9th annual

NORDIC QA FORUM

Clarion Hotel Copenhagen Airport
18th of November 2021

THE NATIONAL AUTHORITIES:

Anna Beckman Gyllenstrand

Hjalti Kristinsson

Line Saxegaard

Thomas Noe Vestergaard Pedersen

Pirjo Hänninen

Specially invited:

"FMD – current status in Europe"

Kristina von Sydow:
e-VIS

- GDP/GMP – the most common deviations

-Control of IT-systems – from an authority perspective

- How to survive an authority inspection

We offer live stream.

Speakers:

Swedish Medical Products Agency:
Anna Beckman Gyllenstrand, Inspector

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

Finnish Medicines Agency:
Pirjo Hänninen
Senior Pharmaceutical inspector

Icelandic Medicines Agency:
Hjalti Kristinsson
Head Of Drug Safety Division

Norwegian Medicines Agency:
Line Saxegaard
Pharmaceutical inspector

e-VIS:
Kristina von Sydow
CEO

RegSmart Life Sciences:
Emil Schwan
Quality consultant, former inspector

Valneva:
Anna Pontén-Engelhardt
VP Quality

AstraZeneca:
Anna Berg
Director Of Quality, Global Supplier Quality (GES) EMEA

Sponsors:

STI FREIGHT MANAGEMENT

Controlant

Partners

The Swedish Life Science Industry Organization sweden BIO

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.

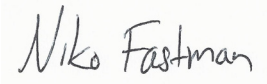
The Nordic QAforum will give you the the opportunity to :

- 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 the 18th of November!

Kind regards,



Niko Fastman
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Our latest QAforum was fully booked early and received 4,49 rating 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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18TH NOVEMBER 2021

NORDIC QA FORUM

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

Expert presentation:
09.20 **FMD – current status in Europe**

– Alert management – real cases and investigations. What happens when the system identifies a potential falsification?

– Latest news: European alert management guidelines & the alert Management system

– Covid-19 vaccines and alerts

Kristina von Sydow, CEO, e-Vis

Danish Medicines Agency:
10.10 **Control of IT-systems – from an authority perspective**

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).

10.45 **Questions to the speakers**

11.00 **Coffee break**

Icelandic Medicines Agency:
11.25 **GDP/GMP – the most common deviations**

– Deviations & findings that surprised us

Hjalti Kristinsson, Head Of Drug Safety Division, Icelandic Medicines Agency

Case study:
12.00 **Development of a Covid vaccine – best practices and lessons learned**

Anna Pontén-Engelhardt, VP Quality, Valneva

12.35 **Questions to the speakers**

12.45 **Lunch**

Finnish Medicines Agency:
13.45 **Remote Inspections / Distant Assessments during pandemic and post pandemic**

– Deviations & findings that surprised us

Pirjo Hänninen, Senior Pharmaceutical Inspector, Finnish Medicines Agency

Case study:
14.20 **End to end quality management – from development to commercialization**

Anna Berg, Director Of Quality, Global Supplier Quality (GES) EMEA, AstraZeneca

Emil Schwan, Quality consultant, former inspector, RegSmart

Emil was previously an inspector at the Swedish Medical Products Agency between 2012 and 2020. He has carried out more than 200 inspections in several different countries.

15.00 **Questions to the speakers**

15.10 **Coffee break**

Swedish Medical Products Agency:
15.35 **Inspections – what you can expect from us**

– What to expect from the authorities regarding supervision of serialization
– GDP/GMP – the most common deviations
– Deviations & findings that surprised us

Anna Beckman Gyllenstrand, Inspector, Swedish Medical Products Agency

Norwegian Medicines Agency:
16.15 **Serialization & Inspection**

Line Saxegaard, Pharmaceutical inspector, Norwegian Medicines Agency:

16.45 **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.

Would you be interested in a live stream? Please contact: niko.fastman@kompetensinstitutet.se

NORDIC QA FORUM

NORDIC
QA FORUM

3 ways to register:

Website: www.nordicqaforum.com/register

E-mail: kundtjanst@kompetensinstitutet.se

Phone: + 46 (0) 8 20 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 20/8! Save 500 kr

Pharma companies:	7990 DKK	**7490 DKK**

Price for solution providers:

Consultants & solution providers:	9490 DKK

Would you be interested in a live stream?
Please contact: niko.fastman@kompetensinstitutet.se

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.

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