The Future of European Pharma

Flexible, Agile and Sustainable

30 September – 1 October 2013

Sheraton Brussels Hotel
Place Rogier, 3
Brussels, 1210 Belgium

www.ISPE.org/2013-Flexible-Facilities-EU-Conference

Register Today!

Honorary Chair: Gert Moelgaard
Past Chair for ISPE / Vice President, Strategic Development, NNE Pharmaplan

Chair: Thomas Zimmer
Senior Vice President, Boehringer Ingelheim GmbH

Co-chair: Robert J E Bowen
Director, Facilities Integration Ltd

Track 1 Leader: Chris Mullen
Head of Operations, Fujifilm Diosynth Biotechnologies

Track 2 Leader: Jean-Francois Dulière
Pharmaceutical Process Technologist, Technip Life Sciences

Track 3 Leader: Chris Reid
Owner, Integrity Solutions Ltd

Keynote Speakers:

Dr. Gabriele Schoenberger, Director, Boehringer Ingelheim GmbH

Dr. Louis Schmukler, President, Global Manufacturing and Supply, Bristol-Myers Squibb

Who should attend?

This conference is directed to Plant and Facility Managers, Production Managers, Product Managers, Systems Designers, Systems and Automation Engineers, Validation Personnel, Software Engineers, Facility Maintenance, Process Engineers, Quality Assurance Engineers, Quality Assurance and Quality Control Staff, other Engineering Staff, Regulatory Professionals as well as all others with an interest in getting a better understanding of the future key challenges affecting pharmaceutical manufacturing.

To be competitive in the global market, companies need to be flexible, agile and sustainable. Operations, Facility Design and IT all play a major role. Through seminars, case studies, workshops and networking events you will learn how to improve your agility and increase your responsiveness to market changes, while achieving improved operational and manufacturing performance.

Track 1: Operations

This track will explore topics related to manufacturing operations, and how to safely and compliantly introduce new products. Know when and how to use shared facilities and understand the impact of changing regulations on your operations. Discuss effective ways to manage the risks that flexibility brings and avoid human errors, which are no longer accepted as root causes of quality issues. Learn how flexible facilities can increase agility to respond to market needs when supported by robust, compliant and sustainable business processes.

Have a deeper understanding of:

- Health-based exposure limits, and how ISPE Risk MaPP can help you meet changing EU GMPs
- The impact of flexibility on your business – from Supply Chain to Engineering and Maintenance to Quality Control and Quality Assurance
- How disposables have moved beyond biotech APIs to provide high-productivity, cost-effective sterile filling lines for a rapidly changing product portfolio

Track 2: Facilities and Plants

Improve your knowledge of the requirements of factory and process design in the pharmaceutical industry. Topics covered include human-centred design, standardised modular plants and portable equipment, as well as the pros and cons of both single-use and stainless steel products.

Learn about:

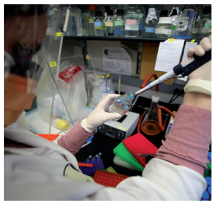
- The challenges that regulatory requirements place on plant and facility design, and how to design and size equipment to implement lean production
- Sustainability and resource efficiency of the flexible facility
- How the health-based residue limits affect facility design

Track 3: IT and Automation

IT and Automation tools are a key asset in flexible, agile facilities. This track highlights the requirements for operating a flexible and multi-purpose facility and managing data and automation; and also explores the use of IT applications to meet required safety and environmental standards. It includes a discussion of new technological developments including virtual collaboration, wireless technology and modelling and simulation tools.

Gain knowledge on:

- Evaluating process and functional risks while maintaining compliance with a flexible operation
- Managing the move from parametrics to attribute approach and exploring the options for process analytical applications (PAT) in flexible manufacturing
- Effective Enterprise Resource Planning and Manufacturing Execution within a flexible process environment



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Conference Fees

EARLY BIRD – ON OR BEFORE 2ND SEPTEMBER				REGULAR/ONSITE – AFTER 2ND SEPTEMBER			
☐ Member ☐ New Member	€ 1,445 € 1,664	☐ Non-Member ☐ Committee	€ 1,750 € 940	☐ Member ☐ New Member	€ 1,645 € 1,864	☐ Non-Member ☐ Committee	€ 1,960 € 940
☐ Academia/Young Professionals/ Emerging Economy			€ 940	☐ Academia/Young Professionals/ Emerging Economy			€ 1,070

Global competition and changing market conditions are increasingly forcing the pharmaceutical industry to become more sustainable, flexible and agile. Pharmaceutical companies need to deliver their products faster, at lower costs and in a more efficient manner. Flexibility – the ability quickly to modify a unit operation or process line – is key to this agility in pharmaceutical manufacturing.

This two-day conference will explore key factors – from operations through to facility and process design – and new IT requirements that contribute to achieving the flexibility necessary to meet these challenges.

The conference will provide insight into the best ways to improve manufacturing productivity and achieve cost effectiveness while maintaining high-quality standards. Specific regulatory focus will be given to the draft revisions of DG SANCO to the Good Manufacturing Practice Chapters 3 and 5, and the draft European Medicines Agency (EMA) guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities.

How to Register

Online: Visit our website:

www.ISPE.org/2013-Flexible-Facilities-EU-Conference

Via Fax: Complete the Registration Form online and fax it to +32-2-743-1550

Questions? Call ISPE Europe at +32-2-743-4422 or email us at ISPEregistrations@associationhq.com

Written confirmation will be sent to you after your registration is processed. For more information visit the event website.

Hotel Information

Visit the conference event website to book the Sheraton Brussels hotel:
www.ISPE.org/2013-Flexible-Facilities-EU-Conference

Room price on 29 – 30 September

Standard Room: €99

Room price on 30 September – 1 October

Standard Room: €179

Prices mentioned above are quoted per room, per night and include taxes, service charges and buffet breakfast.

Area Information and Things to Do

Brussels is a world-class centre of culture and entertainment, with more than 100 museums, beautiful parks, fascinating walks, trendy restaurants and bars.

The Sheraton Brussels Hotel is located in the heart of the city's business district. Just a short walk away you can find Brussels' main shopping areas as well as the renowned square Grand Place and the Brussels Town Hall, one of Belgium's finest civic buildings. In a nearby street is the Manneken-Pis, one of the city's most famous sites.

For more information on the city, we invite you to visit the official Brussels website www.visitbrussels.be

Save the Date for Future Events in Europe

September 2013

Basic GAMP® 5 Training Course, 30 September – 2 October
Brussels, Belgium
www.ISPE.org/2013-Brussels-September-Training

October 2013

Prague Training Courses, 7 – 8 October
Prague, Czech Republic
www.ISPE.org/2013-Prague-October-Training

Operational Excellence Conference, 17 – 18 October
Berlin, Germany
www.ISPE.org/2013-Operational-Excellence-EU-Conference

November 2013

Biotechnology Conference, 13 – 14 November
Strasbourg, France
www.ISPE.org/2013-Biotechnology-EU-Conference