5th annual

NORDIC QA FORUM

Clarion Hotel Copenhagen Airport
16th of November 2017

THE NATIONAL AUTHORITIES:

Emil Schwan

Line Saxegaard

Kristine Frederiksen

Johanna Linnolahti

KEYNOTE SPEAKER:

"Practical implementation of the Falsified Medicines Directive and Delegated Regulation"

Anci Kvarnström:
Project leader for the Swedish Implementation & Consultant for EFPIA

KEY TOPICS:

- Current GMP/GDP & regulatory updates
- The authorities expectations on serialization
- Audit of suppliers and contract acceptors – when is it necessary and how to do it?
- Which are the most common deviations?

Speakers:

Swedish Medical Products Agency:
Emil Schwan
Inspector GMP/GDP

Danish Medicines Agency:
Kristine Frederiksen
Medicines Inspector

Norwegian Medicines Agency:
Line Saxegaard
Pharmaceutical inspector

Finnish Medicines Agency:
Johanna Linnolahti
Senior Pharmaceutical Inspector

Anci Kvarnström:
Project leader for the Swedish,
Implementation & Consultant for EFPIA

Distica:
Vallý Helgadóttir
Department Manager

AstraZeneca:
Anna Berg
Qa Director & QP

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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.

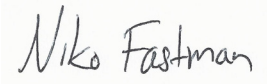
The Nordic QAforum will give you the the opportunity to :

- Understand how the authorities in Sweden, Denmark, Norway 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 16th of November!

Kind regards,



Niko Fastman
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Our latest QAforum was fully booked early and received the grade 4,27 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:
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16TH NOVEMBER 2017

NORDIC QA FORUM

08.30 **Registration, morning coffee & refreshments**

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

Swedish Medical Products Agency:

09.05 **GDP/GMP – Which are the most common deviations?**

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

10.15 **Questions to Emil Schwan**
E-mail your questions to: info@qaforum.se

10.30 **Refreshments & networking break**

CASE STUDY:

11.00 **QA Management of Supply Chain and Distribution**

- Quality System approach
- Process Controlled Distribution
- Risk assessments of Supply chain and Supply Chain traceability

Anna Berg, QA Director & QP,
AstraZeneca

CASE STUDY:

11.45 **Controlling your cold chain through the last mile**

- How a cloud-based solution can enhance visibility, and continuously optimize your entire supply chain

Vallý Helgadóttir, Department Manager, Distica

12.15 **Lunch & networking break**

Expert presentation:

13.15 **Practical implementation of the Falsified Medicines Directive and Delegated Regulation**

- Obligations for different stakeholders
- Functionality of the national systems and the EU Hub
- Implementation – who is doing what?
- What can we learn from the pilots?

Anci Kvarnström, Project leader for the Swedish Implementation & Consultant for EFPIA

Finnish Medicines Agency:

14.20 **The authorities expectations on serialization**

- Opportunities and challenges with serialisation for a regulatory body
- Lessons learned from the serialization pilotscustomers (users and prescribers)
- Serialization – how we will inspect

Johanna Linnolahti, Senior Pharmaceutical Inspector,
Finnish Medicines Agency

15.00 **Questions to the Speakers**

15.10 **Refreshments & afternoon networking break**

Danish Medicines Agency:

15.40 **Current GMP and Regulatory updates**

- how will the updates effect you
- A Regulator's Advice to Ensuring Compliance

Kristine Frederiksen, Medicines Inspector,
Danish Medicines Agency

Norwegian Medicines Agency:

16.15 **Audit of suppliers and contract acceptors – when is it necessary and how to do it?**

- Supplier qualification according to GDP. Who do we need to qualify and how?
- The difference between being a contract acceptor and being a customer
- GDP-relevant outsourced activities, included transportation
- Authority examples from audits

Line Saxegaard, Pharmaceutical inspector,
Norwegian Medicines Agency

17.10 **Final Questions to the Speakers**

17.20 **Chairpersons closing remarks**

17.30 **Cocktail reception & networking**
It has been a long day filled with information. Time to relax and enjoy great conversations over drinks.

2018 dates:

- Qaforum, 18th of April (Sthlm)
  www.qaforum.se
- Nordic Qaforum , 15th of November (Cph)
  www.nordicqaforum.com

NORDIC
QA FORUM

3 ways to register:

Website: www.nordicqaforum.com/register

E-mail: 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

Previous called "Hilton Copenhagen Airport"

Price:

Pharma companies:	7490 SEK

Price for solution providers:

Consultants & solution providers:	9990 SEK

Lunch, coffee and documentation is included in the price.
All prices are excluding VAT.

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KOMPETENS INSTITUTET

Our latest QAforum was sold out and received the grade 4,27 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.

Term s and Conditions
Payment is required 30 days from the date of invoice. 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 occurringwithin thirteen (13) days of the conference. In the event that Kompetensinstitutet cancels an event for any reason, you will receive a complete refund.