7th annual

NORDIC QA FORUM

Clarion Hotel Copenhagen Airport
14th of November 2019

THE NATIONAL AUTHORITIES:


Anna Beckman Gyllenstrand

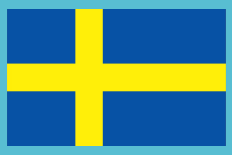
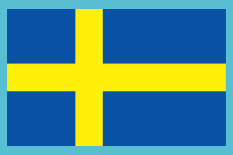

Emil Schwan

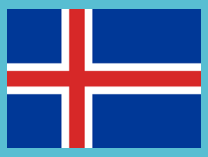
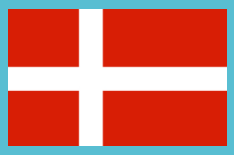

Line Saxegaard


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"

Anna Berg:
QA Director, QP
AstraZeneca

Rickard Collin:
Project Manager
Supply Chain
AstraZeneca

Fully booked
six years in a row.

Secure your
ticket today!

Speakers:

Swedish Medical Products Agency:
Emil Schwan
Inspector GMP/GDP
Anna Beckman Gyllenstrand
Inspector

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:
Anna Berg
QA Director, QP
Rikard Collin
Project manager

Sponsors:

STI FREIGHT MANAGEMENT

Controlant

Partners

The Swedish Life Science Industry Organization swedenBIO

LIF – de forskande läkemedelsföretagen

NORDIC
QAFORUM

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.

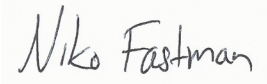
The Nordic QAforum will give you the the opportunity to :

- 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
+ 46 (0) 73 6 7 06 032
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 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:
Our latest QAforum was fully booked early and received the grade 4,49 out of 5.0.
Register today to secure your ticket.

14TH NOVEMBER 2019

NORDIC QA FORUM

08.30 **Registration, morning coffee & refreshments**

09.00 **Chairperson Anna Pontén Engelhardts 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 &
Anna Beckman Gyllenstrand, Inspector,
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**

13 sites around the world were involved in the process.
2000 articles were affected by FMD.

Anna Berg, QA Director, QP, AstraZeneca
Rikard Collin, Project Manager supply chain, 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

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:

Few tickets left

Pharma companies:	7490 DKK

Price for solution providers:

Consultants & solution providers:	9490 DKK

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

LIMITED NUMBER OF TICKETS!
Our latest QAforum was fully booked early.
Secure your ticket today.

Fully booked six years in a row.

Secure your ticket today!

KOMPETENS INSTITUTET

Our latest QAforum was sold out and 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 occurringwithin thirteen (13) days of the conference. In the event that Kompetensinstitutet cancels an event for any reason, you will receive a complete refund.