



NORDIC QAFORUM

Clarion Hotel Copenhagen Airport
14th of November 2019

THE NATIONAL AUTHORITIES:



Emil Schwan



Line Saxegaard



Jon Petur Gudmundsson



Thomas Noe Vestergaard Pedersen



Mirka Laavola



Keynote speakers:



"9 months after 9th of February - current status in Europe"

Kristina von Sydow:
e-VIS



"FMD Implementation – Best practices from AstraZeneca"

Roland Gustafsson:
QA Director, QP
QA Lead for FMD implementation globally for AstraZeneca

Speakers:

Swedish Medical Products Agency:
Emil Schwan
Inspector GMP/GDP

Danish Medicines Agency:
Thomas Noe Vestergaard Pedersen
Medicines Inspector & Team manager

Norwegian Medicines Agency:
Line Saxegaard
Pharmaceutical inspector

Finnish Medicines Agency:
Mirka Laavola
Senior Pharmaceutical inspector

Icelandic Medicines Agency:
Jon Petur Gudmundsson
Inspector

e-VIS:
Kristina von Sydow
CEO

AstraZeneca:
Roland Gustafsson
QA Director, QP

Fully booked six years in a row.
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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, Iceland, 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 & Qaforum
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niko.fastman@kompetensinstitutet.se

Our latest QAforum was fully booked early and received the grade 4,49 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 How to survive an authority inspection - a practical guide

Thomas Noe Vestergaard Pedersen, Medicines Inspector & Team Manager, Danish Medicines Agency

Before joining Danish Medicines Agency in 2013, Thomas worked for 12 years as a manager/director at the Danish pharmaceutical company Statens Serum Institute (now AJ Vaccines).

10.00 Refreshments & networking break

Expert presentation:

10.30 9 months after 9th of February- current status in Europe

- On-boarding to EU Hub
- How to manage a "potential suspect falsification"
- Alert status & alert handling process
- What can we learn and do better?

Kristina von Sydow, CEO, e-Vis

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

12.30 Questions to the speakers

12.45 Lunch & networking break

Norwegian Medicines Agency:

13.45 Serialization in Norway - actual status from the Medicines Agency

Line Saxegaard, Pharmaceutical inspector, Norwegian Medicines Agency

Finnish Medicines Agency:

14.20 Data Integrity and Computerised Systems - recent deficiencies in inspections

Mirka Laavola, Senior Pharmaceutical Inspector, Finnish Medicines Agency

15.00 Refreshments & afternoon networking break

Case study:

15.30 FMD Implementation - Best practices from AstraZeneca

Roland is the QA Lead for FMD implementation globally for AstraZeneca. 13 sites around the world were involved in the process. 2000 articles were affected by FMD.

Roland Gustafsson, QA Director, QP, AstraZeneca

Icelandic Medicines Agency:

16.15 GDP/GMP - the most common deviations

Jon Petur Gudmundsson, Pharmaceutical inspector, Icelandic Medicines Agency

16.55 Final Questions to the Speakers

17.10 Chairpersons closing remarks

17.15 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 Wednesday - 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

Price:

**REGISTER BEFORE
24th of May**

Pharma companies: 7990 DDK

5490 DDK

Price for solution providers:

Consultants & solution providers: 8990 DDK

Lunch, coffee, networking reception and documentation is included in the delegate fee.

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received the grade 4,49 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

You can pay by invoice or by creditcard. Payment is required 30 days from the date of invoice. All prices are excluding VAT. 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.