 - 12.45 Questions and Answers Session – Chairman's Conference Close
***Miquel Galán,* IMA – Telstar sl., Spain**
***Kyran Johnson,* Centocor Biologics, Ireland**

12.45 - 14.15 Lunch

Barrier Isolation Technology Forum

19-20 September 2006

Conference Description

This conference, presented by speakers from Europe, Japan and the US, will offer a global perspective on the latest developments in Barrier Isolation Technology including background information, technology updates, a series of new case studies, regulatory perspective and industry comments. It will also explore state-of-the-art advancements for use in developing and manufacturing pharmaceuticals utilising Barrier Isolation Technology. Any professional working in this continually developing arena will have an excellent opportunity to stay ahead of the curve on current developing technology.

Conference Leaders

Charlotte Enghave, NNE A/S, Denmark
Jack Lysfjord, Valicare, USA

Learning Objectives

- Gain insight into updated technologies applicable to advanced aseptic processing using Barrier Isolation Technology
- Learn about glove testing challenges in Barrier Isolation Systems
- Learn about Bio-decontamination of Barrier Isolation Systems
- Learn what not to do from those who have done it before
- Identify regulatory agency perspectives that will streamline your regulatory submission and approval process
- Learn from case studies
- Learn from benchmarking

Who Should Attend

- Engineers
- Quality assurance (QA), Quality control (QC)
- Production professionals, suppliers, designers
- Project managers
- Professionals engaged in building, commissioning, validating and operating modern pharmaceutical plants
- Engineering support
- Regulatory compliance
- Process control

Agenda

Tuesday, 19 September

09.00 - 09.10 Welcome and Introduction
***Charlotte Enghave,* NNE A/S, Denmark**

09.10 - 09.55 Technology Update 1 "2006 Barrier Isolator Survey"
***Jack Lysfjord,* Valicare, USA**
- A 2006 update on the global and regional trends in the use of barrier isolators for automated aseptic fill finish applications

09.55 - 10.30 Coffee Break

10.30 - 11.15 Technology Update 2 "Glove Testing for Aseptic Barrier Systems – Challenge and Innovation"
***Johannes Rauschnabel,* Robert Bosch GmbH, Germany**
- Overview of available testing principles
- Short comings of glove test procedures
- Innovative approach and results
- Practical aspects of glove management
- Application on different barrier systems

11.15 - 12.00 Technology Update 3 "Restricted Access Barrier Systems: A User's View"
***Jörg Zimmermann,* Vetter Pharma Fertigung GmbH & Co. KG, Germany**
- Regulatory expectations for aseptic operations
- Design aspects: Conventional clean room, RABS or isolator?
- Designing a barrier: From scratch. Retrofitting of existing lines
- Using RABS: A safe and flexible aseptic process
- Daily operations of a RABS line

12.00 - 13.30 Lunch

13.30 - 14.15 Technology Update 4 "New Developments in Vapour Phase Hydrogen Peroxide Decontamination"
***Jim Akers,* Akers Kennedy Associates, USA**
***Mamoru Kokubo*, Shibuya, Japan**
- Process description of VPHP decontamination processes for isolators and clean rooms
- Experimental results regarding VPHP cycle optimisation
- Decontamination case study results from studies done on both isolators of various size and clean rooms
- Discussion of the effect of environmental conditions on vapour phase hydrogen peroxide decontamination spore kill effectiveness
- Discussion of factors that lead to optimised cycle efficiency and reduced process time

14.15 - 15.00 Case Study 1 "Parametric Release of a VPHP Cycle Based on Robust Validation Data"

***Christian Doriath,* Lilly, France**

- Definition of the critical parameters for each different phase of a production VPHP cycle
- How to measure these parameters
- Calculation of the acceptations limits for each critical parameter

15.00 - 15.30 Coffee Break

15.30 - 16.15 Case Study 2 "Closed Vial Technology-Validation Results with the Closed Vial

***Benoit Verjans,* Aseptic Processing Technologies, Belgium**

- Description of the developed closed vial technology
- Improving the quality of aseptic filling compare to glass vial
- Major points addressed during the validation
- Preliminary media fill results

16.15 - 17.00 Case Study 3 "Isolator System and Fast Decontamination Process for Pharmaceutical Compounding Sterile Preparations"

***Norbert Lederle,* Skan, Switzerland**

***Volker Sigwarth,* Skan, Switzerland**

- Overview of realised isolator project for pharmacies and hospitals
- Current requirements of isolator systems for pharmaceutical compounding
- Current requirements of a fast decontamination process
- Design and performance criteria of new isolator system pharmaceutical compounding
- Design and performance criteria of new fast decontamination process

17.00 - 17.30 Questions and Answers Session – Chairman's Day 1 Close

***Charlotte Enghave,* NNE A/S, Denmark**

17.45 - 19.00 Networking Reception

Wednesday, 20 September

09.00 - 09.05 Recap of Day 1 – Introduction of Day 2

***Jack Lysfjord,* Valicare, USA**

09.05 - 09.50 Case Study 4 "Case Study for Design, Construction and Validation of a State-of-the-Art Aseptic Processing Facility"

***James Vogel,* Hospira, USA**

- Optimisation of the design/construct process
- Strategic manufacturing equipment selection
- Validation methodology to support a fast-track project

09.50 - 10.35 Case Study 5 "Processing Large Volume Plasma Products Using Isolator Technology"

***Martin Kern,* Octapharma, Austria**

- Line layout, design principles and process flow
- Bulkfiltration and storage vessel lines
- Bottle preparation and siliconization
- Stopper preparation and transfer system
- Dosing unit
- Crimp-cap marking and OCR-control system

10.35 - 11.05 Coffee Break

11.05 - 11.50 Case Study 6 "Issues with the Use of Isolators for the Handling of Pathogenic Organisms to Pharmaceutical Standards"

***Neil A. Grumbridge,* Health Protection Agency, UK**

- Changing from formaldehyde to VPHP
- Potential issues with the use of negative pressure isolators
- Validation of a decontamination procedure for a multi-use facility

11.50 - 12.20 "Applying API GMP Rules to Developing Seed Banks for New Vaccines"

***Neil A. Grumbridge,* Health Protection Agency, UK**

- Controlling (cross) contamination
- Protecting operators
- Managing risks
- Coping with safety issues

12.20 - 12.30 Questions and Answers Session – Chairman's Conference Close

***Jack Lysfjord,* Valicare, USA**

12.30 - 14.00 Lunch

Developing Investigational Medicinal Product (IMP) Supply Strategies a

21-22 September 2006

Conference Description

This conference is designed for those working with investigational medicinal products (IMPs) and clinical trials who want to further their understanding of outsourcing, new markets and new products and want to develop better ways of working to meet future challenges in these areas. The conference provides an ideal opportunity for delegates to learn and share 'best practice' ideas. Using case studies and real examples, the focus will be on sharing experiences from a wide range of companies in the manufacturing and packaging of investigational medicinal product. Participants will benefit from lessons learned regarding outsourcing from inside and outside our industry.

Conference Leaders

Christine Milligan, Aptuit Consulting, UK
Robert Smith, Genzyme, UK

Learning Objectives

- Apply the knowledge gained from workshops, networking and development of best practice solutions to real problems
- Develop state-of-the-art knowledge and understanding
- Put into practice documented, tangible outputs from the event

Who Should Attend

- IMP professionals
- Group leaders with in-depth experience in the field
- Personnel with two to three years experience looking to increase their knowledge and network

Agenda

Thursday, 21 September

09.00 - 09.15 Welcome and Introduction
***Bernd Steffens,* Boehringer Ingelheim Pharma GmbH & Co. KG, Germany**

09.15 - 10.15 Future of Clinical Development
***Sean Smith,* VP Fisher, UK**

10.15 - 10.45 Coffee Break

10.45 - 11.45 Developing Value Outsourcing Relationships
***Richard Scaife,* Daiichi-Sankyo, UK**

- How have Pharma/CRO relationships functioned historically?
- What is the real value in a client/vendor relationship?
- Is it developed or does it 'just happen'?
- Is there a value link between clinical and clinical supplies?
- What needs to happen to make it work?
- What can make it last long term?

11.45 - 12.45 The Clinical Trial Landscape in India – Perspectives on Management of Clinical Trial Supplies
***Narges Mahaluxmivala,* Quintiles, India**

The presentation describes the differing dynamics of the types of clinical trials conducted in India and their differing impact upon clinical trials supplies management.

- Contemporary India – Socioeconomic changes impacting on clinical trials
- Types of clinical trials outsourced to India – Differing dynamics
- Ethical Specifics – Relatedness to country's needs/placebo usage/therapy provision after study
- Regulatory/import /customs imperatives
- Key messages

12.45 - 14.00 Lunch

14.00 - 14.15 Introduction to Workshops
***Christine Milligan,* Aptuit Consulting, UK**
***Robert Smith,* Genzyme, UK**

Four different workshops will take place at 14.15, and the same workshops will be repeated at 16.00. This will allow you to attend two different workshops during the afternoon. Please find the descriptions of the four workshops below.

Workshop 1. Modern Planning Tools and Techniques for Clinical Trial Supplies
***Sven Grassmann,* Schering AG, Berlin/New Jersey**

How do modern tools perform in actual studies. Case study lead discussion.

- Benefits and limits of study simulation approaches
- Validation of simulation with actual data
- Web-based real-time inventory systems
- Pre- vs. mid-study simulation

Workshop 2. Forecasting and Simulation: Towards Pro Active Steering of the Clinical Supply Chain

Hans Heesakkers, **Aptuit Informatics, USA/The Netherlands**

Throughput times in the clinical supply chain are under pressure and will be decreased further in the upcoming years. This means that the number of "risk-based decisions" will be increased. For that reason the quality of information must become better then "an educated guess".

- Awareness of what forecasting and simulation brings and what not
- The bath tub model
- Performance indicators
- Triggers for discussion
- Are there other ways to reach the same goals?
- How well is my company equipped with knowledge and means to use F&S?
- How does this benchmark against other companies?

Workshop 3. IT/Tech Solutions for GMP/GCP-interface at Clinical Sites

Chris Bland, **Pfizer, UK**

- GMP and GCP: Where are the boundaries?
- An interactive session reviewing case studies to look at a range of issues such as storage, distribution, relabelling, recalls, inspections, etc.

Workshop 4. Building a Global Organisation and Making it Work

Joan Gore, **Eli Lilly, USA**

- Discuss what it means to be global
- Explore the benefits of globalisation
- Identify barriers to globalisation and discuss how to overcome them
- List techniques that can be used to maximise globalisation benefits

14.15 - 15.30 Workshops 1-4

15.30 - 16.00 Coffee Break

16.00 - 17.15 Workshops 1-4

17.15 - 17.30 Questions and Answers Session – Chairman's Day 1 Close

17.45 - 19.00 Networking Reception

19.30 IMP COP Networking Dinner

IMP conference delegates will be invited to the IMP Community of Practice Dinner sponsored by ADAllen Pharma Ltd., Almac Sciences, Aptuit, Cardinal Health, Fisher, GP Solutions (UK) Ltd. and Nerviano Medical Sciences.

Friday, 22 September

08.30 - 09.30 The Regulatory Challenges of Running a Drug/Device Clinical Trial

Duncan MacKay, **Genzyme, UK**

Occasionally manufacturers need to compare surgical and pharmaceutical interventions directly or incorporate concomitant therapy into design of clinical trials. How do you work your way through this?

- What set of regulations must you follow?
- One approval or two?
- How has the introduction of the CT directive affected drug/device trials?
- What guidance is there from the regulators?
- What are the major obstacles to overcome?

09.30 - 10.30 The Changing Face of Labelling

Graham Howieson, **GP Solutions Ltd., UK**

- Multipurpose, multilingual labels
- Advances in material
- New technologies
- Look into the future

10.30 - 11.00 Coffee Break

11.00 - 12.00 Strategies and Practicalities for Comparator Drug Sourcing

Konrad Betzler, **Cardinal, Germany**

- Study design vs. comparator characteristics – Who controls whom?
- Facing regional variations of comparators in global trials
- Controlling the quality of comparators
- Manufacturer, wholesaler, pharmacies or Internet – The intricate paths of the supply chain

12.00 - 13.00 Retest Date Handling for IMPs

Wolfgang Volk, **Merck KGaA, Germany**

- Regulatory requirements: What is the difference between shelf-life, expiry, date and retest date
- Consequences for labelling of IMP's
- Possibility/need to extend labelled retest-dates
- Regulatory/GMP/practical considerations for necessary retest date updates
- Possible handling with external service providers

13.00 - 13.15 Questions and Answers Session – Chairman's Conference Close

Christine Milligan, **Aptuit Consulting, UK**

Robert Smith, **Genzyme, UK**

13.15 - 14.15 Lunch

Quality Risk Management – Guidance and Case Studies

21-22 September 2006

Conference Description

This conference will go beyond the theories contained within the recently approved ICH Q9 document, "Quality Risk Management" to a discussion of implementation strategies. Potential applications for Quality Risk Management will be presented using the framework contained within the related Annex II of the document and following a quality systems approach. Actual case studies will be presented and examples discussed of how others have successfully used Quality Risk Management in the industry and by regulators.

Conference Leaders

Zena Kaufman, Abbott, USA
Stephan Roenninger, F. Hoffmann-La Roche Ltd., Switzerland

Learning Objectives

- Get familiar with aspects of Quality Risk Management throughout the product lifecycle from Europe, US and Japan; from development, through commercialisation and within contract manufacturing environments
- Hear from key regulators and key industry personnel involved with development of ICH guidelines
- Understand the approach to implementing Quality Risk Management solutions from personnel directly involved in the process

Who Should Attend

- Production personnel
- Technical registration personnel
- Regulatory affairs executives
- Quality units (compliance, management, assurance and control)
- Product development
- Technical services disciplines

Agenda

Thursday, 21 September

09.00 - 09.15 Welcome and Introduction
***Zena Kaufman,* Abbott, USA**
***Stephan Roenninger,* F. Hoffmann-La Roche Ltd., Switzerland**

09.15 - 10.00 Quality Risk Management: Why now?
***Peter Gough,* D. Begg Associates, UK**
- The state of pharmaceutical manufacturing circa 2000
- US PAT and 21st century GMP initiatives
- ICH GMP workshops in 2003
- The reasons for Q9
- Content of step 4 version of Q9

10.00 - 10.45 Quality Risk Management: An Industry Perspective
***Takayoshi Matsurmura,* Eisai Co. Ltd., Japan**
- Quality of the drug (medicinal) products in Japan
- Status of ICH Q9 in the revised Japanese pharmaceutical affairs law
- GMP inspection by the Japanese authority (MHLW)
- Risks communication to export products to Japan

10.45 - 11.15 Coffee Break

11.15 - 11.45 ICH Q9: Annex II.1 Quality Management Quality Risk Management as Part of Integrated Quality Management
***Ulrich Becht,* Abbott, Germany**
- Risk-based approaches in quality management
- Integration in existing quality systems
- Impact on quality, cost and time
- Potential applications of risk management
- QP discretion

11.45 - 12.15 ICH Q9: Annex II.7 Laboratory Systems: Quality Risk Management
***Lucinda Buhse,* FDA, USA**
- Role of analytical science in risk management
- Test method variability
- Dissolution as a case study

12.15 - 12.30 Panel Discussion. Questions and Answers
***Zena Kaufman,* Abbott, USA**

12.30 - 14.00 Lunch

14.00 - 14.30 ICH Q9: Annex II.3 Development / Annex II.6 Production Using RM in a Submission for Developing Critical Processing Parameters and Critical to Quality Attributes
***Vincent McCurdy,* Pfizer, USA**
- Risk management tools used to identify CPPs and CQAs
- Building a design space for a submission and manufacturing
- Considerations in deciding what is critical
- Relating design space to a CTD

14.30 - 15.00 Annex II.3 Development Using RM for Process Understanding in a Submission for Developing a Control Strategy

***Fritz Erni,* Novartis, Switzerland**

- New opportunities of ICH Q8
- The impact of the design space concept to quality risk management
- Risk management for selecting design of experiments
- Control strategy-based on process understanding an quality risk management
- Regulatory flexibility: What industry can win

15.00 - 15.15 Panel Discussion. Questions and Answers

***Zena Kaufman,* Abbott, USA**

15.15 - 15.45 Coffee Break

15.45 - 16.15 ICH Q9: Annex II.8 Packaging. A FMEA Approach in Pharmaceutical Packaging

***Jayesh Patel,* F. Hoffmann-La Roche Ltd., USA**

- What is an FMEA
- Types of FMEA
- Benefits of FMEA
- When to use FMEA
- FMEA process
- Elements of an effective FMEA process
- Packaging process FMEA - Case study

16.15 - 16.45 ICH Q9: Annex II.5 Materials Management: Contract Manufacturing and RM

***Annemie Van Schoor,* Pfizer, Belgium**

Why do pharmaceutical companies need a risk-based model for quality management of contracted operations?
A global risk management model for contracted operations and case examples:

- Risk assessment approach: Scope, analysis, identification and evaluation
- Risk ranking
- Risk control: Reduction and acceptance. Periodic review

16.45 - 17.15 Panel Discussion. Questions and Answers

***Stephan Roenninger,* F. Hoffmann-La Roche Ltd., Switzerland**

17.45 - 19.00 Networking Reception

Friday, 22 September

09.00 - 09.15 Recap of Day 1 – Introduction of Day 2

***Zena Kaufman,* Abbott, USA**

09.15 - 09.45 Annex II.2 Regulatory Operations Implementations of Q9 Thinking in the European Regulatory System

***Riccardo Luigetti,* EMEA, UK**

- Implementation of the ICH Q9 document quality risk management in the European regulatory system
- Impact of Q9 on the European good manufacturing practice
- Impact of Q9 on the European GMP inspection system
- Impact of Q9 on the assessment of the quality of medicinal products

09.45 - 10.15 ICH Q9: Annex II.1 Quality Management: Risk Management Practices from an Excipient Supplier Perspective

***Patricia Rafidison,* Dow Corning, France**

- Excipients challenges in the current regulatory environment
- Business risk management practices associated with excipients and their use in pharmaceuticals
- Understanding and interpreting potential risks
- Designing and implementing effective risk management strategy
- Leveraging value from risk practices

10.15 - 10.30 Panel Discussion. Questions and Answers

***Zena Kaufman,* Abbott, USA**

10.30 - 11.00 Coffee Break

11.00 - 11.30 ICH Q9: Annex II. 4 Facilities. Assessing Facilities Needs for the Manufacture of Certain Medicinal Products Using a Risk-Based Approach

***Nigel Hamilton,* Sanofi-Aventis, France**

- This presentation is based upon EFPIA working team resource document
- Example of a risk-based approach for assessing the levels of controls required by assessing the potential consequences of cross contamination
- Typical risk assessment considerations
- The potential severity to the patient in the event of cross contamination
- Assessing both the product and process risks
- Example of product and process risk control measures

11.30 - 12.00 ICH Q9: Annex II.5 Materials Management: QRM in the Selection of Anti-Counterfeiting Measures (e.g. RFID, 2D bare-code)

***Heike Bockholt,* Boehringer Ingelheim GmbH, Germany**

- Counterfeited pharmaceuticals – a growing risk
- Elements in the combat against counterfeiting: Supply chain control and product protection
- Tracking and tracing of pharmaceuticals: RFID-technology vs. 2D-barcode
- Positions of European- and US-health authorities and pharmaceutical associations

12.00 - 12.15 Panel Discussion. Questions and Answers

***Stephan Roenninger,* F. Hoffmann-La Roche Ltd., Switzerland**

12.15 - 12.30 Questions and Answers Session – Chairman's Conference Close

***Zena Kaufman,* Abbott, USA**

***Stephan Roenninger,* F. Hoffmann-La Roche Ltd., Switzerland**

12.30 - 14.00 Lunch

Continuous Processing in the Real World

21-22 September 2006

Conference Description

This conference will explore how to succeed in introducing continuous processing. Continuous processing can give improvements in quality control and yield; it reduces waste and decreases inventory demands; it positively affects supply chain issues and decreases the variability of the product. This conference will identify the issues and provide real solutions to the challenges associated with implementing this concept in both primary and secondary processes. This conference will focus on the difficult technologies associated with powder handling and provide a scientific understanding of the technology involved.

Conference Leaders

Charles Gillham, GlaxoSmithKline, UK
John Nichols, Foster Wheeler Energy Ltd., UK

Learning Objectives

- Understand factors involved in the implementation of a continuous process and identify the management challenges in handling this step
- Change and how it may be overcome: How to change an organisation's culture and promote innovation
- Learn about the impact on QA/QC and regulatory compliance
- Hear case studies from the pharmaceutical industry and others on this approach
- Learn about the potential impact on plant reliability and engineering operations
- Understand equipment design considerations and unit operations
- Understand the relationship with measurement and control
- Hear case studies showing improved yield and decreased costs

Who Should Attend

- Process engineers
- QA/QC personnel
- Regulatory personnel
- Production personnel
- Equipment manufacturers
- Facility design engineers

Agenda

Thursday, 21 September

09.00 - 09.15 Welcome and Introduction
John Nichols, **Foster Wheeler Energy Ltd., UK**

09.15 - 10.45 FDA and Continuous Processing
Chris Watts, **FDA, USA**
- Hear how continuous processing fits with the FDA's active programmes
- Hear how PAT links to continuous processing
- Discuss the regulatory implications of continuous processing

Interactive Workshop on the Regulatory Issues in Utilising Continuous Processing
Lynn Bryan, **ISPE, UK**
Understand the potential regulatory problems and benefits and potential solutions

10.45 - 11.15 Coffee Break

11.15 - 12.00 Primary Case Study 1 – A Case Study Describing the 10-fold Scale-up of an API Manufacturing Process from Batch to Continuous
Peter Thomas, **Genzyme, UK**
- Hear the new and continuing developments at Genzyme
- Highlighting the benefits in plant size, utility and raw material economies
- Reduced environmental impact of the continuous plant over the batch alternative
- Noting the quality implications of continuous manufacturing and how they were overcome

12.00 - 12.45 Primary Case Study 2 – Continuous Processing
Lee Proctor, **Phoenix Chemicals, UK**
- The benefits of continuous processing
- Route selection: Traditional batch vs. continuous manufacture
- The key requirements for developing a continuous process. The mindset required, the challenge of promoting innovative technology within an organisation and demonstrating effective robust scale-up
- Using continuous processing to improve all aspects of a process (holistic design). For example reaction, washing, extraction, distillation and drying

The presentation will introduce these concepts along with four to five case studies from Phoenix describing different continuous technologies that are used to manufacture multi-ton quantities of high value pharmaceutical intermediates.

12.45 - 14.15 Lunch

14.15 - 15.00 The Use of Continuous Feeder Technology in an Innovative Industry

***Ali Naqavi,* Nexpress Kodak, UK**

- Manufacturing overview of toner powder for printers
- Continuous feeder processing
- Batch vs. continuous processing
- Design considerations

15.00 - 15.30 Coffee Break

15.30 - 17.00 Changing Culture

***Eddie Obeng,* Pentacle, UK**

- Recognise why changing technology is often more straightforward than taking hearts, minds and hands with you – and why focus on the "human side" of change is essential to long-term success
- Learn how to make people curious about and engaged with, rather than resistant to change
- Find out how to grow a culture that supports and encourages novelty and innovation
- Discover how to remove the barriers to effective innovation

17.00 - 17.15 Questions and Answers Session – Chairman's Day 1 Close

***John Nichols,* Foster Wheeler Energy Ltd., UK**

17.45 - 19.00 Networking Reception

Friday, 22 September

08.45 - 09.00 Recap of Day 1 – Introduction of Day 2

***Charles Gillham,* GlaxoSmithKline, UK**

09.00 - 09.45 Process Understanding: Designing Continuous Powder Processes

***Jonathan Seville,* School of Chemical Engineering – University of Birmingham, UK**

- What can the pharmaceutical industry learn from other industries?
- How might continuous processes be designed rather than evolved?
- As pharmaceutical goes continuous, what will the processes of choice be?

09.45 - 10.30 Continuous Processing of Pellets Having High API Content

***Jochen Dressler,* Glatt, Germany**

- Learn about "state-of-the-art" continuous processing driving the industry forward with innovation and with cross-industry fertilisation
- Benefit of high drug loaded pellets
- Processing technology
- Controlling continuous processes with respect to PAT

10.30 - 11.00 Coffee Break

11.00 - 11.45 Secondary Case Study 1: Opportunities and Challenges in Continuous Processing

***Christoph Wabel,* Pfizer, Germany**

- Benefits/Risks to the industry
- Practical view to implementation of continuous processes
- Case study examples

11.45 - 12.30 Secondary Case Study 2: Development, Operation and Implementation of a Micro Continuous Granulator/Dryer

***Mike Cliff,* AstraZeneca, UK**

***Charles Gillham,* GlaxoSmithKline, UK**

- Discuss the business drivers for seeking alternate granulation technologies
- Discuss the user requirements and expectations during development of a prototype continuous granulator/dryer
- Share data produced during operation of the prototype
- Highlight some of the issues and benefits around implementing a continuous process into pharmaceutical operation
- Review future implementation strategy

12.30 - 13.00 Questions and Answers – Chairman's Conference Close

***Charles Gillham,* GlaxoSmithKline, UK**

13.00 - 14.00 Lunch

GAMP® Part 11: Update on 21 CFR Part 11 with a Focus on Manufacturin

22 September 2006

Conference Description

This conference will provide an update on the FDA re-examination of 21 CFR Part 11 regulation Electronic Records and Electronic Signatures. A revised proposed Part 11 Rule is expected to be published for comment in 2006. The conference will discuss the impact of changes to regulation and current FDA thinking. Also covered will be other international regulations and expectations in this area, such as EU EMEA and Japanese MHLW regulations and PIC/S guidance.

Presentations will also include an update on relevant GAMP Good Practice Guidance on Manufacturing Execution Systems (MES), with particular reference to the role of Electronic Batch Recording Systems (EBRS) in modern-day manufacturing, as well as case studies showing how risk-based approaches are being applied to electronic recordkeeping systems.

Conference Leaders

Paige Kane, Wyeth BioPharma, USA
Siôn Wyn, Conformity Ltd., UK

Learning Objectives

- Understand current FDA thinking on Part 11: Electronic records and signatures
- Discuss the impact of proposed changes to Part 11
- Learn about other relevant international regulations that apply
- Understand how GAMP guidance can help meet these regulatory requirements
- Hear case studies on how risk-based approaches are being applied to electronic record and signature systems
- Learn how MES and EBRS systems are being used to handle electronic records and signatures in today's manufacturing environment

Who Should Attend

- Computer systems validation personnel
- Compliance requirements executives
- EBRS and MES project managers
- Engineering, QA and computer validation professionals responsible for performing, defining or managing validation and compliance practices
- IT personnel supporting these systems
- System owners
- System users

Agenda

Friday, 22 September

09.00 - 09.15 Welcome and Introduction
***Paige Kane,* Wyeth BioPharma, USA**
***Siôn Wyn,* Conformity Ltd., UK**

09.15 - 10.00 Risk-Based Approaches – An Industry Perspective
***Guy Wingate,* GlaxoSmithKline, UK**
- General principles for risk management of computerised systems
- Practicalities of risk-based approach
- Role of interim controls
- Implications for electronic record and signature regulatory developments
- How the GAMP guidance can help

10.00 - 10.30 Coffee Break

10.30 - 11.15 Electronic Records and Computer Systems Compliance – EU Regulator's Perspective
***Anthony Trill,* MHRA, UK**
- European regulators perspective on ER&ES
- PIC/S guidance
- Other international initiatives including PAT

ng Execution Systems (MES)

11.15 - 12.00 FDA Re-examination of 21 CFR Part 11
***Siôn Wyn,* Conformity Ltd., UK**
- FDA's flexible risk-based approach
- The status of the re-examination
- The new part 11 proposed rule
- Practical approaches to compliance

12.00 - 12.30 Interactive Workshop Session: Record Risk Management
***Paige Kane,* Wyeth BioPharma, USA**
***Siôn Wyn,* Conformity Ltd., UK**
- Identifying GxP records
- Initial risk assessment
- Identifying risk priority
- Choosing suitable record controls to manage risk

12.30 - 14.00 Lunch

14.00 - 14.45 New GAMP Good Practice Guidance on Manufacturing Execution Systems
***Paul Irving,* Lees Gilbert International Ltd., UK**
- MES programme considerations
- Validation and implementation
- System management
- Electronic records and signatures
- Examples of appendices
- Conclusions and benefits

14.45 - 15.30 Practical Case Study: Implementation of a Complete MES/EBRS in the GLP/GMP Area
***Werner Bothe,* Schering AG, Germany**
- Overview of a MES for a pharmaceutical development function
- Electronic batch recording in the drug product development
- Special requirements for a MES and customisation needs
- PAT integration

15.30 - 16.00 Coffee Break

16.00 - 16.45 Practical Case Study: Key Areas for the Implementation of Production System
***Lydia Dolezel,* Eli Lilly, Austria**
- Interfaces to other software (e.g. Warehouse, Ordering, Lab Systems)
- Is there a "design space" for PAT?
- What can or should be adapted – The process or the software?
- Record Retention – What do I do with data from the old system?
- GAMP Themes: User requirements; the importance of process data flow; risk assessment
- FDA citations and how to avoid them

16.45 - 17.15 Practical Case Study: MES, ERP and Automation Systems: Functionality and Objectives
***Yves Samson,* Kereon AG, Switzerland**
- Design study based on project experience
- Functionality inventory
- Configuration evaluation
- Validation consideration
- Electronic record compliance

17.15 - 17.30 Questions and Answers Session – Chairman's Conference Close
***Paige Kane,* Wyeth BioPharma, USA**
***Siôn Wyn,* Conformity Ltd., UK**

General Information

Venue

InterContinental Vienna
Johannesgasse 28
A -1037 Vienna, Austria
Tel: +43 1 711 22 0
Fax: +43 1 713 44 89
www.vienna.intercontinental.com

Description

The InterContinental Vienna is located right beside the famous Stadtpark and just a few minutes walk from the Ringstraße, State Opera House and Stephansplatz. The hotel features 453 guest rooms and suites, all thoughtfully appointed for a comfortable and relaxing stay. The InterContinental Vienna hotel offers its guests a restaurant serving innovative Mediterranean and Viennese cuisine, a Viennese café and the Intermezzo Bar. 24-hour room service provides the option of dining in the comfort and privacy of the guest room. Hotel facilities include a modern fitness centre, 24-hour business centre, hairdresser, limousine service, garage and a souvenir shop.

Accommodation

A block of rooms has been reserved at the venue for the ISPE delegates at the preferential rate of € 195 for a single room and € 205 for a double room (includes service and taxes; excludes breakfast, which is available for an extra cost). This offer is limited and we encourage you to register as early as possible.

To book your accommodation at the InterContinental Vienna, please send your accommodation reservation request together with your conference registration to ISPE Registration Services (Fax: +32 2 743 1584). Reservations cannot be processed and guaranteed without a credit card number. Accommodation and any extras are to be settled by each delegate directly with the hotel upon check-out. Changes in bookings or cancellations are accepted only in writing, and are sent directly to ISPE Registration Services prior to the event and no later than 8 September. The hotel is entitled to charge the entire value of the room reservation in case of cancellations received later than 48 hours before arrival. Other hotel options are available at your own arrangements.

Access

The Hotel is situated 20 km away from the Vienna International Airport. The estimated taxi fare (one way) from the airport to the hotel is approximately € 30 (20 minutes). The airport also provides a direct train connection, called CAT – City Airport Train, to the city centre (16 minutes) for € 3. It is also possible to use the City Air Terminal bus which takes 20 minutes to the city centre and costs € 5. The station is a ten-minute walk from the hotel. The closest Metro station is Stadtpark.

Badges

Name badge must be worn at all times. Delegates not wearing their badges will be denied entrance to conferences.

Recommended Dress

Business Casual.

Site Visits

Enjoy Wednesday afternoon away from the classroom and participate in site visits to the plants of some key leaders in our industry. The Congress programme offers you the opportunity to visit one of three pharmaceutical plants and one food processing site:

Boehringer Ingelheim Austria is the centre of oncology research and development and one of the two main locations for biopharmaceutical development and production of the international Boehringer Ingelheim Group. The company is involved in marketing and sales in Austria (human pharmaceuticals and animal health). Based in Vienna the Boehringer Ingelheim Regional Centre is responsible for the Austrian market as well as 28 countries in Central and Eastern Europe.

Intervet, a Netherlands-based company, is a leading company in veterinary pharmaceuticals. As part of Akzo Nobel, Intervet runs 19 production units worldwide. The Vienna branch combines a manufacturing and packaging facility with a local marketing and sales department. Intervet Vienna as a manufacturing site is a strategic plant in the fields of hormone and non hormone solid dosage forms (implantable tablets, coated and non-coated tablets and granulates) with a very high export rate.

Octapharma, a Swiss-based company, is an independent, global plasma fractionation specialist. Its core business is the development, production and sale of high quality plasma derivatives. Octapharma Austria is one of the four production facilities producing Octaplas, Octagam, Human Albumin, Octanate, Octanine, Atenativ and Octaplex.

Schlumberger is Austria´s oldest Sparkling Wine producer – founded in 1842 by Robert A. Schlumberger. Schlumberger is market leader in the premium sparkling wine segment in Austria, using the “Méthode Traditionnelle”. Today, the company exports to more than 20 countries worldwide and is one of Europe’s leading sparkling wine houses.

Delegates can choose one of the four possible visits. Please indicate your choice on the enclosed Registration Form.

Note that **the number of participants is limited for each visit** and therefore entrance will be allocated on a first come, first serve basis. The fee for one site visit is € 25 per person. ISPE will provide bus transportation from the Congress venue to the different plants and back. Departure time will be at 14.00, after lunch, with return at the end of the afternoon, around 18.00. Ask the registration desk for more information.

Sponsorship Opportunities

ISPE offers high-visibility, low-cost exclusive sponsorship opportunities for suppliers to the global healthcare manufacturing industry. ISPE sponsorship packages include the following benefits.

- A literature display table near the ISPE Registration/Welcome area
- Company name printed on event materials (agendas) distributed to delegates
- Company logo on event page of ISPE website, up to three months prior to event
- Company logo displayed on signs at food/beverage functions

To book your sponsorship, please contact:
Françoise Rajewski
European Sales Manager
Tel: + 32 2 743 1581 / Fax: + 32 2 743 1578
E-mail: francoise@associationhq.com

Table Top Exhibits

ISPE offers companies the opportunity to present their products face-to-face with potential customers in an informal atmosphere in conjunction with the ISPE Vienna Congress. Morning and afternoon refreshments are served in the exhibition area to attract the maximum number of conference participants to see your display.

ISPE offers three different opportunities:

- 19-20 September (2 days)
- 21-22 September (2 days)
- 19-22 September (4 days)

ISPE Europe's Table Top Exhibits typically sell out fast. To date, there are limited spaces available.
To book your Table Top, please contact:
Isabella Vanpeteghem
European Events Logistics Coordinator
Tel: + 32 2 743 4422 / Fax: + 32 2 743 1584
E-mail: isabella@associationhq.com

ISPE Registration Desk Hours

ISPE Registration desk will be open at the following times:

Sunday, 17 September	17.00 - 19.00
Monday, 18 September	08.00 - 18.00
Tuesday, 19 September	08.00 - 17.00
Wednesday, 20 September	08.00 - 19.00
Thursday, 21 September	08.00 - 17.00
Friday, 22 September	08.00 - 10.00

Global On-line Career Centre for the Pharmaceutical Industry

Looking for an exciting new job? Interested in reaching the most qualified candidates? Make your search fast, easy, targeted and successful. The ISPE Global On-line Career Centre, at www.ispe.org, is available to better serve the needs of both employers and job seekers around the world.

Searching for an Employee?

ISPE's Global On-line Career Centre gives employers access to an extensive on-line database of curriculum vitaes (CVs), entry to a targeted group of pharmaceutical manufacturing professionals and the ability to conduct searches by country as well as worldwide. Finding your next employee is just a mouse-click away.

Looking for a Job?

Get your job search started by using ISPE's complimentary Global On-line Career Centre. Apply directly to a prospective employer and, if you are an ISPE Member, post your CV at no charge.

For more information on the ISPE Global On-line Career Centre, contact Kristien Bossuyt by e-mail: kristien@associationhq.com, tel: + 32 2 743 4422, or visit www.ispe.org.

List of Exhibitors

Aptuit
ATMI Packaging
BD Medical – Pharmaceutical Systems
Biopharma Technology Ltd
Commissioning Agents, Inc.
CPS Pharma
Crane Process Flow
Technologies
Egemin
Fisher Clinical Services
Foster Wheeler
GEA Niro-Pharma Systems
Honeywell GmbH
IDC
Ima Telstar
Matcon Group Limited
Nerviano Medical Sciences
Pertinence
Pharmadule
Propack Data GmbH
Stedim
Yokogawa Europe

Sponsors

Siemens
Commissioning Agents, Inc.

Networking Opportunities

Opening Reception

Monday, 18 September (18.30 - 20.00)

This Cocktail Reception hosted by the Germany/ Austria/Switzerland Affiliate will take place in the Vienna Konzerthaus, one of the largest and most artistically progressive institutions in international music life. During the season from September to June, some 750 wide-ranging events take place and more than 600.000 visitors can listen to around 2.500 different compositions. The Vienna Konzerthaus – together with the Vienna State Opera House and the Musikverein – is central to Vienna's reputation as one of the world's leading music capitals. Additionally, 2006 is a very special year for Vienna celebrating the 250th anniversary of its musical genius Wolfgang Amadeus Mozart.

When the Vienna Konzerthaus was officially opened in 1913, it was one of the most modern buildings in the Danube Monarchy. It set new standards for its architecture, visitor-friendly atmosphere, construction technology and modern facilities. Architecturally the Konzerthaus presented a rare combination of Historism, Secessionism and Art Nouveau styles. The Vienna Konzerthaus represents a living, evolving tradition, coloured by the spirits of its artists and the enthusiasm of its audiences.
The Vienna Konzerthaus is walking distance from the hotel.

Join this networking opportunity to meet your peers in an informal setting and enjoy the delights of Viennese cuisine and music.

Networking Receptions

(Tuesday, 19 September and Thursday, 21 September)

ISPE receptions are an excellent opportunity to meet with exhibitors, experts and peers to learn about their newest technologies in a fun and casual environment. Enjoy an informal chat and some drinks and snacks with your colleagues, at the InterContinental Hotel.

Lunches and Coffee Breaks

Enjoy a complimentary lunch to gear up for the afternoon's activities. A hot cup of coffee or tea in the exhibition area will offer you a well-deserved break in a busy day.

Mark your Calendar!

ISPE Brussels Conference

4-7 December 2006

Sheraton Hotel and Towers

Brussels, Belgium

For more information contact europeregistrations@ispe.org or visit www.ispe.org/GlobalCalendar

Note: A photographer will be present at the Congress on Monday, 18 September and Tuesday, 19 September. If you do not wish to have your picture taken and used in future ISPE promotional materials, please inform the photographer directly.

Registration and Cancellation Policies

Registration Fees

Congress registration fees include:

- Congress material
- Refreshment breaks
- Lunches
- Networking Reception
- Exhibit hall access

If you have registered as a nonmember, you are entitled to a complimentary one-year membership in ISPE. To receive an ISPE membership application form, please tick the box on the registration form. Your membership application must be returned to ISPE within 30 days in order to activate your membership. ISPE membership is individual and must be paid in full to qualify for the Member fee. If you have questions regarding your membership status, please contact ISPE by tel: + 32 2 743 4422 or fax: + 32 2 743 1584.

Payment

Payment must accompany registration form. Registration will not be processed nor confirmed without payment in Euro (€). All registrations sent by fax must include the necessary payment information. American Express, Visa or EC/MasterCard is accepted. Please complete the appropriate spaces and sign the registration form.

Early Registration Deadline

To benefit from the early registration deadline, payment must be received on or before 4 August 2006. After this date, you will be charged the standard registration fee.

Confirmation

Upon receipt of payment, a proof of payment will be sent to you, along with your confirmation letter (time permitting). Hotel accommodation is not included in the registration fee.

Please present your registration confirmation letter at the ISPE Registration Desk at the InterContinental Vienna. You will receive your congress materials and personal name badge.

If you do not receive your confirmation letter, please contact ISPE at:

ISPE Registration Services
Avenue de Tervueren, 300
B-1150 Brussels - Belgium
Tel: + 32 2 743 4422
Fax: + 32 2 743 1584
E-mail: europeregistrations@ispe.org

In order to be listed in the official delegate roster, you must be registered and paid by **8 September 2006.**

Cancellation Policies

Full refunds, less a handling fee of € 100 per registrant, will be granted to requests received in writing before or on 1 September. No refunds will be granted for requests received after 1 September. Telephone cancellations will not be accepted.

Liability

ISPE reserves the right to cancel or reschedule any conference and/or to change instructors. Please be advised that ISPE is not responsible for any airfare/hotel penalties or other travel charges you incur. In case of Government intervention or regulation, military activity, strikes or any other circumstances that make it impossible or inadvisable for the ISPE Vienna Congress to take place at the time and place provided, the participant shall waive any claim for damages or compensation except the amount paid for registration after deduction of actual expenses incurred in connection with the Congress and there shall be no future liability on the part of either party.

Substitutions

If a delegate is unable to attend, substitutions will be accepted; however, nonmembers substituting for Members must pay the difference in fees prior to the start of the event. ISPE can not be held responsible for lost airfare due to cancellations.

ISPE Notice

The speakers invited to present ISPE's programmes are leading professionals in their field. Should it be necessary, substitutions may be made. Every precaution is taken to ensure accuracy, but ISPE cannot accept responsibility for the accuracy of information distributed or contained in these programmes, or for any other opinion expressed.

Group Discounts

Save 10%: Three to five participants from the same company location attending Congress at a single venue save 10% on the registration fees.

Save 15%: Six to ten participants from the same company location attending Congress at a single venue save 15% on the registration fees.

Save 20%: Eleven or more participants from the same company location attending Congress at a single venue save 20% on the registration fees.

Discounts cannot be combined and Member and nonmember pricing applies. Cancellations are not permitted but substitutions will be accepted.

To benefit from group discount, you must fill in a group registration form, available at www.ispe.org/goto_ViennaCongress. All forms must be sent at the same time.

Emerging Economy Countries Discount

ISPE is offering 50% discount off the normal early/late registration fees to Members from Emerging Economy countries. To review the list of eligible countries visit:

www.ispe.org/EmergingEconomyList.

The discount will automatically apply when registration is processed.

Registration Form

Please return to ISPE Registration Services
Avenue de Tervueren, 300 • B-1150 Brussels • Belgium
E-mail: europeregistrations@ispe.org or **Fax: + 32 2 743 1584**

VieCong2

I. Delegate Information

ISPE Member: ❑ Yes, membership number _____ ❑ No

Prefix: _____ First Name: _____ Last Name: _____

JobTitle: _____ Company: _____

Address: _____

_____

City _____ Postal Code: _____ Country: _____

Telephone: _____ Fax: _____

Mobile: _____

E-mail: _____

Company VAT number (mandatory): _____

❑ I wish to keep my data confidential and it is given only for use by ISPE and its local Affiliates and Chapters.

❑ I do not wish my information to be printed in the Membership Directory or on Conference Attendee Listings.

II. Congress Registration

Please select the conference you wish to attend (one conference per 2 day event).

18 September

❑ Plenary Day: Science-Based Manufacturing for the Next Decade

❑ Opening Reception hosted by the Germany/Austria/Switzerland (D/A/CH) Affiliate

❑ Yes, I will attend the Reception ❑ No, I will not attend the Reception

For accompanying person, please indicate below the name (cost per person is € 45)
First Name _____ Last Name _____
For additional persons, please make copies.

19-20 September

❑ PAT - The Science, Its Applications and Regulatory Implications

❑ Lyophilisation - Technologies and Practice

❑ Barrier Isolation Technology Forum

20 September

❑ Site Visits (afternoon)

Only available in conjunction with Congress Registration.
Please indicate your preferred choices: Boehringer Ingelheim, Intervet, Octapharma, Schlumberger
1. _____ 2. _____ 3. _____ 4. _____

21-22 September

❑ Developing Investigational Medicinal Product (IMP) Supply Strategies and Working Practices to Meet Future Trends in Clinical Research

❑ Quality Risk Management – Guidance and Case Studies

❑ Continuous Processing in the Real World

22 September

❑ GAMP® Part 11: Update on 21 CFR Part 11 with a Focus on Manufacturing Execution Systems (MES)

III. Congress Registration Fees

Prices below do NOT include VAT.

GROUP DISCOUNT NOW AVAILABLE! GROUP REGISTRATION FORM AVAILABLE ONLINE.

	Payment received on or before 4 August 2006		Payment received after 4 August 2006		Academia		Government	
	Member	Nonmember*	Member	Nonmember*	Early Member	Late Member	Member	Nonmember*
❑ Full Congress (Plenary Day + 2 Conference Sets + Opening Reception) Please select the conferences you will be attending-one conference per two-day event	€ 1645	€ 1825	€ 2045	€ 2225	€ 823	€ 1023	€ 1023	€ 1053
❑ 3-Day Package (Plenary Day + 1 Conference Set + Opening Reception)	€ 1100	€ 1280	€ 1500	€ 1680	€ 550	€ 750	€ 750	€ 780
❑ 19-20 September Conferences (1,5 days)	€ 750	€ 930	€ 1150	€ 1330	€ 375	€ 575	€ 575	€ 605
❑ 21-22 September Conferences (1,5 days)	€ 750	€ 930	€ 1150	€ 1330	€ 375	€ 575	€ 575	€ 605
❑ Plenary Day (Monday, 18 September – Fee includes Opening Reception)	€ 545	€ 725	€ 745	€ 925	€ 295	€ 375	€ 395	€ 425
❑ 22 September GAMP® Part 11 (MES)	€ 500	€ 680	€ 700	€ 880	€ 250	€ 330	€ 350	€ 380
❑ Opening Reception (Monday, 18 September)	€ 45	€ 45	€ 45	€ 45	€ 45	€ 45	€ 45	€ 45
❑ Site Visit	€ 25	€ 25	€ 25	€ 25	€ 25	€ 25	€ 25	€ 25

* This nonmember rate entitles you to a one-year membership in ISPE at no additional charge. Student fees: € 100 per Conference or € 300 for full Congress. Proof of full-time student status is required. ISPE Members from Emerging Economy Countries can benefit from a 50% discount on the regular registration fee. Visit www.ispe.org/EmergingEconomyList to review the list of eligible countries. The discount will automatically apply when registration is processed.

❑ First time attendee

❑ Please tick this box if you wish to become a Member. An ISPE Membership application form will be sent to you and must be returned to ISPE within 30 days in order to activate your membership.

IV. Method of Payment

20% Austrian VAT should be included in total payment

Sub-Total: € _____
Opening Reception: _____ x € 45 € _____
Site Visit: € 25 € _____
20% VAT: € _____
Total Due: € _____

Credit Card: ❑ Amex ❑ Visa ❑ EC/MasterCard
Credit card number: _____ Expiry Date: _____
Cardholder's name: _____ Signature: _____

V. Special Needs (dietary,....): _____

VI. Hotel Reservation

Please make the following reservation for me at the InterContinental Vienna, Johannesgasse 28, A-1037 Vienna, Austria.

❑ Single room € 195 ❑ Double room € 205
(including service and taxes, excluding breakfast)
❑ Smoking
❑ Non-smoking (Subject to availability)

Arrival date: _____/09/2006
Departure date: _____/09/2006

Please guarantee my hotel reservation with the following credit card (mandatory):
❑ AMEX ❑ VISA ❑ EC/MasterCard
Credit card number: _____
Expiry Date: _____
Cardholder's name: _____
Signature: _____

VII. Signature

By signing, I agree with the ISPE Registration and Cancellation Policies (see page 23).

Date: _____ Signature: _____