



# NORDIC QA FORUM

## Implementation of the new EU GDP

Crowne Plaza, Copenhagen Towers  
13th of November 2013

### KEYNOTE SPEAKERS:



**Swedish Medical  
Products Agency**  
**Tor Gråberg**  
Chief Pharmaceutical Inspector



**Danish Health &  
Medicines Authority**  
**Annette Byrholt Hansen**  
Head of Inspection

### KEY TOPICS:

- Implementation of the new EU GDP
- How to proceed and become compliant
- Key best practices from AZ & Novonordisk
- Transport Validation: a step-by-step guide
- Continius Quality Improvement

### Chairperson:

**AstraZeneca Sweden Operations:**  
**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

**Novo Nordisk:**  
**Jannick Rosengaard Jakobsen**  
Regional QA Manager

**Meda:**  
**Karin Hultman**  
Senior Quality Assurance Manager

**MSD:**  
**Annmargret Tallberg**  
Executive Director Regulatory Affairs  
Scandinavia & Baltics

**PlantVision:**  
**Tony Forsberg**  
Quality manager

**AstraZeneca Sweden Operations:**  
**Anna Pontén-Engelhardt**  
Director Quality Assurance

**Kemwell:**  
**Katarina Holmström**  
Senior Quality Professional

**STI Scandinavia:**  
**Stefan Lundvall**  
Logistics specialist

Goldsponsor:



Sponsors:



PlantVision



invest in skåne  
part of business region skåne



Partners

medicon valley alliance

Creating Opportunities

The Swedish Life Science Industry Organization  
**sweden BIO**





# NORDIC QA FORUM

Dear Colleague,

The release of the updated EMA GDP guidelines will have a huge impact on the industry. 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 and Denmark will interpret the changes in the GDP.
- Find out best practices from leading companies; AstraZeneca, Novo Nordisk and MSD.
- Network with other senior QA & RA professionals.
- Learn how to implement the new GDP to your organisation.

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 13th of November!  
Kind regards,

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

**Our latest QAforum was fully booked early and received the grade 4,19 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:

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08.30 Registration, morning coffee & refreshments

09.00 Chairperson´s Welcome & Opening Remarks

Danish Health & Medicines Authority:

09.10 Current GMP & Regulatory updates

- How will the updates effect you?

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

Swedish Medical Products Agency:

09.55 Implementation of the revised EMA GDP guidelines

- What are the challenges for the industry in implementing the new requirements?

- Potential issues with implementation.

- How to proceed and become compliant?

Tor Gråberg, Chief Pharmaceutical Inspector, Swedish Medical Products Agency

10.50 Refreshments & networking break

CASE STUDY 1:

11.30 Ensuring compliance in the supply chain: the quality perspective

- Ensuring GDP compliance with external authorities and new regulations

- Evaluating different legislation across the Nordic countries

- Auditing and other supply chain security considerations

Jannick Rosengaard Jakobsen, Regional QA Manager, Novo Nordisk A/S

CASE STUDY 2:

12.15 Quality assurance of the supply chain

- Conflict between cost and compliance?

- After audits – trust or verification?

Anna Pontén-Engelhardt, Director Quality Assurance, AstraZeneca Sweden Operations

CASE STUDY 3:

13.00 Transport validation - how to do it and how to find the right level?

Stefan Lundvall, Logistics specialist Life Science, STI Scandinavia

13.15 Lunch & networking break

CASE STUDY 4:

14.10 Continuous quality improvement

Tony Forsberg, Quality Manager, PlantVision

CASE STUDY 5:

14.40 Implementing a quality management system to ensure compliance

- Which effects did we get with our QMS and how did it affect our QA-department?

Katarina Holmström, Senior Quality Professional, Kemwell AB

15.10 Refreshments & afternoon networking break

CASE STUDY 6:

15.45 Implementation of the new GDP to your organization

- These changes have MSD made in Sweden, Denmark, Norway & Finland regarding the new GDP?

Annmargret Tallberg, Executive Director Regulatory Affairs Scandinavia & Baltics, MSD

CASE STUDY 7:

16.20 Recall on patient level – lessons learned

- Our process on recalls

- How well did our recall process work when we had to use it?

- How do we manage information (timing and content)?

Karin Hultman, Senior Quality Assurance Manager, Meda AB

16.50 Chairperson´s closing remarks

17.00-18.00 Cocktail reception & networking

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

Next QAforum: 3 April 2014, Stockholm www.QAforum.se





# NORDIC QA FORUM

## 3 ways to register:

**Website:** [www.kompetensinstitutet.se/registration](http://www.kompetensinstitutet.se/registration)

**E-mail:** [kundtjanst@kompetensinstitutet.se](mailto:kundtjanst@kompetensinstitutet.se)

**Phone:** +46 (0) 736 706 032

## VENUE:

**Crowne Plaza Copenhagen Towers**  
Ørestads Boulevard 114-118  
Copenhagen  
Phone nr to the venue:  
+45 88 77 66 55

Transport from Copenhagen Airport:  
- Distance: 3 km.  
- Complimentary Shuttle Available  
- Time by Taxi: 7 minutes

Train/Subway from Airport:  
- Time By Train/Subway: 7 minutes  
- Station Name: Oerestad  
- It takes 3 minutes to walk from the station to the venue.

## Price:

Pharma companies: 7 490 SEK

## Price for solution providers:

Consultants & solution providers: 8 990 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.

### Terms 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 fifteen (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 one year from the date of issuance of such credit. No credit will be issued for any cancellations occurring within thirteen (13) days of the conference. In the event that Kompetensinstitutet cancels an event for any reason, you will receive a complete refund.