



# NORDIC QAFORUM

Clarion Hotel Copenhagen Airport  
12th of November 2020

## THE NATIONAL AUTHORITIES:



Anna Beckman  
Gyllenstrand



Mihai-Andrei  
Florescu



Jon Petur  
Gudmundsson



Thomas Noe  
Vestergaard Pedersen



Mirka  
Laavola



## Specially invited:



" 21 months with FMD -  
current status in Europe"

**Kristina von Sydow:**  
e-VIS

## Speakers:

### Swedish Medical Products Agency:

Mihai-Andrei Florescu  
Inspector GMP/GDP

Anna Beckman Gyllenstrand  
Inspector

### Danish Medicines Agency:

Thomas Noe Vestergaard Pedersen  
Medicines Inspector & Team manager

### Finnish Medicines Agency:

Mirka Laavola  
Senior Pharmaceutical inspector

### Icelandic Medicines Agency:

Jon Petur Gudmundsson  
Inspector

### e-VIS:

Kristina von Sydow  
CEO

- GDP/GMP – the most common deviations
- Annex 1 – How will it affect you
- How to survive an authority inspection 2021, a practical guide

**EARLY BIRD**  
Save 500kr  
Register by 18th of Sept.

## 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, 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 in Copenhagen the 12th 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.

08.45 Registration, morning coffee & refreshments

09.15 Chairperson Anna Pontén Engelhardt welcome & opening remarks

Expert presentation:

09.25 21 months with FMD- current status in Europe

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

- Alert management around Europe. Similarities and differences. Could there be one alert management process for whole Europe?

- Change management for a pan-european system. How do you handle change management for one eco-system with 30 systems owners?

Kristina von Sydow, CEO, e-Vis

10.25 Questions to Kristina von Sydow, e-Vis

10.40 Refreshments & networking break

Danish Medicines Agency:

11.10 How to survive an authority inspection 2021 - 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).

12.15 Lunch & networking break

Swedish Medical Products Agency:

13.15 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

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

14.20 Questions to the speakers

14.40 Refreshments & afternoon networking break

Finnish Medicines Agency:

15.10 Annex 1 – How will it affect you

- Deviations & findings that surprised us

Mirka Laavola, Senior Pharmaceutical Inspector, Finnish Medicines Agency

Icelandic Medicines Agency:

16.00 GDP/GMP – the most common deviations

- Deviations & findings that surprised us

Jon Petur Gudmundsson, Pharmaceutical inspector, Icelandic Medicines Agency

16.30 Final Questions to the Speakers

17.00 Chairpersons closing remarks

Early bird discount available!

Please read the last page of this PDF

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](http://www.nordicqaforum.com/register)

**E-mail:** [kundtjanst@kompetensinstitutet.se](mailto: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 by  
18th of September  
6990 DKK**

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.

## Would you be interested in a live stream?

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

Fully booked  
7 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

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/)