



NORDIC QAFORUM

Clarion Hotel Copenhagen Airport
14th of November 2018

THE NATIONAL AUTHORITIES:



Emil
Schwan



Line
Saxegaard



Kristine
Frederiksen



Mervi
Saukkosaari



KEYNOTE SPEAKERS:



"Delegated Regulation soon in force:
- Are we ready?
- What can we learn from the pilots?"

Anci Kvarnström:

Project leader for the Swedish
Implementation & Consultant for EFPIA



"International Inspections
- Lessons Learned"

Tor Gråberg:

Head of Operations Quality Compliance
and External Affairs, AstraZeneca

Speakers:

Swedish Medical Products Agency:

Emil Schwan
Inspector GMP/GDP

Danish Medicines Agency:

Kristine Frederiksen
Medicines Inspector

Norwegian Medicines Agency:

Line Saxegaard
Pharmaceutical inspector

Finnish Medicines Agency:

Mervi Saukkosaari
Senior Pharmaceutical Inspector, head of section

Anci Kvarnström:

Project leader for the Swedish,
Implementation & Consultant for EFPIA

AstraZeneca:

Tor Gråberg
Head of Operations Quality Compliance
and External Affairs

Few tickets left

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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 14th of November!

Kind regards,

Niko Fastman
Project Manager Nordic QAforum
niko.fastman@kompetensinstitutet.se
+ 46 (0) 73 6 7 06 032

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 initiative!"

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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08.30 Registration, morning coffee & refreshments

09.00 Chairperson Anna Pontén Engelhardt welcome & opening remarks

Danish Medicines Agency:

09.15 Current GMP and Regulatory updates

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

Kristine Frederiksen, Medicines Inspector, Danish Medicines Agency

10.00 Refreshments & networking break

Expert presentation:

10.30 Delegated Regulation 161/2016 soon in force - are we ready?

- Obligations for different stakeholders
- Functionality of the national systems and the EU Hub
- Implementation - who is doing what?
- What can we learn from the pilots?

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

Swedish Medical Products Agency:

11.20 Serialization - how we will inspect

- What to expect from the authorities regarding supervision of serialization

Emil Schwan, Inspector GMP/GDP, Swedish Medical Products Agency

12.00 Questions to Emil Schwan & Anci Kvarnström E-mail your questions to: info@qaforum.se

12.20 Lunch & networking break

Finnish Medicines Agency:

13.20 Risk management through the product life-cycle

Mervi Saukkosaari, Senior Pharmaceutical Inspector & head of section, Finnish Medicines Agency

Expert presentation:

14.00 International Inspections Lessons Learned

- How to convert audit learnings into robust and sustainable knowledge
- How can we improve our way of working

Tor Gråberg, Head of Operations Quality Compliance and External Affairs, AstraZeneca

Before joining AstraZeneca in 2015 Tor Gråberg worked 11 years as the Chief Pharmaceutical Inspector at Swedish Medical Products Agency.

15.00 Refreshments & afternoon networking break

Norwegian Medicines Agency:

15.40 GDP/GMP - Which are the most common deviations?

Line Saxegaard, Pharmaceutical inspector, Norwegian Medicines Agency

16.30 Final Questions to the Speakers

17.00 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.

Pre-conference networking:

If you arrive on Tuesday - feel free to attend the informal pre-conference networking at Clarions Axis Bar and Lounge starting at 20.00. Hosted by Controlant and Nordic Qaforum.





NORDIC QA FORUM

3 ways to register:

Website: www.nordicqaforum.com/register

E-mail: kundtjanst@kompetensinstitutet.se

Phone: +46 (0) 8 23 03 73

VENUE:

Clarion Hotel 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

Previous called "Hilton Copenhagen
Airport"

Price:

Pharma companies: 7990 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
the last four years.

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.

Terms and Conditions

Payment is required 30 days from the date of invoice. The booking is binding after you received a confirmation of the booking. 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 occurring within thirteen (13) days of the conference. In the event that Kompetensinstitutet cancels an event for any reason, you will receive a complete refund.