NORDIC QA FORUM

Clarion Hotel Copenhagen Airport
November 21st, 2024

THE NATIONAL AUTHORITIES:


Peter Borgå


Emil Schwan


Eva Tollefsen


Thomas Noe Vestergaard Pedersen


Katja Belt


Guðrún Selma Steinarsdóttir






Specially invited:

"European Shortages Monitoring Platform – how will it impact the industry?"

Véronique Davoust
Pfizer

- GDP/GMP – the most common findings
- European Shortages Monitoring Platform
- Fiscal import
- Inspections of wholesalers
- The responsibility of MAH

+ much more

We offer live stream

Speakers:

Danish Medicines Agency:
Thomas Noe Vestergaard Pedersen *Medicines Inspector & Team manager*
Finnish Medicines Agency:
Katja Belt *Senior Pharmaceutical inspector*
Norwegian Medicines Agency:
Eva Tollefsen *Pharmaceutical inspector*
Swedish Medical Products Agency:
Peter Borgå *Pharmaceutical inspector*
Swedish Medical Products Agency:
Emil Schwan *Pharmaceutical inspector*
The Danish Medicines Verification Organisation (DMVO):
Marie Louise Shee *Managing Director*
Pfizer:
Véronique Davoust *Global Supply Global Quality Operations, Regulatory Intelligence*
Novo Nordisk Denmark:
Irene Bøggild *Quality Manager & RP*
Icelandic Medicines Agency:
Guðrún Selma Steinarsdóttir *Expert*

Partners:

STI FREIGHT MANAGEMENT
TAKING QUALITY THE EXTRA MILE

cencora
PharmaLex

lif The research-based pharmaceutical industry

The Swedish Life Science Industry Organization
swedenBIO

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 opportunity to :

- Understand how the authorities in Sweden, Denmark, Iceland, Norway and Finland will interpret the changes.
- Find out best practices.
- Network with other senior QA 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 November!

Kind regards,

Niko Fastman
Project Manager Nordic QAforum & Qaforum
+ 46 (0) 73 6 7 06 032
niko.fastman@kompetensinstitutet.se

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 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 4,51 out of 5.0.
Register today to secure your ticket.

NOVEMBER 21ST, 2024

NORDIC QA FORUM

08.30 **Registration, morning coffee & refreshments**

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

Expert presentation:

09.20 **European Shortages Monitoring Platform – how will it impact the industry?**

– What is the ESMP and how will it work?
– How will this new initiave impact pharma industry and supply chain?
– When is the platform coming live and how can the industry start preparing? What parts of the company will it involve?
- Will the ESMP replace national initiatives? How can companies and national authorities interact around the ESMP?
- How can the ESMP be set up on time with the right quality?
- EFPIAs/MfE initiative to use EMVS (European Medicinces Verification System) in connection to the

Véronique is responsible for the monitoring and analysis of global and European emerging regulations and guidelines. Furthermore, she ensures the communication and implementation of the guidelines and regulations within the firm, as well as the coordination of responses to the authorities.

She is deeply involved in Trade Associations activities (eg. European Federation of Pharmaceutical Industries and Associations (EFPIA) or the French LEEM), serving on leadership teams in quality or supply chain. She currently supports the development of EMA's European Shortages Monitoring Platform (ESMP) as Efpia's subject matter expert.

Véronique Davoust, Global Supply Global Quality Operations, Regulatory Intelligence, Pfizer

Case study:

10.00 **Handling counterfeit in an affiliate**

Irene Bøggild, Quality Manager & RP, Novo Nordisk Denmark

10.25 **Questions to the speakers**

10.40 **Coffee break & networkking**

Norwegian Medicines Agency:

11.10 **Inspections of wholesalers**

- Inspections of wholesalers with common Nordic quality organizations
- The most common deviations, 2021-2024
- Deviations/findings that surprised me

Eva Tollefsen, Pharmaceutical inspector, Norwegian Medicines Agency

Icelandic Medicines Agency:

11.45 **Pharmacovigilance: Patient safety**

-Role of the distributor and Marketing Authorization Holders
-The importance of collaboration

Guðrún Selma Steinarsdóttir, Expert, Icelandic Medicines Agency

FMD:

12:05 **Falsified Medicines Directive**

- How we deal with alerts - How we work with improving quality on both the industry and end-user side
- What are the learnings from implementing the FMD in Denmark?
– What is the current status working with the FMD and what is currently in focus for the Danish Medicine Verification Organization?
– Future changes and development?

Marie Louise Shee, Managing Director, The Danish Medicines Verification Organisation (DMVO)

12.35 **Questions to the speakers**

12.50 **Lunch**

Danish Medicines Agency:

13.50 **Dicillin-recall case Part 2: Next steps from an authority perspective**

- Impact on inspection practices - Coming changes in guidance documents to prevent the issue to reoccur
- The most common deviations, 2021-2024
- Deviations/findings that surprised me

Thomas Noe Vestergaard Pedersen, Medicines Inspector & Team Manager, Danish Medicines Agency

Finnish Medicines Agency:

14.20 **Common issues in supplier management in GMDP environment**

- The most common deviations, 2021-2024

Katja Belt, Senior Pharmaceutical Inspector, Finnish Medicines Agency

14.55 **Questions to the speakers**

15.10 **Coffee break & networkking**

Swedish Medical Products Agency:

15.40 **Import of medicinal products into the EES – which transactions are acceptable and which are not?**

- The responsibility of MAH: requirements for GMP and GDP oversight

Emil Schwan, Pharmaceutical Inspector, Swedish Medical Products Agency

Peter Borgå, Pharmaceutical Inspector, Swedish Medical Products Agency

16.45 **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.

NORDIC
QAFORUM

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 21st 2024:	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

@KOMPETENSINSTITUTET

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/