3rd annual

NORDIC QA FORUM

Hilton Copenhagen Airport
19th of November 2015

THE NATIONAL AUTHORITIES:

Jon Boutelje

Bjørg Abotnes

Annette Byrholt Hansen

Johanna Linnolahti

Few seats left

KEY TOPICS:

- Current GMP & regulatory updates
- How to proceed and become compliant
- Supply chain integrity
- Quality Risk Management
- Methods for enhanced product security
- Transport validation

Chairperson:

AstraZeneca:
Anna Pontén-Engelhardt,
Director Quality Assurance

Speakers:

Swedish Medical Products Agency:
John Boutelje, Pharmaceutical Inspector

Danish Health & Medicines Authority:
Annette Byrholt Hansen, Head of Inspection

Norwegian Medicines Agency:
Bjørg Abotnes, Pharmaceutical inspector

Finnish Medicines Agency:
Johanna Linnolahti, Pharmaceutical Inspector

Oxo Pharma:
Arnaud Huc, Quality Efficiency Industrial Pharmacist

Formpipe GXPi:
Keith Williams

PlantVision:
Linda Pell, Senior Consultant

World Courier:
Michael Fleischer, Global Quality Director

Gold sponsor:

Formpipe.

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The Swedish Life Science Industry Organization
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NORDIC
QA FORUM

Dear Colleague,

There has never been a more relevant time to have a unique platform dedicated to discuss the key challenges that you and your peers are facing in the field of Quality Assurance and Regulatory Affairs.

The Nordic QAforum will give you the the opportunity to :

- Understand how the authorities in Sweden, Denmark, Norway and Finland will interpret the changes.
- Find out best practices.
- Network with other senior QA & RA professionals.
- Learn how to implement the new requirements.

Nordic QAforum is a must-attend conference dedicated to supporting your work in QA and RA by facilitating high-level networking opportunities with your peers and providing leading industry knowledge.

I look forward to meeting you in Copenhagen the 19th of November!

Kind regards,

Niko Fastman
Project Manager Nordic QAforum
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+ 46 (0) 73 6 7 06 032
www.nordicqaforum.com

Our latest QAforum was fully booked early and received the grade 4,22 out of 5.0. Register today to secure your ticket.

Testimonials of our previous QAforum:

"Very good conference. Lots of opportunities to network with colleagues."
Tomas Wahlgren, AstraZeneca

"Fantastic selection of topics and speakers. This was one of the best events I have participated in."

" I appreciated the networking and the opportunity to listen to MPA. Excellent initiativ!"

TARGET AUDIENCE:
The Nordic QAforum is of particular interest to management and personnel from pharmaceutical companies as well as from distributors and service providers involved in quality assurance and regulatory affairs.

LIMITED TICKETS AVAILABLE:
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19TH NOVEMBER 2015

NORDIC QA FORUM

08.30 **Registration, morning coffee & refreshments**

09.00 **Chairperson Anna Pontén-Engelhardts welcome & opening remarks**

Danish Health & Medicines Authority:

09.10 **Current GMP & Regulatory updates**

- How will the updates effect you?
- A Regulator's Advice to Ensuring Compliance

Annette Byrholt Hansen, Head of Inspection, Danish Health & Medicines Authority

Swedish Medical Products Agency:

09.50 **Practical implementation of the new requirements in the EU GMP & GDP**

- Implementation of Quality Risk Management (QRM)
- Supply chain integrity
- What are the challenges for the industry in implementing the new requirements?
- What are the most common deviations?

John Boutelje, Pharmaceutical Inspector, Swedish Medical Products Agency

10.40 **Refreshments & networking break**

Expert presentation:

11.10 **Methods for enhanced product security**

- Serialization/aggregation
  - o What challenges needs to be handled within the business?
  - o How can the requirements of the EU Directive 2011/62 be met?

- Aggregation
  - o What is Aggregation?
  - o What challenges can we anticipate and identify at the production line?

- Validation/QA
  - o Effective validation strategy - how to handle the requirements?

- Wholesaler
  - o What changes in practice to be expected?
  - o Challenges ahead the production line.

Linda Pell, senior consultant, PlantVision

Finnish Medicines Agency:

11.40 **Transport validation - what are the minimal demands on temperature validation**

- Audit of your supply chain suppliers – when is it necessary and how to do it?
- Management of the supply chain
- Temperature monitoring during transportation

Johanna Linnolahti, Senior Pharmaceutical Inspector, Finnish Medicines Agency

12.20 **Lunch & networking break**

Expert presentation:

13.20 **Supplier qualification and regulatory compliance in international biopharm logistics**

Michael Fleischer , Global Quality Director, World Courier

Expert presentation:

13.50 **Quality Efficiency by Design**

- How a business process management approach can improve performance, guarantee inspection readiness of your QMS and reduce doc & training efforts.

Arnaud Huc , Quality Efficiency Industrial Pharmacist, Oxo Pharma part of the Altran group.

ROUNDTABLE DISCUSSION:

14.20 **How to proceed and become compliant?**

14.45 **Refreshments & afternoon networking break**

Expert presentation:

15.20 **GxP regulatory requirements and cloud computing**

- What are the regulatory risks with cloud and how to stay compliant (Annex 11)?
- Which validation approaches should be used?

Keith Williams, Formpipe GXPi

Norweigan Medicines Agency:

15.50 **Regulation of wholesaling**

- Implementation of EU regulation
- What do we expect from a wholesaler?

Bjørg Abotnes, Pharmaceutical inspector, Norwegian Medicines Agency

16.30 **Final Questions to the Speakers**

16.45 **Chairpersons closing remarks**

16.50 **Cocktail reception & networking**

It has been a long day filled with information. Time to relax and enjoy great conversations over drinks.

NORDIC
QA FORUM

3 ways to register:

Website: www.nordicqaforum.com/register

E-mail: kundtjanst@kompetensinstitutet.se

Phone: + 46 (0) 736 706 032

VENUE:

Hilton Copenhagen Airport
Ellehammersvej 20
Copenhagen
Phone nr to the venue:
+45 32 50 15 01

Transport from Copenhagen Airport:
2 min walk through a covered walk-way

Price:

Pharma companies:	7490 SEK

Price for solution providers:

Consultants & solution providers:	9990 SEK

Fully booked in 2013 & 2014. Secure your ticket today!

Lunch, coffee and documentation is included in the price.
All prices are excluding VAT.

LIMITED NUMBER OF TICKETS!
Our latest QAforum was fully booked early.
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KOMPETENS INSTITUTET

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About QAforum:
QAforum, a division of Kompetensinstitutet, provides a forum to address the critical issues facing the Pharmaceutical Industry today. QAforum utilizes workshops and conference formats to facilitate a learning environment for pharmaceutical professionals working within the areas of quality assurance and regulatory affairs.

Term s and Conditions
Payment is required 30 days from the date of invoice. You may substitute delegates at any time by informing QAforum. For any cancellations received in writing not less than fourteen (14) days prior to the conference, you will receive a 90% credit of the invoiced amount to be used at another Kompetensinstitutet conference which must occur within two years from the date of issuance of such credit. No credit will be issued for any cancellations occurringwithin thirteen (13) days of the conference. In the event that Kompetensinstitutet cancels an event for any reason, you will receive a complete refund.