



**Nordic
Affiliate**

ENGINEERING
PHARMACEUTICAL
INNOVATION

Invitation to a Conference of ISPE Nordic in Copenhagen – Denmark

Quality by Design,

The conference will give an overview of initiatives globally on Quality by design, Regulatory inspection approach of a product/company working by Quality by design and Case presentations from different companies showing their experience in implementing Quality by design.

Tuesday, 20th May 2008.

Place:

**H.Lundbeck
Ottiliavej 9,
DK 2500 Valby**

ISPE Nordic Conference Quality by Design

Tuesday 20th May 2008

PROGRAMME

- 8:30 – 9:00** **Registration**
- 9:00 – 9:10** **Welcome & Introduction**
Linda Frederiksen, H.Lundbeck, Denmark
- 9:10 – 10:00** **Product Quality Lifecycle Implementation by Bruce Davis, Astrazeneca**
Product Quality Lifecycle Implementation programme (PQLI) deals with practical and pragmatic aspects of implementation of ICH Q8, Q9 and Q10. (Pharmaceutical Development, Risk Management and Quality Systems). Bruce Davis will give information on the background to PQLI and current status of the work as well as providing insight on topic areas of Criticality, Design Space and Control Strategy.
- 10:00 – 10:50** **ASTM by Line Lundsberg-Nielsen, NNE Pharmaplan.**
ASTM is an international standard organisation and the committee E55 on Manufacture of Pharmaceutical Products develops standards that support the pharmaceutical industry in developing and manufacturing high quality pharmaceutical products based on a scientific and risk-based approach, including PAT and QbD.
Line Lundsberg-Nielsen will present the committee E55, approved standards incl. The new Risk Based Verification and Continuous Quality Verification stands, work in progress and the corporation with ISPE.
- 10:50 – 11:20** **Coffee Break**
- 11:20 – 12:10** **ICH Q8/Q9/Q10 by Fritz Erni, Novartis**
Fritz Erni will present the new approach to pharmaceutical development and manufacturing in the context where the paradigm changes from blind compliance to better understanding. Topics as science based approach, increased importance of Quality Risk Management as well as the possibility of reducing cost significantly through product and process understanding will be discussed. Introduction of design space leading to reduced post approval changes as well as control strategies leading to real time release will also be covered.
- 12:10 – 12:40** **EMA's PAT TEAM by Claus Mortensen, Danish Medicines Agency.**
Claus Mortensen will present the status of the work of the EMA PAT Team. The presentation will cover inspections issues in relation to PAT submissions – as well as a discussion on how to improve regulatory compliance to drive Success into PAT processes.
- 12:40 – 13:40** **Lunch**

- 13:40 – 14:30** **Design Space Analytical Methods by Fritz Erni, Novartis**
Fritz Erni will give an introduction to the use of Design Space on Analytical Methods as a tool to better understanding of the analytical methods and how this can support innovation. The presentation will cover the advantages both in the better understanding of the analytical methods as well as the benefits in reduced post approval changes and an optimized technical transfer and know how transfer. Issues as Science based change management and Quality risk management based validation will also be discussed.
- 14:30 – 15:20** **Case API by Lundbeck Employee**
Lundbeck will present a case where Quality by Design have been implemented in the manufacturing of an API. The presentation will cover the challenges and experiences such as use of risk and science based approach in practise, change management and the benefits gained.
- 15:20 - 15:50** **Coffee Break**
- 15:50 – 16:20** **CASE Drug Product**
to be decided
- 16:20 – 16:30** **Closing Words & Feedback**
- 16:30 – 17:00** **Networking reception**

Venue: Auditorium C2,
 H.Lundbeck,
 Ottiliavej 9
 DK 2500 Valby

H.Lundbeck is located very close to Kastrup Airport, just a 15 minutes drive, and approx. 15 minutes from the centre of Copenhagen and the Central Station.

ISPE Nordic Conference

Quality by Design

Tuesday, 20th May 2007 in Copenhagen, Denmark

Registration Form

Please register to Charlotte Givskov, H. Lundbeck A/S before April 22nd, 2008
by e-mail CNGI@lundbeck.com or fax +4536437230

Last Name: Mr./ Mrs. _____ First Name: _____
Title: _____
Company: _____
Street: _____
Area 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 if you wish to reserve

- .. A Certificate of Attendance after the event

Fees (payable in DKK):

.. Member of ISPE:	€	220
.. Non-Member ^{*)} :	€	410
.. Academia/Regulatory Member:	€	40
.. Academia/Regulatory Non-Member ^{*)} :	€	70
.. Student Member:	€	20
.. Students Non-Member ^{*)} :	€	35

^{*)} 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: _____

Cancellation policy:

Substitution can be made up to the day of the event, but please inform ISPE Nordic of the name of the substitute and whether the substitute is a member of ISPE (including membership number). Kindly note that memberships are personal. Cancellation can be done up to two weeks prior to the event. ISPE Nordic reserves the right to issue an invoice for € 100 in handling fee for cancellations less than two weeks prior to the event. ISPE Nordic reserves the right to issue an invoice for the full fee in case of cancellation on the day of the event or if no cancellation request is submitted to ISPE Nordic.

Please provide an e-mail address for confirmation message

For questions call Linda Frederiksen +4536437060 or mail LJF@lundbeck.com
or mail Charlotte Givskov CNGI@lundbeck.com