NORDIC QA FORUM

Hilton Copenhagen Airport
20th of November 2014

THE NATIONAL AUTHORITIES:


Paul Hargreaves


Tor Gråberg


Hilde Ringstad


Annette Byrholt Hansen
Claus Mortensen


Anne Junttonen

KEY TOPICS:

- Implementation of the EU GDP
- Current GMP & Regulatory uppdates
- How to proceed and become compliant
- Transport Validation
- Quality riskmanagement

Fully booked in 2013! Secure your ticket today

Chairperson:

AstraZeneca:
Anna Pontén-Engelhardt,
Director Quality Assurance

Speakers:

Swedish Medical Products Agency:
Tor Gråberg, Chief Pharmaceutical Inspector

Danish Health & Medicines Authority:
Annette Byrholt Hansen, Head of Inspection

Danish Health & Medicines Authority:
Claus Mortensen, Inspector

Norwegian Medicines Agency:
Hilde Ringstad, Director of Department

Kemwell:
Katarina Holmström, Senior Quality Professional

Finnish Medicines Agency:
Anne Junttonen, Chief Pharmaceutical Inspector

PlantVision:
Tony Forsberg, Quality manager

MHRA:
Paul Hargreaves, expert inspector GMDP

World Courier:
Alan Bryan, Director of Integrated Services

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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 in the GDP.
- Find out best practices.
- Network with other senior QA & RA professionals.
- Learn how to implement the new GDP to your organisation.
- Keynote speach from MHRA

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 20th of November!
Kind regards,

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

Our latest QAforum was fully booked early and received the grade 4,22 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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20TH NOVEMBER 2014

NORDIC QA FORUM

08.30 **Registration, morning coffee & refreshments**

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

Danish Health & Medicines Authority:

09.05 **Current GMP & Regulatory updates**

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

Annette Byrholt Hansen, Head of Inspection, Danish Health & Medicines Authority
Claus Mortensen, Inspector, Danish Health & Medicines Authority

Swedish Medical Products Agency:

09.40 **Practical implementation of the EU GDP**

- What is the difference between the new and the old GDP?
- What are the challenges for the industry in implementing the new requirements?
- What are the most common deviations?

Tor Gråberg, Chief Pharmaceutical Inspector, Swedish Medical Products Agency

10.40 **Refreshments & networking break**

GDP EXPERT:

11.10 **New GDP and its impact on operational quality and risk management approaches**

- What risks are associated with road transports – and how can you mitigate their impact?

Alan Bryan, Director of Integrated Services, World Courier

Finnish Medicines Agency:

11.40 **Transport validation -what are the minimal demands on temperature validation**

- Audit of your supply chain suppliers – when is it necessary and how to do it?
- Management of the supply chain
- Temperature monitoring during transportation

Anne Junttonen, Chief Pharmaceutical Inspector, Finnish Medicines Agency

Norweigan Medicines Agency:

12.15 **Regulation of wholesaling in Norway**

- Implementation of new EU regulation
- What do we expect from a wholesaler?

Hilde Ringstad, Director of department of inspection, Norwegian Medicines Agency

QUESTIONS TO THE SPEAKERS:

12.40 **Questions to the speakers**

13.00 **Lunch & networking break**

CASE STUDY:

14.00 **Validation of computerized systems - What should you do to fulfil regulatory requirements in practice?**

- How could you decide what to include in the validation?
- How could you by using scalability and risk assessment streamline the validation work?
- How could you use the suppliers to streamline the validation work?
- Practical examples of validation of a Document Management System.

Tony Forsberg , Quality Manager, PlantVision

CASE STUDY:

14.30 **Good documentation practice & experiences from implementing Document management system**

- Managing documents, CC, CAPA and deviations
- Using a process driven IT system to support compliance and efficiency

Katarina Holmström, Senior Quality Professional, Kemwell

ROUNDTABLE DISCUSSION:

15.00 **How to proceed and become compliant?**

15.30 **Refreshments & afternoon networking break**

MHRA:

16.00 **Falsified medicines and MHRA interaction with law enforcement**

- Overview and history
- Changed regulatory perspective
- Situation today-numbers (GB/European perspective)
- Contra (counter) measures
- Future

Paul Hargreaves, Inspection, Enforcement & Standards Division, Medicines and Healthcare Products Regulatory Agency (MHRA)

16.45 **Final Questions to the Speakers**

17.00 **Chairperson Anna Pontén-Engelhardts closing remarks**

17.10 **Cocktail reception & networking**

It has been a long day filled with information. Time to relax and enjoy great conversations over drinks.

NORDIC
QA FORUM

3 ways to register:

Website: www.nordicqaforum.com/register

E-mail: kundtjanst@kompetensinstitutet.se

Phone: + 46 (0) 736 706 032

VENUE:

Hilton 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:

Pharma companies:	7490 SEK

Fully booked in 2013. Secure your ticket today!

Price for solution providers:

Consultants & solution providers:	9 990 SEK

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

LIMITED NUMBER OF TICKETS!
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KOMPETENS INSTITUTET

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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 90% 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.