10th annual

NORDIC QA FORUM

Clarion Hotel Copenhagen Airport
24th of November 2022

THE NATIONAL AUTHORITIES:

Emil Schwan

Jón Pétur Guðmundsson

Line Saxegaard

Thomas Noe Vestergaard Pedersen

Eija Harjuketo

Specially invited:

"Development of audits and inspections – today and for the future"

Tor Gråberg:
AstraZeneca

- GDP/GMP – the most common deviations
- Annex 1 & Annex 21 – how to remain complient
- How to survive an authority IT-inspection

+ much more

We offer live stream

Speakers:

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

Finnish Medicines Agency:
Eija Harjuketo
Senior Pharmaceutical inspector

Icelandic Medicines Agency:
Jón Pétur Guðmundsson
Inspector

Norwegian Medicines Agency:
Line Saxegaard
Pharmaceutical inspector

Swedish Medical Products Agency:
Emil Schwan
Inspector GMP/GDP

e-VIS:
Kristina von Sydow
CEO

AstraZeneca:
Tor Gråberg
Head of Operations Quality Compliance & External Affairs

Novo Nordisk Norway AS:
Bjørg Abotnes
Head of Quality & Compliance

Partners:

Controlant

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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, 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 24th of November!

Kind regards,

Niko Fastman

Niko Fastman
Project Manager Nordic QAforum & Qaforum
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Our latest Nordic Qaforum received the overall rating 4,12 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 4,12 out of 5.0.
Register today to secure your ticket.

24TH OF NOVEMBER 2022

NORDIC QA FORUM

08.30 **Registration, morning coffee & refreshments**

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

Icelandic Medicines Agency:

09.20 **Annex 21**

– How remain compliant when Annex 21 comes into effect?

Jón Pétur Guðmundsson, Inspector, Icelandic Medicines Agency

FMD:

09.55 **Falsified Medicinces Directive – implementation, business as usual or heading to the future?**

– What do we see in the future of the EMVS and how will this impact the Nordic countries and the stakeholders in the Nordic countries?
– How can the Nordics impact the evolution of the EMVS?
– What evolution do we wish to see for the EMVS?

Kristina von Sydow, CEO, e-Vis

10.20 **Questions Jón Pétur & Kristina**

10.30 **Coffee break & networking**

Finnish Medicines Agency:

10.55 **Annex 1 and the new revision**

– How remain compliant when Annex 1 comes into effect?

Eija Harjuketo, Senior Pharmaceutical Inspector, Finnish Medicines Agency

Danish Medicines Agency:

11.30 **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 Eija and Thomas**

12.20 **Lunch**

Expert presentation:

13.20 **Development of audits and inspections – today and for the future**

Tor Gråberg, Head of Operations Quality Compliance and External Affairs, AstraZeneca

Norwegian Medicines Agency:

14.00 **Quality risk management and how to apply within GDP**

Line Saxegaard, Pharmaceutical inspector, Norwegian Medicines Agency:

14.40 **Questions to Tor and Line**

14.50 **Coffee break & networking**

Case study:

15.20 **Drug shortages – challenges and lessons learned**

– Trust between pharma companies and Health authorities
– Increasingly challenging supply situation
– Learnings during the pandemic

Bjørg Abotnes , Head of Quality & Compliance, Novo Nordisk Norway AS

Swedish Medical Products Agency:

15.55 **Deviations & findings 2019-2022**

Emil Schwan, Inspector GMP/GDP, Swedish Medical Products Agency

16.40 **Final Questions to the Speakers**

17.05 **Chairpersons closing remarks**

17.10 **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.

Interested in a live stream?
Please contact:
kundtjanst@kompetensinstitutet.se

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 19th of August!
Save 500 DKK

Nordic Qaforum 24th of November 2022:	7990 DKK	**7490 DKK**

Interested in a Live stream?

Please contact: kundtjanst@kompetensinstitutet.se

KOMPETENS INSTITUTET

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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