



**Nordic
Affiliate**

ENGINEERING
PHARMACEUTICAL
INNOVATION

INVITATION
ISPE Nordic Annual Meeting 2008
in Stockholm

**Trends in Pharmaceutical Industry and Efficiency in
Operations**

The conference will provide insight into some of the future business models and challenges faced by the Pharmaceutical Industry and strategies on ways to respond. It will also highlight the Engineer's and the Regulator's approach and roles. The afternoon session will explain how QbD, PAT, ASTM E2500, PQLI all comes together in new/old plants with new/old products in terms of increased quality, shorter delivery time and better economy. New technologies for increased efficiency and the new GAMP 5 implementation will be presented and discussed.

Thursday, 20 November 2008

Place:

Clarion Hotel Sign
Östra Järnvägsgatan 35
STOCKHOLM

(close to Central Station & Arlanda Express)

ISPE Nordic Annual Meeting 2008 – 20 November 2008

Welcome to ISPE Nordic's Annual Meeting 2008!

We look forward to seeing you at the main event of the year for all members of ISPE Nordic - our Annual Meeting. This year the meeting is back in Stockholm.

The Annual Meeting is the opportunity to meet and network with the broadest representation of our more than 1,000 Nordic members from pharmaceutical and biotech companies, suppliers, engineering & consulting companies, academia and regulators within ISPE Nordic as well as our international speakers. We are especially pleased to have high level presentations from both regulatory authorities as well as some of the largest pharmaceutical companies in the Nordic region. Presentations from professional services will highlight changes in the Pharmaceutical Industry and discuss how this could impact on your business and career!

ISPE Nordic has grown significantly the past years and we are now more than 1,000 members! This size of the organisation makes it possible to offer more interesting and attractive activities, obvious already from the enclosed programme.

The Annual Meeting is a full day event but still provides a number of options for you. Stay for the day, or just pick the items that suit you best:

- Participate in the Conference on "Trends in Pharmaceutical Industry and Efficiency in Operations".
- Visit the table top exhibition in the meeting room
- Continue with the Annual General Meeting for ISPE Nordic, with a first launch of the 2009 programme, reports from the Board, and election of Board Members.
- Participate in GAMP Nordic Annual Meeting.
- Conclude the evening with the Social events, Cocktail Reception and the Annual Meeting Dinner with entertainment – the place to meet your peers from the industry.

Welcome to a full day of attractions!

The dinner party with entertainment after the annual meeting we pursue to develop to the Nordic Pharma and Biotech industries' Social Event of the Year. You just have to be there, because everyone else will come. We have as a tradition - the possibility for you to host a dinner table and invite your colleagues or your customers to the dinner. Please see the enclosed registration form for more details.

Of course you still can participate as an individual in the programme, too!

We look forward to welcome you to the Annual Meeting! For details about this, and other coming events, please visit our website: www.ispe.org/nordic.

Sincerely,
ISPE Nordic



Sakari Salla

Chairman
VENUE



SIGN, STOCKHOLM
BY CHOICE HOTELS



For your room booking
email:

Sofia.Nordquist@choice.se
with card details. See more
info below.



The largest hotel in Stockholm, location

Stockholm's largest hotel is located in the heart of Stockholm city adjacent to the Central Station and Arlanda Express (airport express train) facing the Norra Bantorget Square. Clarion Hotel Sign wants to wish you a warm welcome.

Hotel Accommodation

50 rooms have been pre-booked at a special rate of SEK 1.595 (single) or 1.755 (double) exc. VAT per night including breakfast. For booking, email Sofia Nordquist [Sofia.Nordquist@choice.se] with your credit card details, type of card, name, number and valid date and how many nights you want to stay, 19/11 or 20/11 or both. In case you don't show up, the room will be charged to your card –if rooms can't be rented out. There are probably still more room's available end of October/early November, but Clarion can't hold them for us due to internal rules. An early booking will guaranty you a room! Any questions on hotel bookings at Clarion – call Sofia on +46 8 676 98 43.

There is a choice of hotels in the area if you prefer. For more details:

<http://www.booking.com/city/se/stockholm.html>

TABLE TOP EXHIBITION

The conference will include a table top exhibition. Please use the registration form to book a table.

SPONSOR TABLES AT THE ANNUAL MEETING DINNER

You will be able to reserve a table for eight persons and invite special guests to join you at the annual meeting dinner. ISPE membership is not required for dinner guests. Your guests may also attend the day conference at a special conference fee of Euro 220. Please use the registration form to book a table

PROGRAMME
ISPE Nordic Annual Meeting,
Trends in Pharmaceutical Industry and Efficiency in
Operations

Thursday 20 November 2008

- 8:15 – 9:00** **Registration & Coffee**
- 9:00 – 9:15** **Welcome & Introduction**
Sakari Salla, Chief Consultant NNE Pharmaplan Sweden, Chairman ISPE Nordic
- 9:15– 10:00** **“Pharma 2020: The Vision” and “R&D 2020 Virtual R&D”**
Johnathon Marsall, Advisory Director, PriceWaterhouseCoopers
Our speaker will highlight some of the issues and key findings addressed in PWC’s recent papers; “Pharma 2020: The Vision” and “R&D 2020 Virtual R&D”. The papers provide insight into some of the future business models and challenges faced by the pharmaceutical industry and strategies on ways to respond.
- 10:00 – 11:00** **Current challenges in the Pharmaceutical Industry – how will they impact on Engineers, today and tomorrow**
Mikael Uhno, VP Engineering, Facilities Management and Safety Health & Environment, AstraZeneca Operations
The Pharma Industry is currently going through a major financial turnover and companies are developing strategies and plans on how to prepare for a different future. What should an Engineer be thinking about in his everyday life to be better suited and prepared for the changes already here or coming in the near future...and more importantly how will this future look like? Is there a future and will it be different compared to what has been?
- 11:00 – 11:30** **Coffee Break & Table Top Exhibition & Networking**
- 11:30 – 12:15** **Risk management tools for inspectors**
Tor Gråberg, Chief Pharmaceutical Inspector, Head of Drug Inspectorate, Medical Products Agency Sweden
The presentation will highlight the new approach of risk management as a tool for better use of inspection resources. The association with ICH Q9 and its implementation within EU-GMP and the Compilation of Community Procedures will be addressed. The model for risk-based planning for inspections of pharmaceutical manufacturers will be explained.

- 12:15 – 13.15 Lunch & Table Top Exhibition & Networking**
- 13.15 – 14.15 Connecting products plants and Quality by Design**
Bruce Davis “Global Consulting” and Chairman of ISPE
 Bruce Davis will describe the principles behind ICH guidance Q8, Q9 and Q10 (pharmaceutical development, risk management and pharmaceutical quality systems) that support Quality by Design (QbD) principles. He will then show the link from this to the ISPE Product Quality Lifecycle Implementation (PQLI) initiative and describe some of the practical work that is being done to support QbD. He will also cover what ASTM are doing on standards. He will provide his thoughts on how the QbD initiative is linked to Lean and to Products, processes and plants.
- 14.15 – 15.00 Lean manufacturing principles to increase competitiveness,**
Simon Orchard, Site Leader Pfizer Strängnäs
- 15.00 – 15.20 How Continuous Production can increase efficiency in**
Operations, Barry Johnsson Process Development Manager,
Alfa Laval
- 15.20 - 15.50 Coffee Break & Table Top Exhibition & Networking**
- 15.50 – 16.30 A GAMP Nordic Forum Annual Lecture:**
GAMP5 "A risk based approach to compliant GxP Computerized
Systems", Sion Wyn, Director, Conformity Ltd., UK
 Our speaker will guide us through key concepts, based on current and innovative industry thinking, that underpin the rest of the document.
- Key Concepts**
- Life Cycle Approach within a QMS
 - Scaleable Life Cycle Activities
 - Process and Product Understanding
 - Science-Based Quality Risk Management
 - Leveraging Supplier Involvement
- 16.30 – 16.50 Panel discussion & questions to presenters**
- 16.50 - 17:00 End of Conference, Closing Words & Feedback**
- 19:00 Cocktails**
- 19:30 Annual Meeting Dinner with entertainment**
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17:20 – 18:00 Annual General Meeting of ISPE Nordic Affiliate

The Affiliate Chairman's Report
Sakari Salla, Chairman

The Treasurer's Report
Morten Munk, Treasurer

Election of Members to the Board

Any other business

ISPE Nordic BOARD OF DIRECTORS 2008

Sakari Salla, *Chairman*, NNE Pharmaplan, Sweden
Anders Bredesen, *Vice Chairman*, YIT Building Systems AS, Norway
Markus Karlsson, *Secretary* STERIS Corp./Pharma and Research, Finland
Morten Munk, *Treasurer*, CMC Biopharmaceuticals A/S, Denmark
Charlotte Enghave, *Past Chairman*, NNE Pharmaplan, Denmark
Bo Norrman, *Mälardalen University*, Sweden
Wendy Klem, *Sykehusapotekene ANS*, Norway
Stefan Åkerman, *Elomatic Pharmaceutical Engineering*, Finland
Joachim Nordenberg, *Power Alstom*, Norrköping, Sweden
Erik Bach, *H. Lundbeck A/S*, Denmark
SVEIN Ivar Holm, *Aker Bio Marine*, Norway
Linda Frederiksen, *H. Lundbeck A/S*, Denmark
Jukka Rantanen, *Copenhagen University, Faculty of Pharmaceutical Sciences*, Denmark
Carl-Fredrik Mandenius, *Linköping University, Division of Biotechnology*, Sweden
Margareta Häggström, *Semcon Caran*, Sweden
Hans Sundin, *Past Chairman*, Oasmia, Sweden
Gert Möllgaard, *Past Chairman*, NNE Pharmaplan

18:00 – 18:30 Annual General Meeting of GAMP Nordic

The Annual Activity Report of GAMP Nordic

The Treasurer's Report

Election of Members to the Steering Committee

Any Other Business

GAMP Nordic STEERING COMMITTEE 2008

Anders Bredesen, *Chairman*, YIT Building Systems AS, Norway
Niels Boye Petersen, *Secretary*, Siemens A/S, Building Technologies, Denmark
Hasse Greiner, *Novo Nordisk A/S*, Denmark
Anna Kälvevemark, *Pharmadule AB*, Sweden
Christer Fors, *InformaIT Pharma Solutions*, Sweden
Siri Segalstad, *Segalstad Consulting as*, Norway
Jens Seest, *Novo Nordisk A/S*, Denmark
Peter Werner Christensen, *NNE Pharmaplan*, Denmark
Martin Esping, *Acobia FLUX*, Sweden
Göran Slätt, *Deputy Representative* Honeywell, S

Registration Form

ISPE Nordic Annual Meeting

20 November 2008 – Clarion Sign Hotel, Sweden

Please fax or e-mail to Anneth Rooslien Nilsson, NNE Pharmaplan, before 5 November 2008
Fax + 46 8 59 49 6099 – E-mail AhRN@nnepharmaplan.com, tel +46 8 59 49 60 38

Participant

Name: Mr./ Ms. _____

Title: _____

Company: _____

Street: _____

Zip code: _____ City: _____ Country: _____

Tel.: _____ Fax: _____

E-mail: _____

.. Member of ISPE – Personal Membership No. _____

.. Non-Member of ISPE – Participation must include a 1-year membership of ISPE. An ISPE membership application form must be completed at the event and given to the conference staff or faxed to ISPE Nordic

.. Student / Academia / Regulatory

Please check the session(s) you wish to attend

.. Conference (including lunch and coffee)

.. Annual General Meeting (conference participants and/or members only)

.. GAMP Nordic Annual Meeting

.. Dinner (conference participants and/or members and/or invited guests only)

Please check if you wish to reserve

.. Table Top for exhibition

.. Dinner table (for eight persons) for your company and invited guests

.. Dinner table and (number of) ___ conference seats for invited guests

Fees (payable in DKK)

.. Conference Fee – Member of ISPE: € 220

.. Conference Fee – Non-Member^{*)}: € 410

.. Conference Fee – Academia/Regulatory Member: € 40

.. Conference Fee – Academia/Regulatory Non-Member^{*)}: € 70

.. Conference Fee – Student Member: € 20

.. Conference Fee – Students Non-Member^{*)}: € 35

.. Annual Meeting Dinner including reception: € 65

.. Dinner table for eight persons:

(Discount €100 /person if fewer + €100 p/p if more) € 850

.. Table top Exhibition: € 500

Total due: € _____

^{*)} Includes 1-year membership of ISPE with all membership benefits – please visit www.ispe.org

Payment by

.. An invoice issued to your company is the preferred way of payment.

Please specify invoicing address if different from the above address.

Alternatively one of the following credit cards can be used:

.. Visa Card number: _____ Exp. Date: _____ CVV: _____

.. Master Card number: _____ Exp. Date: _____ CVV: _____

Issuing of invoices and credit card drawn are typically done after completion of the event.

Date: _____ Signature: _____

Please provide an email address for confirmation message.



About ISPE

ISPE (The International Society for Pharmaceutical Engineering) is the world's largest not-for-profit association dedicated to educating and advancing pharmaceutical manufacturing professionals and their industry.

Founded in 1980, today ISPE serves more than 25,000 members in 80 countries.

We are an independent organization led by the world's top pharmaceutical manufacturing professionals. We provide an inviting and neutral environment for experts, technologists, regulators, consultants and students to exchange ideas and practical experience. As a vibrant community, ISPE's members work together to improve the industry, while helping each other make better choices, more quickly than ever before.

In addition to conducting educational conferences and training courses, ISPE also publishes a bi-monthly journal, *Pharmaceutical Engineering*, and a monthly membership newsletter, *ISPEAK*, to keep members abreast of the latest developments in the healthcare technology industries.

ISPE members have worked with the US Food & Drug Administration (FDA) on a variety of projects, which have assisted professionals by enhancing industry practices worldwide. ISPE and FDA collaborations include the SUPAC equipment addendum listing for which both the Agency and ISPE were awarded the Hammer Award by then-Vice President Al Gore's office, and the production of the Pharmaceutical Engineering Baseline® Guide Series. These Guides offer industry professionals a foundation from which to work in interpreting regulatory requirements for facility design and process implementation.

About the Nordic Affiliate

The Nordic affiliate was initiated in 2000. The Affiliate consists of the Nordic countries: Sweden, Norway, Denmark, Finland and Iceland. The Nordic membership has since grown to over 1.000 members with active regional representation in all Nordic countries.

The Nordic Affiliate Board of Directors is made up of the Chairman, Vice Chairman, Treasurer, Secretary, Past Chairman, and elected members. In addition, members can be co-opted for other duties. All members are volunteers and as such many have to fit in their ISPE activities with fulltime jobs. The Nordic Board of Directors meets four to five times per year.

The Nordic Affiliate plans to have eight yearly events with a variety of the key ISPE Nordic focus areas. A visible, local member benefit for ISPE Nordic should include the opportunity to network and share experiences with colleagues in the local area.

www.ispe.org/nordic