



NORDIC QAFORUM

Clarion Hotel Copenhagen Airport
November 23rd, 2023

THE NATIONAL AUTHORITIES:



Peter Borgå



Margrét Lilja Heiðarsdóttir



Eva Tollefsen



Thomas Noe Vestergaard Pedersen



Minna Kurronen



Specially invited:



"The challenges for MAH"

Tor Gråberg:
AstraZeneca

Speakers:

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

Finnish Medicines Agency:
Minna Kurronen
Senior Pharmaceutical inspector

Icelandic Medicines Agency:
Margrét Lilja Heiðarsdóttir
Expert in the Inspection and Supply Unit

Norwegian Medicines Agency:
Eva Tollefsen
Pharmaceutical inspector

Swedish Medical Products Agency:
Peter Borgå
Pharmaceutical inspector

e-VIS:
Kristina von Sydow
CEO

AstraZeneca:
Tor Gråberg
Head of Operations Quality Compliance & external affairs

Anna Berg
Head of Operational Excellence & QMS, External Quality

NorthX Biologics:
Karolina Nordin
Head of Quality Assurance, QP

- GDP/GMP – the most common findings
- Annex 1 – how to remain compliant
- GDP - What are the most important requirements to focus on in 2023/2024?

+ much more

We offer
live stream

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 in November!

Kind regards,

Niko Fastman
Project Manager Nordic QAforum & Qaforum
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**Our latest Nordic Qaforum received the overall rating 4,51 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 4,51 out of 5.0.
Register today to secure your ticket.

08.30 Registration, morning coffee & refreshments

09.15 Chairperson Anna Pontén Engelhardtts
welcome & opening remarks

Icelandic Medicines Agency:

09.20 Drug shortages and guidelines for reporting to
authorities

Margrét Lilja Heiðarsdóttir, expert in the Inspection and Supply
Unit, Icelandic Medicines Agency

Expert presentation:

09.50 Keeping on top of regulations - GDP

- Differences and similarities in the Good Distribution practices for Medicinal products for human use and Veterinary medicinal products
- What are the most important requirements to focus on in 2023/2024?
- How does the changes impact YOU as Wholesaler or Responsible Person?

Anna Berg, Head of Operational Excellence & QMS, External Quality,
Astra Zeneca

10.20 Questions to the speakers

10.30 Coffee break & networking

Norwegian Medicines Agency:

11.00 Computerized systems in GDP-inspections,
approach, challenges and experiences

Eva Tollefsen, Pharmaceutical inspector,
Norwegian Medicines Agency

Finnish Medicines Agency:

11.30 GDP – the most common findings

Minna Kurronen, Senior Pharmaceutical Inspector,
Finnish Medicines Agency

FMD:

12.00 Falsified Medicines Directive, Substandard Medicines
and Quality Deficiencies

- What is the difference between a falsified medicine and a quality deficiency?
- Can the EMVS be used to ensure quality in the entire supply chain?
- Could the system in addition to the initial purpose be used to simplify the supply chain and increase quality?

Kristina von Sydow, CEO, e-Vis

12.25 Questions to the speakers

12.40 Lunch

Expert presentation:

13.35 The challenges for MAH

- European Medicines Agency reflection paper
- Being an MAH

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

Case study:

14.15 Annex 1 – How do we stay compliant?

- Practical experiences from implementation of EU-GMP Annex 1 at a manufacturing site

Karolina Nordin, Head of Quality Assurance & QP, NorthX Biologics

14.45 Questions to the speakers

15.00 Coffee break & networking

Danish Medicines Agency:

15.30 Recall case in Denmark and Iceland 2023

- This talk will present a complex recall case in 2023, involving recall of pharmaceuticals in Denmark and Iceland. Including following topics:
- Collaboration between EU authorities
 - Handling the press
 - Case evaluation in EMA-IWG and OMCL

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).

Swedish Medical Products Agency:

16.00 How to survive a QC laboratory inspection

Peter Borgå, Pharmaceutical Inspector,
Swedish Medical Products Agency

16.50 Final Questions to the Speakers

17.15 Chairpersons closing remarks

17.20 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.

Interested in a live stream?

Please e-mail:
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:

Nordic Qaforum November 23rd 2023: 7990 DKK

Lunch, coffee, networking reception evening before the conference, networking reception after the conference, documentation and certificate of participation is included in the delegate fee.

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.

Terms and Conditions

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