



# NORDIC QAFORUM

Clarion Hotel Copenhagen Airport  
18th of November 2021

## THE NATIONAL AUTHORITIES:



Virve Reiman-Suijkerbuijk



Hjalti Kristinsson



Line Saxegaard



Thomas Noe Vestergaard Pedersen



Siv Jantunen



## Specially invited:



"FMD – current status in Europe"

Kristina von Sydow:  
e-VIS

## Speakers:

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

**Finnish Medicines Agency:**  
Siv Jantunen  
Senior Pharmaceutical inspector

**Icelandic Medicines Agency:**  
Hjalti Kristinsson  
Manager/Inspector, GxP inspections and supply

**Norwegian Medicines Agency:**  
Line Saxegaard  
Pharmaceutical inspector

**Swedish Medical Products Agency:**  
Virve Reiman-Suijkerbuijk  
Chief Inspector

**e-VIS:**  
Kristina von Sydow  
CEO

**Valneva:**  
Anna Pontén-Engelhardt  
VP Quality

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

- GDP/GMP – the most common deviations
- Control of IT-systems – from an authority perspective
- How to survive an authority inspection

We offer  
live stream.

## Sponsors:



## Partners





# 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  
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 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 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:

Our latest QAforum was fully booked early and received the grade 4,49 out of 5.0. Register today to secure your ticket.

08.30 Registration, morning coffee & refreshments

09.15 Chairperson Anna Pontén Engelhardt  
welcome & opening remarks

#### Expert presentation:

09.25 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

10.15 Questions to Kristina von Sydow

10.30 Coffee break & networking

#### Icelandic Medicines Agency:

11.00 GDP/GMP – the most common deviations

– Deviations & findings that surprised us

**Hjalte Kristinsson**, Manager/Inspector, GxP inspections and supply, Icelandic Medicines Agency

#### Danish Medicines Agency:

11.35 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).

12.10 Questions to Hjalte and Thomas

12.20 Lunch

#### Case study:

13.20 Development of a Covid vaccine – opportunities, challenges and lessons learned

**Anna Pontén-Engelhardt**, VP Quality, Valneva

#### Case study:

14.00 Supplier quality oversight in external supply

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

14.40 Coffee break & networking

#### Swedish Medical Products Agency:

15.10 Current GMP & Regulatory updates

**Virve Reiman-Suijkerbuijk**, Chief Inspector, Swedish Medical Products Agency

#### Finnish Medicines Agency:

15.25 Remote Inspections / Distant Assessments during pandemic and post pandemic

– Deviations & findings that surprised us

**Siv Jantunen**, Senior Pharmaceutical Inspector, Finnish Medicines Agency

#### Norwegian Medicines Agency:

16.00 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.

## Pre-conference networking:

If you arrive on Wednesday - welcome to the informal pre-conference networking at Clarions Bar starting at 20.00. Hosted by Controlant and Nordic Qaforum.

## Would you be interested in a live stream?

Please contact:  
niko.fastman@kompetensinstituttet.se

## 2022 dates:

– Qaforum, 6h of April (Sthlm)  
[www.qaforum.se](http://www.qaforum.se)

– Nordic Qaforum, 17th of November (Cph)  
[www.nordicqaforum.com](http://www.nordicqaforum.com)



# NORDIC QA FORUM

## 3 ways to register:

**Website:** [www.nordicqaforum.com/register](http://www.nordicqaforum.com/register)

**E-mail:** [kundtjanst@kompetensinstitutet.se](mailto: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:

7990 DKK

## Interested in a Live stream?

Please contact: [niko.fastman@kompetensinstitutet.se](mailto:niko.fastman@kompetensinstitutet.se)



KOMPETENS  
INSTITUTET

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### 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

In the event that Kompetensinstitutet cancels an event for any reason, you will receive a complete refund.

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. Kompetensinstitutet reserves the right to change date, format or to cancel an event. Complete terms & conditions: [www.kompetensinstitutet.se/villkor/](http://www.kompetensinstitutet.se/villkor/)