4th annual

NORDIC QA FORUM

Hilton Copenhagen Airport
17th of November 2016

THE NATIONAL AUTHORITIES:

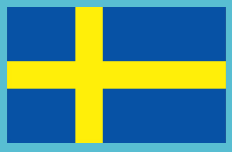

Sigríður Ólafsdóttir

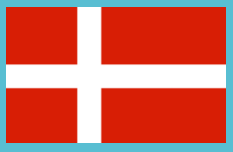
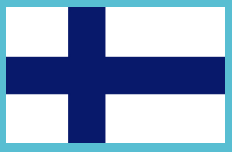

Javad Mohammadnejad


Bjørg Abotnes


Claus Mortenssen


Anne Junttonen

KEYNOTE SPEAKER:

"Practical implementation of the Falsified Medicines Directive and Delegated Regulation"

Anci Kvarnström:
Project leader for the Swedish Implementation & Consultant for EFPIA

KEY TOPICS:

- Current GMP/GDP & regulatory updates
- Annex 16 – How will the updates effect you?
- How the authorities expect pharmaceutical manufacturers and wholesale distributors to work to prevent and detect fraud – both proactive and reactive in production and distribution

Speakers:

Swedish Medical Products Agency:
Javad Mohammadnejad, Inspector GMP/GDP

Danish Health & Medicines Authority:
Claus Mortenssen, Inspector

Norwegian Medicines Agency:
Bjørg Abotnes, Pharmaceutical inspector

Finnish Medicines Agency:
Anne Junttunen, Chief Inspector

PlantVision:
Lina Stange, senior consultant

Icelandic Medicines Agency:
Sigríður Ólafsdóttir, Head of Inspection

Anci Kvarnström:
Project leader for the Swedish, Implementation & Consultant for EFPIA

ÅF Industry:
Ann Weidensjö, senior quality & validation lead consultant
Anna Sumic, consultant

Recipharm:
Staffan Widegren, Director of Corporate Projects

Swedish Orphan Biovitrum:
Eva Hanö, Project Manager
Ginger Nikolaev, Project Manager

Gold sponsor:

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LIF – de forskande läkemedelsföretagen

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.

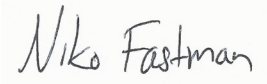
The Nordic QAforum will give you the the opportunity to :

- Understand how the authorities in Sweden, Denmark, Norway, Iceland 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 17th of November!

Kind regards,



Niko Fastman
Project Manager Nordic QAforum
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Our latest QAforum was fully booked early and received the grade 4,27 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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Register today to secure your ticket.

17TH NOVEMBER 2016

NORDIC QA FORUM

08.30 **Registration, morning coffee & refreshments**

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

Danish Health & Medicines Authority:

09.05 **Current GMP & Regulatory updates**

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

Claus Mortensen, Inspector,
Danish Health & Medicines Authority

Icelandic Medicines Agency:

09.30 **How we expect pharmaceutical manufacturers and wholesale distributors to work to prevent and detect fraud – both proactive and reactive in production and distribution**

Sigridur Ólafsdóttir, Head of Inspection,
Icelandic Medicines Agency

Expert presentation:

10.10 **Continued Process Verification – Developing a Monitoring Strategy and Maintaining a State of Control**

Ann Weidensjö, Senior Quality & Validation Lead Consultant &
Anna Sumic, Consultant, ÅF Industry AB

10.40 **Refreshments & networking break**

Expert presentation:

11.10 **Practical implementation of the Falsified Medicines Directive and Delegated Regulation**

- Obligations for different stakeholders
- Functionality of the national systems and the EU Hub
- Implementation – who is doing what?

Anci Kvarnström, Project leader for the Swedish Implementation & Consultant for EFPIA

Case study:

12.00 **The bumpy road of Serialization – an ongoing travel**

Eva Hanö, Project Manager & **Ginger Nikolaev,** Project Manager
Swedish Orphan Biovitrum

12.30 **Questions to the speakers**

12.45 **Lunch & networking break**

Case study:

13.40 **Embracing best practice to exceed customer expectations: yesterday, today and tomorrow**

Staffan Widegren, Director of Corporate Projects, Recipharm

Expert Presentation:

14.10 **Data Integrity**

- How to identify & define an Electronic Record?
- How to create value during your contemporary effort to identify, plan and implement changes to ensure the requirements of Data Integrity?
- Examples of established technical solutions for regulated areas in Supply Chain - Production, Laboratory (QC).

Lina Stange, senior consultant, PlantVision

Swedish Medical Products Agency:

14.40 **Annex 16 – How will the updates effect you?**

Javad Mohammadnejad, Inspector GMP/GDP,
Swedish Medical Products Agency

15.20 **Refreshments & afternoon networking break**

Finnish Medicines Agency:

15.50 **How to handle shortage risk of medicines in GMP non-compliance situations**

- assessing the criticality of the affected products
- the communication between pharma companies and their customers (users and prescribers)

Anne Junttunen, Senior Pharmaceutical Inspector,
Finnish Medicines Agency

Norwegian Medicines Agency:

16.20 **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?
- Authority examples from audits

Bjørg Abotnes, Pharmaceutical inspector,
Norwegian Medicines Agency

16.50 **Final Questions to the Speakers**

17.05 **Chairpersons closing remarks**

17.10 **Cocktail reception & networking**
It has been a long day filled with information. Time to relax and enjoy great conversations over drinks.

The latest Nordic QAforum was sold out and received the grade 4,27 out of 5.0.

Register here: www.nordicqaforum.com

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

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.
Secure your ticket today.

Fully booked in 2012, 2013 & 2014. Secure your ticket today!

KOMPETENS INSTITUTET

Our latest QAforum was sold out and received the grade 4,27 out of 5.0.

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 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.