8th annual

NORDIC QA FORUM

12th of November 2020

THE NATIONAL AUTHORITIES:


Anna Beckman Gyllenstrand

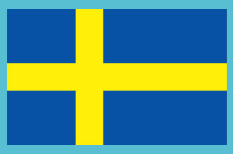
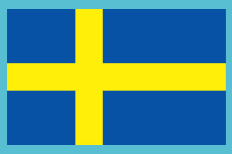

Mihai-Andrei Florescu

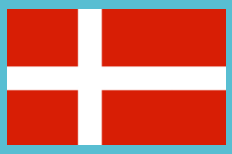
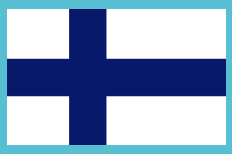

Hjalti Kristinsson


Line Saxegaard


Thomas Noe Vestergaard Pedersen


Pirjo Hänninen

Specially invited:

" 21 months with FMD - current status in Europe"

Kristina von Sydow:
e-VIS

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

We offer live stream.

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:
Hjalti Kristinsson
Head Of Drug Safety Division

Norwegian Medicines Agency:
Line Saxegaard
Pharmaceutical inspector

e-VIS:
Kristina von Sydow
CEO

Ipsos MORI:
Kelly Beaver
Managing Director

Controlant:
Ada Pálmadóttir
Director of Pharmaceutical Validation and Compliance

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.

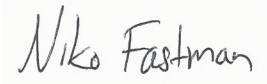
The Nordic QAforum will give you the the opportunity to :

- 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 12th of November!

Kind regards,



Niko Fastman
Project Manager Nordic QAforum & Qaforum
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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:
Our latest QAforum was fully booked early and received the grade 4,49 out of 5.0.
Register today to secure your ticket.

12TH NOVEMBER 2020

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

Expert presentation:

09.20 **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

10.15 **Questions to Kristina von Sydow, e-Vis**

10.30 **Monitoring the quality of COVID-19 test kits with real-time visibility technology**

Kelly Beaver, Managing Director, Ipsos MORI
Ada Pálmadóttir, MPharm, MBA, Director of pharmaceutical validation and compliance, Controlant

11.00 **Coffee break**

Icelandic Medicines Agency:

11.20 **GxP Inspections during Covid19 pandemic – adapting to a new reality**

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

11.50 **Questions to the speakers**

12.20 **Lunch**

13.10 **End2End visbility of your cold chain**

Ulf Svanstam, Managing Director, STI Freight Management

Danish Medicines Agency:

13.20 **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).

Finnish Medicines Agency:

14.00 **Annex 1 – How will it affect you**

– Deviations & findings that surprised us

Pirjo Hänninen, Senior Pharmaceutical Inspector, Finnish Medicines Agency

14.35 **Questions to the speakers**

14.50 **Coffee break**

Swedish Medical Products Agency:

15.15 **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

Mihai-Andrei Florescu, Inspector GMP/GDP &
Anna Beckman Gyllenstrand, Inspector,
Swedish Medical Products Agency

Norwegian Medicines Agency:

16.15 **Q&A**

– Ask your questions to Norwegian Medicines Agency

Line Saxegaard, Pharmaceutical inspector,
Norwegian Medicines Agency:

16.35 **Final Questions to the Speakers**

17.00 **Chairpersons closing remarks**

Next Nordic Qaforum (Copenhagen):
18 november 2021

Next Qaforum (Stockholm):
5 maj 2021

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

Price:

Pharma companies:	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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