Early bird deadline: 12 October 2007

UPDATED Programme

Hear and learn from experts and worldwide regulators to keep abreast of current trends, challenges and practical solutions.

- **Containment Technology Forum**
  discuss and hear case studies on recent developments in containment, including RISK-MAPP
- **Packaging Challenges for Tomorrow**
  understand emerging packaging technologies and the latest regulatory requirements
- **Lean, Green and Sustainable Manufacturing**
  learn how to be "lean yet green" under current regulatory, commercial and environmental pressures
- ***BPC (API) Baseline® Guide* – New Guide Review and Workshop**
  grasp the philosophy behind the Guide and apply its concepts in a hands-on workshop
- **Heating, Ventilation and Air Conditioning: the Best Current Practice in the Industry**
  find out about the best current practices towards building robust HVAC systems
- **Sterile Regulations, Practices and Case Studies**
  get the latest information on cleanroom regulations, including an update on the EU Annex 1 revision

ISPE

Amsterdam Conference

26-29 November 2007

NH Grand Hotel Krasnapolsky - Amsterdam, The Netherlands

Early bird deadline:
12 October 2007

Exhibit and Sponsorship Opportunities Available

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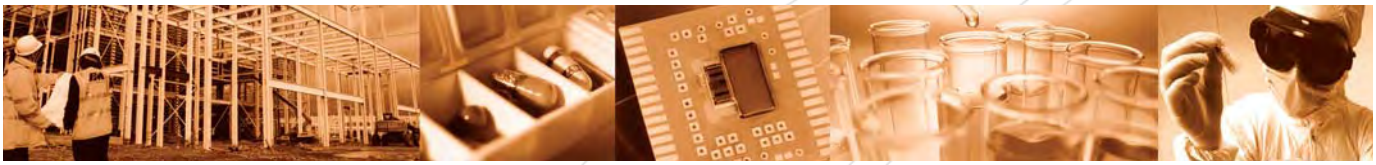
Programme-at-a-Glance

Monday, 26 November	Tuesday, 27 November	Wednesday, 28 November	Thursday, 29 November
Containment Technology Forum		*BPC (API) Baseline® Guide* – New Guide Review and Workshop	
Packaging Challenges for Tomorrow		HVAC: the Best Current Practice in the Industry	
Lean, Green and Sustainable Manufacturing		Sterile Regulations, Practices and Case Studies	
ISPE Table Top Exhibition	ISPE Table Top Exhibition	ISPE Table Top Exhibition	ISPE Table Top Exhibition
Networking Reception		Networking Reception	



Containment Technology Forum

▶ **26 - 27 November**

Seminar Leaders:
Peter Marshall, AstraZeneca, UK
Johannes Rauschnabel, Robert Bosch, Germany

Seminar Description

This seminar will examine the latest developments used in the containment of potent compounds within the pharmaceutical industry at all scales, from R&D facilities to manufacturing, together with an update on the latest industry guidance documents.

Leading international speakers will provide a global perspective on the regulatory expectations for compliance in health and safety and GMP, and will discuss the development of a practical and compliant risk assessment strategy.

Through case studies they will demonstrate the use of innovative equipment and technology, as well as the impact of containment on the planning, design and construction of facilities. Moderated workshops on hot topics of containment practice will also be offered, such as the use of placebos in performance assessment and the experience with flexible containment systems.

Take Back to Your Job

- Information from case studies on current issues related to containment and its pharmaceutical applications
- A network of contacts who can share their experience and help you solve problems
- Techniques to successfully select and test containment systems
- New information on the *RISK-MAPP Baseline® Guide* and the associated *ISPE Containment Good Practice Guide*

Agenda

Monday, 26 November

10.00 – 10.15 | **Welcome and Introduction**
Peter Marshall, AstraZeneca, UK

10.15 – 11.15 | **RISK-MAPP Update**
Julian Wilkins, PharmaConsult US, USA

- Progress and purpose of *RISK-MAPP Baseline® Guide*
- Progress on supporting documents (cleaning and containment guides)

11.15 – 12.15 | **Regulators' View**
Catherine Lefevre, French regulatory authority

- Regulatory view of GMP implications of containment/RISK-MAPP and other issues with quality and containment application to pressure regimes
- Brief overview of hygiene for engineers. Current hot issues in hygiene that may affect engineers and hygiene from European IH Forum/BOHS Conference

12.15 – 13.45 | **Lunch**

13.45 – 14.40 | **Risk Ranking**
Marc Abramowitz, Johnson and Johnson, USA

14.40 – 15.15 | **Application of SMEPAC**
Richard Denk, Hecht, Germany

- Case study on application of SMEPAC methodology

15.15 – 15.45 | **Workshop / Discussion Round Tables**

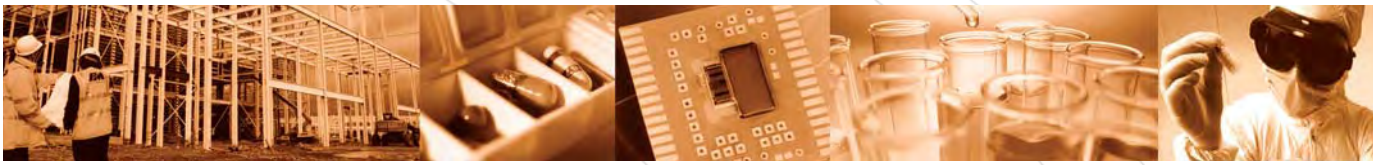
- RISK-MAPP and its impact
- Contents of the proposed *ISPE Containment Good Practice Guide*
- Containment for sterility and aseptic operation
- Equipment testing and protocols

15.45 – 16.15 | **Break**

16.15 – 17.15 | **Workshop / Discussion Round Tables (continuation)**

17.15 – 17.45 | **Questions and Answers, Close of Day 1**
Peter Marshall, AstraZeneca, UK
Johannes Rauschnabel, Robert Bosch, Germany

17.45 – 19.00 | **Networking Reception**



Tuesday, 27 November

8.30 – 8.45 | **Review of Day 1, Introduction of Day 2**
Johannes Rauschnabel, Robert Bosch, Germany

8.45 – 9.30 | **Case Study: Containment for Aseptic Processing**
Frank Generotzky, Baxter Oncology, Germany

- Compounding of cytotoxics
- Containment for sterile filling of cytotoxics
- Isolator technology: long term experiences

9.30 – 10.15 | **Case Study: SHE and GMP Controlled Media Preparation in Biopharmaceutical Plant (Upgrade)**
Martin Friemann, Centocor, The Netherlands
Joost Nieuwlaat, JOA, The Netherlands

- Process insight selection of engineering controls
- Design considerations for effective containment when dealing with biopharmaceutical material
- Compromises between SHE and GMP concerns
- Practical learnings

10.15 – 10.45 | **Break**

10.45 – 11.30 | **Case Study: API Reactor Charging**
Speaker will soon be confirmed

- Review of experience with Hycoflex clean break system

11.30 – 12.15 | **Case Study: Formulation Facility Containment Upgrade**
David Ambrose, Boehringer Ingelheim, USA
Michelle Frisch, Powder Systems, USA

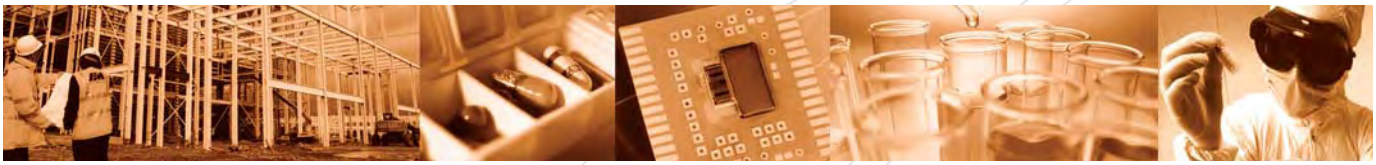
- Project which involved upgrading a formulation facility for containment, retrofitting to existing equipment including granulators, mills and a fluid bed dryer
- Project from inception through implementation to commissioning
- Insight into a major containment upgrade

12.15 – 12.30 | **Review of Workshops, Questions and Answers**
Peter Marshall, AstraZeneca, UK
Johannes Rauschnabel, Robert Bosch, Germany

12.45 – 14.15 | **Lunch**

14.15 – 15.15 | **Containment Engineering in the Nuclear Industry**
Dave Barker, Gravatom, UK

15.15 – 16.15 | **Questions and Answers, Close of Seminar**
Peter Marshall, AstraZeneca Pharmaceuticals, UK
Johannes Rauschnabel, Robert Bosch GmbH, Germany



Packaging Challenges for Tomorrow

▶ **26 - 27 November**

Seminar Leaders:
Linda McBride, Enturia Inc., USA
David Williams, Calico Associates Limited, UK

Seminar Description

This seminar will include case studies and will focus on emerging packaging technologies for the future. It will specifically address the development of anti-counterfeiting strategies and will also provide a review of the latest, most efficient technologies and an update on Radio Frequency Identification (RFID). Recent developments for cGMP requirements will be discussed, as well as facility flexibility to meet marketing and regulatory needs. A European regulator has been invited to give an update on the latest EU regulatory developments.

Take Back to Your Job

- An understanding of the latest anti-counterfeiting strategies and technologies utilised by other industries (such as RFID)
- New information on the latest packaging technologies focusing on efficiency, waste reduction, error reduction, multi-purpose operations and line change-overs
- Information on the impact of the newly-implemented regulations of ISO 15378 and Braille applications
- An update on the latest regulatory findings and regulatory requirements
- An update on the *Packaging, Labelling and Warehousing Baseline® Guide*

Agenda

Monday, 26 November

10.00 – 10.15 | **Welcome and Introduction**
Linda McBride, Enturia Inc., USA
David Williams, Calico Associates Limited, UK

10.15 – 11.00 | **Anti Counterfeiting Strategy**
David Williams, Calico Associates Limited, UK

- Risk assessment
- Commercial implications
- Overt vs. covert

11.00 – 11.45 | **Security Techniques Overview**
James Bevan, Vandagraf International Limited, UK

- Variety
- Suitability for purpose
- Selection

11.45 – 12.30 | **An Update on RFID**
Chris Johnson, Cypak, Sweden

- Technology and standards developments
- Applications - security, compliance and ROI
- How to select an RFID system

12.30 – 13.30 | **Lunch**

13.30 – 14.30 | **Anti Counterfeiting Workshop**
David Williams, Calico Associates Limited, UK
James Bevan, Vandagraf International Limited, UK

14.30 – 15.30 | **ISO 15378 Introduction**
Tony Harper, Pharmaceutical and Medical Device Technology Consultants, UK

- Adoption
- Engagement
- Practical benefits

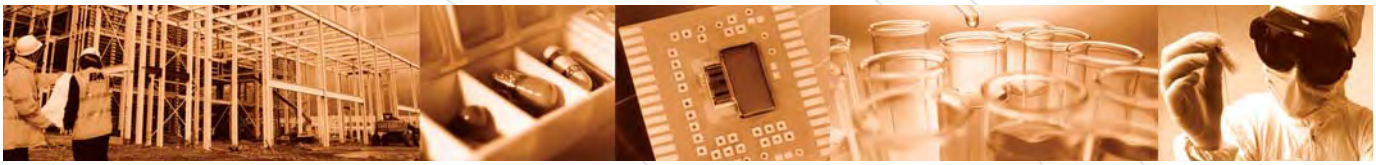
15.30 – 16.00 | **Break**

16.00 – 17.00 | **Braille Update**
Andy Carrier, Ark-Pharma Graphics, UK

- EU directive
- Current application
- Use of standards
- Future

17.00 – 17.30 | **Questions and Answers, Close of Day 1**
Linda McBride, Enturia Inc., USA
David Williams, Calico Associates Limited, UK

17.30 – 19.00 | **Networking Reception**



Tuesday, 27 November

8.30 – 8.45 | **Review of Day 1 and PACLAW Update**
Linda McBride, Enturia Inc., USA

8.45 – 9.45 | **Regulatory Topic**
Representative of Swedish regulatory authority has been invited

9.45 – 10.30 | **Flexibility and Automation**
Lars Olsen, NNE Pharmaplan, Denmark

- Trends in technology and packaging philosophy
- Integration into factory systems
- Decision making for ROI

10.30 – 11.00 | **Break**

11.00 – 12.00 | **Turn Key Project for Lights Out Operation**
Thomas Ruhland, Robert Bosch, Germany

- Case study of a fully integrated capsule line
- WLAN line control and monitoring
- Risk based validation
- Project management, customer – supplier relationship and lessons learned

12.00 – 13.00 | **Handling Packaging Complexity in an Agile Supply Chain**
Peter Janssen, Pfizer, Belgium

- Competing demands
- One product
- Individual market packs
- Decouple market orders to production

13.00 – 14.00 | **Lunch**

14.00 – 15.00 | **Validation Implications of Integration**
Jon Davey, Provalidus Ltd., UK

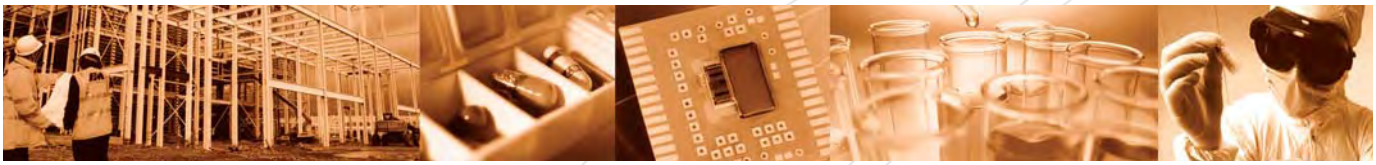
- Issues
- Practical approach
- The way forward

15.00 – 16.00 | **Implementation of OEE System Measurement in Packaging Area**
Andrej Petkovic, Krka Pharmaceuticals, Slovenia

- Understanding overall equipment effectiveness
- Six big losses
- Calculating OEE
- OEE and lean manufacturing

16.00 – 16.45 | **Panel Discussion**
Linda McBride, Enturia Inc., USA
David Williams, Calico Associates Limited, UK

16.45 – 17.00 | **Questions and Answers, Close of Seminar**
Linda McBride, Enturia Inc., USA
David Williams, Calico Associates Limited, UK



Lean, Green and Sustainable Manufacturing

▶ **26 - 27 November**

Seminar Leaders:
Trevor Deeks, Emergent BioSolutions, UK
Edward Kobelski, Pfizer, USA

Seminar Description

Using case studies and break-out sessions, this interactive seminar will focus on current trends and developments in manufacturing and will take a close look at the manufacturing strategies used by today's leading companies to respond to current regulatory, commercial and environmental pressures.

All aspects of pharmaceutical manufacturing will be covered, including:

- requirements and expectations during the development from Phase I to Phase III
- product lifecycle management and an integrated technology approach
- the challenges of technology transfer for complex processes
- operational effectiveness, lean manufacturing and continuous processing
- facility design for continuous processing and operational effectiveness
- supply chain management
- the impact of the Clinical Trials Directive on the clinical supply chain
- sustainability, green processes and waste handling

Take Back to Your Job

- A greater appreciation of how the pharmaceutical sector is addressing the challenges of lean yet green manufacturing
- An understanding of how these challenges can be met by process and facility design
- Practical experiences provided first-hand by companies that have successfully responded to the current challenges
- The most current information on the regulatory and practical hurdles that must be overcome to introduce modern manufacturing methods

Agenda

Monday, 26 November

10.00 – 10.15 | **Welcome and Introduction**
Edward Kobelski, Pfizer, USA

Session 1:
Process Design, Development and Technology Transfer

10.15 – 11.00 | **Designing and Developing a Manufacturing Process, Requirements from Phase I to Phase III**
Trevor Deeks, Emergent BioSolutions, UK

- Data requirements from Phase I to Phase III
- GMP expectations during development
- Validation and stability testing during development
- The future of process validation

11.00 – 11.45 | **An Integrated Technology Approach to Product Lifecycle Management (PLM)**
Cathal Strain, Pfizer Global Manufacturing, USA

- The information management challenge for the pharmaceutical industry
- The manufacturing IT architecture – gaps in contemporary solutions
- Filling the IT gap – using modelling and simulation to support Tech Transfer, and overall PLM
- The future for pharmaceutical manufacturing – enabling PLM, Quality by Design and lean manufacturing

11.45 – 12.30 | **Case Study: Technology Transfer and Scale-up of a Live Vaccine**
Gary Whale, Emergent BioSolutions, UK

- Development phase appropriate technology transfer approaches
- Essentials for successful late development phase technology transfer
- Considerations for successful scale-up of a late phase manufacturing process
- Technology transfer and scale-up: measurement of success

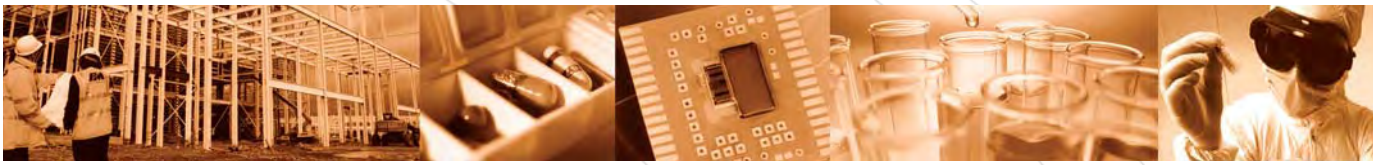
12.30 – 14.00 | **Lunch**

Session 2:
Operational Effectiveness and Lean Manufacturing

14.00 – 14.45 | **Introduction to Lean Manufacturing**
Anita B. Albrechtsen, Novo Nordisk, Denmark

- Methodology and tools
- Process improvements
- Lean six sigma in quality and development

14.45 – 15.30 | **Impact of Continuous API Processing on Manufacturing Efficiency**
Huw Thomas, Foster Wheeler, UK



- Introduction to a case study - purpose and methodology
- The comparison of batch and continuous plant design
- Other considerations in the transition from batch to continuous processing

15.30 – 16.15 | **Break**

16.15 – 17.00 | **Facility and Operations Design for Continuous Processing**
Robert Baker, Bovis Lend Lease Technology, UK

- What are the objectives in a lean operation?
- Where is the money?
- How can facilities help or hinder?

17.00. – 17.45 | **Questions and Answers, Close of Day 1**
Trevor Deeks, Emergent BioSolutions, UK
Edward Kobelski, Pfizer, USA

17.45 – 19.00 | **Networking Reception**

Tuesday, 27 November

9.00 – 9.15 | **Review of Day 1, Introduction of Day 2**
Trevor Deeks, Emergent BioSolutions, UK

Session 3: Supply Chain Management

9.15 – 10.00 | **A Supply Chain Model for Clinical API Manufacturing**
Edward Kobelski, Pfizer, USA

- Transitioning from a science to a business based organisation
- Success factors in organisational change
- Measuring the effectiveness of a research-based business
- Future opportunities

10.00 – 10.45 | **Applying Logistics Simulation on Process Development, Technology Transfer and Supply Chain Management**
Markus Klug, Profactor Research and Solutions, Austria

- Simulation for improved process understanding of in-house production and complex logistics
- Benefits and risks of simulation modelling
- Challenges of pharmaceutical processes
- Examples of simulation applications and their benefits

10.45 – 11.15 | **Break**

11.15 – 12.00 | **Predicting the Market and Meeting Customer Needs**
Speaker will soon be confirmed

Session 4: Sustainability and Green Processing

12.00 – 12.45 | **Sustainable Pharmaceutical Facility Design**
Peter Barry, Fluor Limited, UK

- Defining sustainability
- Legislative pressures for sustainable design
- Practical measures to achieve sustainable designs
- Benefits and costs of sustainable measures

12.45 – 14.00 | **Lunch**

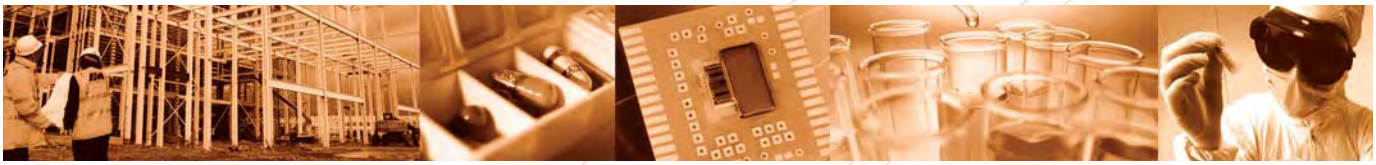
14.00 – 14.45 | **Risk and Waste Handling with Custom Manufacturing/Chemicals**
Martin Clausen, Lonza AG, Switzerland

- Handling of hazardous compounds
- Risk minimisation efforts
- Waste handling and waste reduction concept

14.45 – 15.30 | **Green Chemistry in the Pharmaceutical Industry**
Andy Wells, AstraZeneca Global Process Research and Development, UK

- Metrics – where we are and where we would like to be
- What is a "green" solvent?
- Strategies for a more environmentally-friendly synthesis
- The ACS Green Chemistry Roundtable

15.30 – 16.00 | **Questions and Answers, Close of Seminar**
Trevor Deeks, Emergent BioSolutions, UK
Edward Kobelski, Pfizer, USA



BPC (API) Baseline® Guide – New Guide Review and Workshop

▶ **28 – 29 November**

Seminar Leaders:
Damian Greene, Pfizer, USA
Dr. Trish Melton, MIME Solutions Ltd., UK

Seminar Description

The cost of constructing new API facilities or refurbishing existing ones continues to rise, in many cases due to inconsistent interpretation of regulatory expectations. ISPE and engineering representatives from the pharmaceutical industry have entered in a partnership with the US Food and Drug Administration (FDA) to enhance understanding of Baseline cGMP expectations for facilities. The resulting *API Baseline® Guide* is intended to offer a consistent interpretation, while still allowing a flexible and innovative approach to facility design, construction, commissioning, qualification and validation.

This seminar is the European launch of the *API Baseline® Guide* published in June 2007, which is a complete revision of the June 1996 *Bulk Pharmaceutical Chemicals Baseline® Guide*. The launch will summarise the major changes and in particular ensure that the regulatory concepts are clear and well understood.

The majority of the seminar, however, will be an applications workshop, which will address the challenge of upgrading existing API facilities to meet contemporary cGMP expectations, while dealing with physical and financial constraints.

Subject matter experts from the Active Pharmaceutical Ingredients Community of Practice (API COP) will guide delegates as they work through key chapters of the guide. In particular, the workshops will focus on the decision process to allow a risk-based approach to constructing or refurbishing facilities. This will give delegates hands-on practice on how to apply the guide using a realistic case study.

This seminar was developed in association with the ISPE Active Pharmaceutical Ingredients Community of Practice and is particularly relevant to existing or future API community members.

▶ ***Complimentary copy of the API Baseline® Guide provided.***

Take Back to Your Job

- An understanding of the key changes to the Guide:
  - Regulatory concepts (including link to ICH Q7a)
  - New and modified chapters
- The application of selected Guide chapters through "hands-on" experience using a realistic case study involving an API Facility Revamp Project:
  - Risk assessment
  - Facility, layout and architecture
  - Facility and equipment cleaning
  - Containment
  - Multipurpose facilities.

Agenda

Wednesday, 28 November

10.00 - 10.20 **Welcome and Introduction to the Revised Guide**
Damian Greene, Pfizer, USA

- The background to the revision of the *API Baseline®* Guide
- The scope of the revised Guide
  - Chapter overview
  - Applicability to new and refurbished facilities
- Summary of key features within the guide and key changes from the previous Guide

10.20 - 11.20 **Regulatory Philosophy and Guide Concepts Chapter**
Betsy Fritschel, Johnson and Johnson, USA

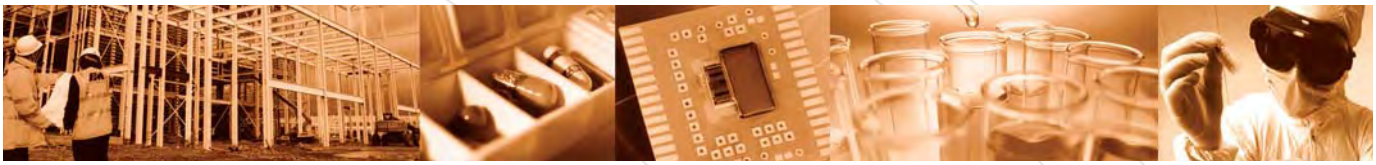
- Relative roles of ICH Q7A GMPs for APIs and the ISPE *API Baseline® Guide*
- Key definitions to improve understanding and communication
  - Critical, process step, levels of protection
  - API starting material, API intermediate

11.20 - 11.40 **Introduction to the API Community of Practice**
Damian Greene, Pfizer, USA

- Overview of ISPE's Communities of Practice, and specifically the API Community
- How the API COP can enable you to be more effective in your work
- Activities being carried out by the COP and how these address the needs for collaboration, sharing of best practices, access to knowledge and innovation

11.40 - 12.00 **Case Study Introduction**
Dr. Trish Melton, MIME Solutions Ltd., UK

- Introduction of a case study based on the refurbishment of an existing facility so that it is able



to process different APIs
- Sessions around each chapter pose a challenge for delegates to work through, with expert facilitation
- Workshop: delegates address layout, containment and cleaning issues while considering the nature of multipurpose production within a risk based approach

12.00 - 13.30 | **Lunch**

13.30 - 15.00 | **Risk Assessment Chapter and Workshop**
Dr. Trish Melton, MIME Solutions Ltd., UK

- Introduction to the risk assessment approach and to the use of the four-stage process which systematically looks at the risks associated with the facility designation, the process, contamination and systems
- Workshop: delegates conduct a risk assessment on the case study API facility

15.00 - 15.30 | **Break**

15.30 - 17.00 | **Facility Layout Chapter and Workshop**
Dennis Fortune, Foster Wheeler Energy, UK

- Brief overview of the new chapter, noting new concepts and principles
- Tools used to develop a facility layout
- Workshop: delegates develop a layout for the case study API facility and evaluate the impact on key architectural features

17.00 - 17.30 | **Feedback from Workshops, Questions and Answers**
Damian Greene, Pfizer, USA
Dr. Trish Melton, MIME Solutions Ltd., UK

- An opportunity for the delegates to discuss the output of the two workshop sessions
- An opportunity for the facilitators to highlight issues raised during the workshop sessions

17.30 - 17.45 | **Close of Day 1**
Dr. Trish Melton, MIME Solutions Ltd., UK
Damian Greene, Pfizer, USA
Lynn Bryan, ISPE Education Advisor, UK

17.45 - 19.00 | **Networking Reception**

Thursday, 29 November

9.00 - 9.15 | **Review of Day 1**
Damian Greene, Pfizer, USA
Dr. Trish Melton, MIME Solutions Ltd., UK

9.15 - 10.45 | **Facility and Equipment Cleaning Chapter and Workshop**
Anthony Ward, Pfizer, UK

- Overview of the new chapter
- Importance of equipment design for cleanability
- Introduction to how a risk based approach can be applied to the development of a cleaning strategy, to support the design of a BPC facility
- Delegates will use the chapter principles to develop a cleaning strategy for the case study API facility

10.45 - 11.00 | **Break**

11.00 - 12.30 | **Containment Chapter and Workshop**
John Nichols, Foster Wheeler Energy, UK

- Introduction to ISPE's holistic approach to containment design using the project drivers
- Interaction of containment with levels of protection and other design aspects such as layout
- Workshop: delegates use the chapter principles to develop a containment strategy for the case study API facility, considering appropriate containment solutions

12.30 - 14.00 | **Lunch**

14.00 - 15.10 | **Multipurpose and Pilot Plant Chapter and Workshop**
Dr. Trish Melton, MIME Solutions Ltd., UK
Anthony Ward, Pfizer, UK

- Introduction to the key challenges in designing a multipurpose facility: the concepts of base configuration and process operating boundary and the importance of conceptual design and risk assessment in defining both
- Difference in approach for scale up facilities and manufacturing plants: promote the importance of flexibility vs. rigidity in facility/equipment layouts
- Workshop: delegates highlight specific issues with the case study API facility as related to these two chapters

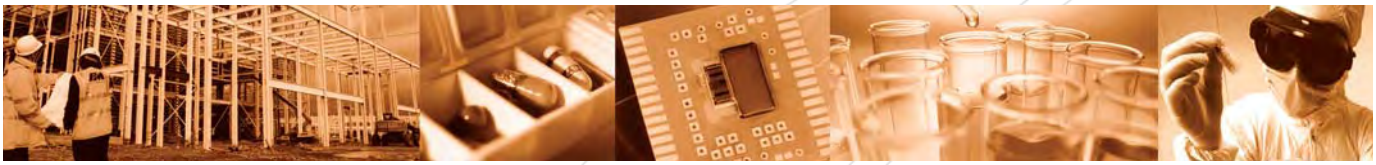
15.10 - 16.10 | **API Facility Compliance Trends - A Regulator's View**
Chris Cullen, Irish Medicines Board, Ireland

- Overview of the trends and current issues with new and refurbished API facilities

16.10 - 16.40 | **API Master Class**
Panel: all speakers from day 1 and 2

- An opportunity for the delegates to "ask the experts" about specific API facility issues
- The panel members will each comment on specific issues raised by delegates, giving their views on how issues can be resolved and how risk based decisions can be taken

16.40 - 16.45 | **Close of Seminar**
Damian Greene, Pfizer, USA
Dr. Trish Melton, MIME Solutions Ltd., UK



HVAC: the Best Current Practice in the Industry

▶ **28 - 29 November**

Seminar Leaders:
Pierre Le Meur, SPEC Conseils, France
Alan Mac Neice, Elan, Ireland
Gordon Farquharson, Bovis Lend Lease, UK

Seminar Description

Correctly designed and optimally operating HVAC (heating, ventilating, and air conditioning) systems are fundamental to the pharmaceutical industry's capability of developing and manufacturing safe and efficacious products; protecting the environment; and creating a safe workplace for personnel.

This ISPE seminar will provide cutting-edge information and case studies from OSD, sterile and potent product manufacture that illustrate the best current practice in our industry. The latest guidance concerning air filtration, cleanroom standards and good engineering practice will be explained in depth. A study from the microelectronics world will show some of the techniques involved in this field of contamination control. The efficient application of integrated commissioning and qualification techniques for HVAC will be illustrated, as well as the application of energy efficient techniques and technologies, which often conflict with the demands of quality and safety critical systems.

Take Back to Your Job

- Air filtration standards and practice: revisions to EN 1822 and filtration testing requirements
- Practical HVAC applications for sterile, potent and micro-electronics products
- An understanding of the principles, issues and control techniques for pressurisation of critical areas
- The latest thinking about BMS and FMS systems and their qualification
- An understanding of air filtration issues and practice for cleanroom and safety ventilation applications
- Knowledge of conservation technologies and options for HVAC, and the conflicts with safety and quality criticality
- GAMP practices applied to the BMS and EMS systems

Agenda

Wednesday, 28 November

10.00 - 10.15 | **Welcome and Introduction**
Pierre Le Meur, SPEC Conseils, France
Alan Mac Neice, Elan, Ireland

10.15 - 11.15 | **HEPA Filters**
Tim Triggs, DOP Solutions, UK

- The revision to EN 1822
- Photometers and aerosol generators
- Avoiding leak test failure
- Good testing practice
- High temperature filters
- Latest developments in filter media

11.15 - 12.15 | **Pressurisation, Theory and Practice**
Fred Brown, Bovis Lend Lease, UK

- Application to pressure regimes
- Setting levels
- Room leakage estimation
- Room leakage measurement
- Control methods
- Stability and monitoring

12.15 - 13.45 | **Lunch**

13.45 - 14.45 | **Facilities for Potent Compounds**
Emilio Moia, Foster Wheeler Italiana, Italy

- Case study
- Potency of materials
- Facility layout and process equipment
- Environmental control specifications
- HVAC systems configuration

14.45 - 15.45 | **Energy Efficiency In and Out of the Cleanroom**
Stephen Bryan, AstraZeneca, UK

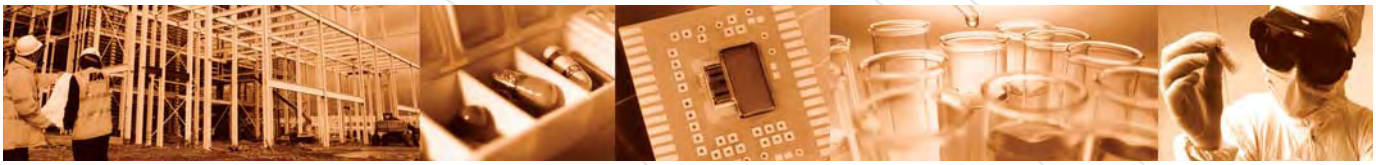
- Optimising operations to save energy and cost
- Energy saving projects in existing facilities
- Sustainable engineering, designing new facilities with "green" in mind
- Key Performance Indicators - prove you are improving

15.45 - 16.15 | **Break**

16.15 - 17.15 | **Case study from the Micro Electronics Industry**
Speaker will soon be confirmed

- Processes to be accommodated
- Cleanliness classification
- HVAC system engineering including fan-filter systems
- Energy efficient cooling systems

17.15 – 17.45 | **Questions and Answers, Close of Day 1**
Pierre Le Meur, SPEC Conseils, France
Alan Mac Neice, Elan, Ireland



17.45 – 19.00 | **Networking Reception**

Thursday, 29 November

9.00 - 9.15 | **Review of Day 1, Introduction of Day 2**
Pierre Le Meur, SPEC Conseils, France
Alan Mac Neice, Elan, Ireland

9.15 - 10.15 | **Developing a Time-effective, Compliant Maintenance and Testing Programme**
Ulla Thomsen, Novo Nordisk, Denmark
Gordon Farquharson, Bovis Lend Lease, UK

- The business drives for improved utilisation
- Management structure and organisation
- Managing improved up-time
- Outsourcing and control of resources
- Achieving guaranteed start up

10.15 - 10.45 | **Break**

10.45 - 11.45 | **Good Automated Practice for HVAC: Requirements, Architecture, Qualification**
Yves Samson, Kereon AG, Switzerland

- Baseline Guide position: minimal requirements for HVAC, BMS and facility management systems
- Architecture evaluation, Good Engineering Practice and qualification: BMS, DCS, PLC/SCADA
- Case studies: proposals for selecting an appropriate architecture:
  - BMS based implementation
  - Automated HVAC and implementation
  - Automated HVAC with integrated monitoring

11.45 - 12.45 | **Revision to Annex 1 for Sterile Products: Impact on Environmental Systems**
Rob Walker, Rob Walker GMP Consultancy Ltd., UK

- Review of the changes
- Impact on facility design
- Impact on HVAC systems
- Impact on EMS systems
- Programmes for compliance

12.45 - 14.15 | **Lunch**

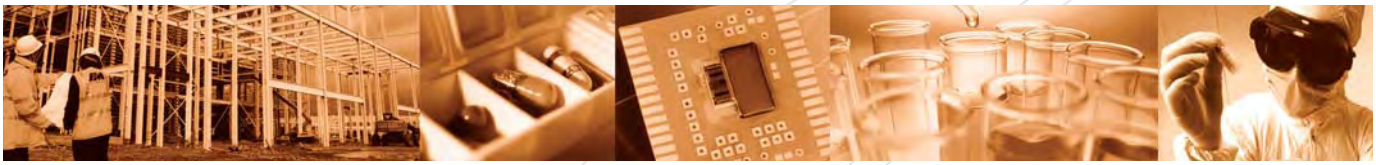
14.15 – 15.15 | **FDA Perspective on Critical HVAC and Environmental Control Systems**
Brenda Uratani, Food and Drug Administration, USA

- HVAC related non-compliances found in the field
- How to present an HVAC system to an inspector: style, depth and material
- Level of detail inspectors need to know for a steriles facility HVAC
- Ownership and knowledge of systems expected to be evident during inspection/investigation
- Regulatory expectations for evidence of failure mode testing of critical HVAC systems; power failure and recovery

15.15 – 16.15 | **Use of Trace Gas for Qualification of HVAC Systems**
Pål Kjetil Eian, Norconsult, Norway

- Qualification parameters - contamination dispersion, recovery time, containment
- Available agents
- Trace gas vs. smoke testing
- SF6 gas theory and basic methodology
- Case study: cleanroom recovery time
- Case study: biological containment facility, Norconsult, Oslo, Norway

16.15 – 16.30 | **Questions and Answers, Close of Seminar**
Pierre Le Meur, SPEC Conseils, France
Alan Mac Neice, Elan, Ireland



Sterile Regulations, Practices and Case Studies

▶ **28 - 29 November**

Seminar Leaders:
Berthold Düthorn, Robert Bosch, Germany
Nunzio Genoni, Jacobs, Italy

Seminar Description

This seminar will provide background information, new technology updates, case studies and the opportunity for discussion on key issues influencing operations in the field of advanced aseptic processing. Speakers will review current cleanroom standards for both EU GMP and FDA cGMP, including an update on the EU Annex 1 revision. Barrier technology will also be covered, such as isolators to enhance aseptic operations and required sterility assurance level. Achievements in skids and modular process delivery systems for product processing will be addressed. Workshops will enable in-depth exchange of experience.

Take Back to Your Job

- Practical knowledge of project execution
- New and updated information on cleanroom regulations including EU Annex 1
- Insights on aseptic filling operations
- Real world solutions to optimise production
- Ways to apply advanced aseptic technology

Agenda

Wednesday, 28 November

10.00 - 10.10 | **Welcome and Introduction**
Berthold Düthorn, Robert Bosch, Germany
Nunzio Genoni, Jacobs, Italy

10.10 - 10.15 | **Welcome and Introduction**
Lynn Bryan, ISPE Education Advisor, UK

10.15 – 11.00 | **Concept of Campaign in Aseptic Processes Using RABS Technology**
Marco Malaguti, GlaxoSmithKline, Italy

- Definition of campaign
- Regulatory requirements
- Risk and opportunities related to campaign
- Validation approach
- Case study: example of application in powder aseptic filling

11.00 - 11.45 | **Improving the Efficiency of Filling in an Isolator**
Charlotte Enghave, NNE Pharmaplan, Denmark

- Business case for implementing campaign filling in an isolator
- Evaluation of "need to have" elements in a batch change over
- Future improvements business case for implementing campaign filling in an isolator

11.45 - 12.00 | **Questions and Answers**
Berthold Düthorn, Robert Bosch, Germany
Nunzio Genoni, Jacobs, Italy

12.00 - 13.15 | **Lunch**

13.15 - 14.00 | **Case Study: Combined Vial/Cartridge Filling Operation in RABS Technology**
Gerald Bürkle, Vetter Pharma, Germany

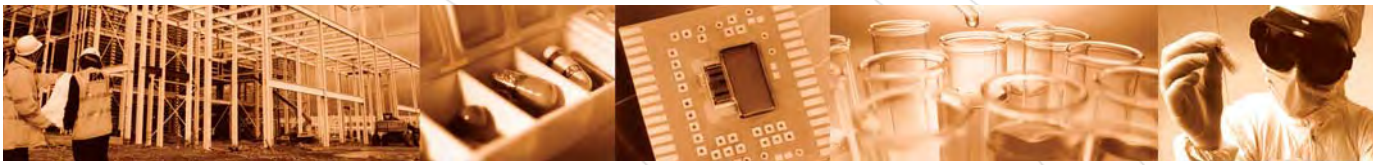
- Reasons and challenges
- Building and layout
- Facility and lines - production ideas
- Combi-line for vials/cartrigdes - basic facts
- Videos of production lines

14.00 - 14.20 | **Case Study: Eli Lilly Sesto Project Highlights**
Silvio Padoin, Eli Lilly, Italy

- Design, Construction, Commissioning and Qualification of Highly Computer Integrated Manufacturing plant for parenteral products

14.20 - 15.00 | **Eli Lilly Sesto Project: Automation and System Integration - Paperless Approach**
Riccardo Colzi, Eli Lilly, Italy

- MES: the heart of an integrated architecture
- The concept of PMX-Scada light integration



- Workcenter automatic set-up
- ER/ES to comply on Part 11 for a paperless approach
- Reviewing by exception

15.00 - 15.30 | **Break**

15.30 - 16.15 | **Eli Lilly Sesto Project: Modular Design and Skid Mounted Delivery of a Formulation Unit**

Massimiliano Ammannito, Eli Lilly, Italy
Deniz Yalav, Jacobs Italia, Italy

- SKID approach
- "On-site" vs. "at vendor's site" work: pro and cons
- Commissioning and qualification execution strategy
- Learning curve
- Lessons learned
- Success factors

16.15 - 17.00 | **Eli Lilly Sesto Project: Commissioning and Qualification of a Cartridge Filling Line**

Roberto Faucitano, Eli Lilly, Italy
Daniele Paoli, Eli Lilly, Italy
Berthold Düthorn, Robert Bosch, Germany

- Project outline
- Workload and resource planning
- "On-site" vs. "at vendor's site" work: pro and cons
- Lessons learned
- Success factors
- Integration between commissioning, qualification and computer software validation

17.00 - 17.15 | **Review of Day 1**

Berthold Düthorn, Robert Bosch, Germany
Nunzio Genoni, Jacobs, Italy

17.15 - 19.00 | **Networking Reception**

Thursday, 29 November

8.30 - 8.45 | **Review of Day 1**

Berthold Düthorn, Robert Bosch, Germany
Nunzio Genoni, Jacobs, Italy

8.45 – 9.30 | **Pre-investment Approach for Room Decontamination with VHP**

Christian Bachofen, Bickel and Bachofen, Switzerland

- HVAC and room finishing design for VHP room de-contamination
- Automation implications
- Pre-investment in HVAC and room finishing to allow future installation of VHP decontamination systems

9.30 – 10.15 | **A New Approach to Sterilisation and Depyrogenation for Advanced Aseptic Processing**

Johannes Rauschnabel, Robert Bosch, Germany
Jochen Feichtinger, Robert Bosch, Germany

- Innovation in plasma sterilisation
- Basics, mechanics and results
- Technology and realization
- Impact and future potential

10.15 – 10.20 | **Introduction to Workshops**

Berthold Düthorn, Robert Bosch, Germany
Nunzio Genoni, Jacobs, Italy

- Four simultaneous workshops are planned in addition to the question and answer sessions. The topics of these workshops will be chosen by the delegates, based on issues presented by speakers and additional, proposed "hot topics"

10.20 – 10.45 | **Break**

10.45 – 12.30 | **Leaders' Workshops (4)**

12.30 - 13.30 | **Lunch**

13.30 - 14.00 | **Moderators' Presentation of Workshop Results (each 5 min)**

14.00 - 14.30 | **EU GMP Annex 1 - An Update**

Rob Walker, Rob Walker GMP Consultancy Ltd., UK

- Update on the revision of EU GMP Annex 1
- Influence for manufacturing operations
- Differences in room classification

14.30 - 15.00 | **Break**

15.00 - 15.45 | **VHP Sterilisation of Freeze Dryers**

Ralph Gross, GEA Lyophil, Germany

- VHP sterilisation for vacuum and atmospheric
- Applications
- Comparison with heat sterilisation process
- Validation aspects
- Alternative set-up of the system

15.45 - 16.30 | **Regulatory Aspects from the FDA**

Brenda Uratani, Food and Drug Administration, USA

16.30 - 16.45 | **Questions and Answers, Close of Seminar**

Berthold Düthorn, Robert Bosch, Germany
Nunzio Genoni, Jacobs, Italy

General Information

Venue

NH Grand Hotel Krasnapolsky
Dam 9
1012 JS Amsterdam - The Netherlands
Tel: +31 20 554 91 11
Fax: +31 20 622 86 07
Email: nhkrasnapolsky@nh-hotels.nl
Website:
http://grandkrasnapolsky.hotel-rez.com

Accomodation

A block of rooms has been reserved at the venue for the ISPE delegates at the preferential rate of €200 for a single/double room (excludes breakfast and city tax). This offer is limited and we encourage you to register as early as possible.

To book your accommodation at the NH Grand Hotel Krasnapolsky, 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 checkout. Changes in bookings or cancellations are accepted only in writing, and are to be sent directly to ISPE Registration Services prior to the event and **no later than 16 November 2007**. 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

Overlooking Dam Square, the NH Grand Hotel Krasnapolsky is located in the heart of Amsterdam's historic centre. Trend-setting shopping streets are just around the corner and so are cultural highlights such as the Royal Palace, "Beurs van Berlage" and the "Nieuwe Kerk".

Trains depart every 10 minutes from Schiphol Airport to the Amsterdam Central Station (single ticket €3.60) and the hotel is only a seven minute walk from Central Station.

A shuttle bus departs from Schiphol Airport every 30 minutes, from 6.00 to 20.00, and can drop you off in front of the hotel. The duration of the trip is about 40 minutes, and tickets (one-way €19) are available at the "Connection" desk of the Schiphol Plaza tourist office.

A taxi ride from Schiphol Airport to the hotel costs about €40.

ISPE Registration Desk Hours

Sunday, 25 November	17.00 - 19.00
Monday, 26 November	8.00 - 17.00
Tuesday, 27 November	8.00 - 18.00
Wednesday, 28 November	8.00 - 17.00
Thursday, 29 November	8.00 - 10.00

Recommended Dress

Business casual

Badges

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

Table Top and Sponsorship Opportunities

Table Top and Sponsorship Opportunities

Sponsorship Opportunities

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

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

With these opportunities you can enhance your brand and corporate image, differentiate your company from the competition and build awareness.

To learn about other ISPE benefits and to book your sponsorship, please contact:

Elmarie Herloff-Petersen
Tel: +32 2 789 2337 / Fax: +32 2 743 1578
E-mail: elmarie.herloff-petersen@associationhq.com

ISPE Table Top Exhibitions

ISPE offers companies the opportunity to present their products and services face-to-face with potential customers in an informal atmosphere in conjunction with the ISPE Amsterdam Conference. Morning and afternoon refreshments are served in the exhibition area to attract the maximum number of Conference participants to see your display, and to encourage networking and information exchange.

ISPE offers three different opportunities:

- 26-27 November (2 days)
- 28-29 November (2 days)
- 26-29 November (4 days)

ISPE Europe's Table Top Exhibitions typically sell out fast.
To date, limited spaces are available - don't miss out!

To book your Table Top, please contact:

Said Laghmari
Tel: + 32 2 743 4422 / Fax: + 32 2 743 1584
E-mail: said@associationhq.com

List of Exhibitors*

Siemens

ATMI LifeSciences

ILC Dover

Foster Wheeler

Extract Technology

Yokogawa

Stedim Biosystems

Buss-SMS-Canzler

Pharmadule

Niro Pharma Systems

HECHT Anlagenbau

Bürkert

Zotefoams plc

Vink Industry - Pharmaceutical Services

*This list is not comprehensive. It includes only exhibitors confirmed before printing this brochure.

Registration and Cancellation Policies

Registration Fees

Conference registration fees include:

- Conference material
- Refreshment breaks
- Lunches
- A 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 the registration form. Registration will not be processed nor confirmed without payment in Euros (€). All registrations sent by fax must include the necessary payment information. American Express, Visa and EC/MasterCard are 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 **12 October 2007**. 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 NH Grand Hotel Krasnapolsky. You will receive your conference materials and personal name badge.

If you do not receive your confirmation letter, please contact:
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 16 November 2007.

Cancellation Policies

Full refunds, less a handling fee of €100 per registrant, will be granted to requests received in writing before or on 9 November 2007. No refunds will be granted for requests received after 9 November 2007. Telephone cancellations will not be accepted.

Liability

ISPE reserves the right to cancel or reschedule any conference and/or to change speakers. 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 Amsterdam Conference 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 conference 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 will 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 conference at a single venue save 10% on the registration fees.
Save 15%: Six to ten participants from the same company location attending conference at a single venue save 15% on the registration fees.
Save 20%: Eleven or more participants from the same company location attending conference at a single venue save 20% on the registration fees.

Discounts cannot be combined and Member and nonmember pricing applies. Group registrations must be submitted at the same time. Substitutions will be accepted. To benefit from a group discount, you must fill in a group registration form. This form is available at **www.ispe.org/amsterdamconference**

Emerging Economy Countries Discount

ISPE is offering a **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

AmsConf2
Please return to:
ISPE Registration Services
Avenue de Tervueren, 300
B-1150 Brussels, Belgium
Email: europeregistrations@ispe.org Fax: + 32 2 743 1584

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. Conference Registration

Please select the seminar you wish to attend (one seminar per two-day event).
Prices below do NOT include VAT.

GROUP DISCOUNT NOW AVAILABLE!
GROUP REGISTRATION FORM AVAILABLE ONLINE @ www.ispe.org

	Payment received on or before 12 October 2007		Payment received after 12 October 2007		Academia		Government	Student**
	Member	Non member*	Member	Non member*	Early Member	Late Member	One Price	One Price
❑ **Full Conference** (26-29 November 2007) Please select below the seminars you will be attending (one seminar per two-day event)	€1800	€2142	€2520	€2862	€1000	€1400	€1400	€300
26-27 November								
❑ Containment Technology Forum	€1000	€1190	€1400	€1590	€500	€700	€700	€150
❑ Packaging Challenges for Tomorrow	€1000	€1190	€1400	€1590	€500	€700	€700	€150
❑ Lean, Green and Sustainable Manufacturing	€1000	€1190	€1400	€1590	€500	€700	€700	€150
28-29 November								
❑ *BPC (API) Baseline® Guide*- New Guide Review and Workshop	€1000	€1190	€1400	€1590	€500	€700	€700	€150
❑ HVAC: the Best Current Practice in the Industry	€1000	€1190	€1400	€1590	€500	€700	€700	€150
❑ Sterile Regulations, Practices and Case Studies	€1000	€1190	€1400	€1590	€500	€700	€700	€150

* This nonmember rate entitles you to a one-year membership in ISPE at no additional charge.

** Proof of full-time student status is required.

ISPE Members from Emerging Economy Countries can benefit from a 50% discount off 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.

Group discount: To benefit from the group discount, you must complete a group registration form. This form is available at www.ispe.org/amsterdamconference.

❑ 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**.

III. Method of Payment

19% Dutch VAT should be included in total payment.

Seminar Fees € _____
Sub-Total: € _____
19% VAT: € _____
Total Due: € _____

❑ Credit Card: ❑ **AMEX** ❑ **VISA** ❑ **EC/MasterCard**

Credit card number: _____ Expiry date: _____

Cardholder's name: _____ Signature: _____

IV. Special Needs (dietary or other): _____

V. Hotel Reservation

Please make the following reservation for me at the
NH Grand Hotel Krasnapolsky, Dam 9, 1012 JS Amsterdam, The Netherlands.
❑ Single room €200 ❑ Double room €200 (excluding breakfast and city tax)
❑ Smoking ❑ Non-smoking (Subject to availability)
Arrival date : ___ /11/2007 Departure date : ___ /11/2007

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

VI. Signature

By signing, I agree with the ISPE Registration and Cancellation Policies (see previous page).
Date: _____ Signature: _____

Success in the life science industry is based on excellent environmental conditions. Let Siemens be your reliable partner providing safe, secure and compliant environments along each step of your value chain. Your investment is protected because we focus on the entire life cycle of your installation. Your environments are compliant because our solutions are based on all-inclusive systems and services developed specifically for the life science industry, and we can offer you decades of knowledge and experience in this industry – worldwide.

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