

ISPE NEWS
FOR IMMEDIATE RELEASE



For more information contact:

Claudia Fortes

Marketing and Communications Manager

ISPE European Office

Tel: +32 2 789 2341

Email: claudia.fortes@associationhq.com

ISPE presents an outstanding opportunity to discuss hot topics and key concerns with senior pharmaceutical regulators and industry leaders.

Brussels, Belgium - 22 February 2011 – Delegates to the **Regulatory Affairs Forum** during the upcoming ISPE conference in Frankfurt have the opportunity hear the latest regulatory news from Europe, the USA and Japan and to meet and discuss their challenges and concerns with an outstanding group of senior regulatory representatives. Confirmed attendees include David Cockburn (EMA), Tor Gråberg (Chairman, PIC/S), Rick Friedman and Moheb Nasr (USFDA) and Sabine Kopp (WHO) together with representatives of the regulatory agencies of Japan, Ireland and Sweden. This is a unique opportunity for delegates to put their business-critical review and compliance questions to a highly distinguished international panel of speakers in an interactive half-day session.

The ISPE New Strategies and Business Benefits Conference, which runs from 11-14 April 2011 also provides opportunities to learn about latest pharmaceutical industry and regulatory trends in a series of two-day seminars, featuring real-life case studies, interactive workshops and technical updates. **OSD Manufacturing: Facility and Technology Advances** will address topics such as multipurpose/multiproduct facilities, continuous versus batch manufacturing and the issues surrounding outsourcing. **Quality Risk Management: Focused Practical Application** will be workshop-based and offer delegates the opportunity to hear about applications that have worked for others and formulate their own QRM strategies. **Sterile Products Manufacturing: Maintaining Compliance** features a keynote presentation on regulatory trends from Chairman of PIC/S, Tor Gråberg plus the EU regulatory perspective on green pharma, sustainability and views on what the factory of the future will look like. **Pharmaceutical Water Systems: Cost Effective Design and Maintenance Trends** will look at best practices in design, operation and maintenance; it will also address the ongoing discussion of non-distillation techniques for production of WFI. **Supply Chain Integration to Maximise Profit and Compliance** presents a review of the challenges facing pharmaceutical supply chains, including counterfeiting and globalisation of materials sourcing. There will be updates on initiatives from WHO and Rx-360. **GAMP®: IT Infrastructure Innovation and Compliance** will identify the issues and risks associated with innovative approaches to service provision and technology such as cloud computing, open source software and virtualisation.

Each of these seminars features a panel of subject matter experts from leading pharmaceutical companies such as Pfizer, Bayer Healthcare, Genentech and Novartis; supported by engineering expertise from industry suppliers and academics. Speakers from regulatory agencies in Germany, Sweden and Ireland will also participate.

In addition to the conference's educational sessions, two training courses will also be offered as part of the conference. The training agenda features a brand-new ISPE training course, "[Risk-Based Approaches to GxP Process Control Systems](#)," which will make its global debut at this conference. This session, led by instructor Hilary Mills-Baker, WSP CEL, Ltd., UK, will discuss how to apply the concepts covered in ISPE's recently-released [GAMP® Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems](#). Participants will also receive a complimentary copy of the guide as part of the course.

The second training course entitled "[HVAC for Pharmaceutical Facilities](#)", held by instructor Gordon Farquharson, Critical Systems Ltd., UK, will identify the critical and non-critical parameters affected by HVAC and know-how to control them, based on [ISPE Good Practice Guide: Heating, Ventilation and Air Conditioning](#).

The goal of the Frankfurt Conference is to help attendees gain a better understanding of current and future industry highlights and acquire a new set of skills. ISPE's leading expertise in pharmaceutical engineering will offer participants a unique access to latest industry and regulatory trends.

Complete registration and program details for the ISPE 2011 Frankfurt Conference, are available at www.ISPE.org/2011FrankfurtConference.

###

About ISPE

ISPE, the International Society for Pharmaceutical Engineering, is the Society of choice for 22,000 technical professionals working in or serving the manufacturing sector or drug development in the pharmaceutical industry in 90 countries. ISPE aims to be the catalyst for "Engineering Pharmaceutical Innovation" by providing Members with opportunities to develop their technical [knowledge](#), exchange practical experience within their [community](#), enhance their [professional](#) skills, and collaborate with global regulatory agencies and industry leaders. Founded in 1980, ISPE offers online learning opportunities for a global audience and has its worldwide headquarters in Tampa, Florida, USA; its European office in Brussels, Belgium; an Asia Pacific office in Singapore; and its newest office in Shanghai, China. Visit www.ISPE.org for additional Society news and information.