

First announcement of the  
**3<sup>rd</sup> Scandinavian Conference**

## Current Status of Quality in Research and Development

**4-5 October 2006, The IDA Conference Centre, Copenhagen,  
Denmark**

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**Organized by  
The Danish Quality Assurance Group (DKG) &  
The Swedish Association of Research Quality Assurance (SARQA)**

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### **OBJECTIVES**

The goal of this Conference is to give an updated status of quality issues in research and development in the regulated areas of the biotechnological, chemical and pharmaceutical industry. It will provide a forum for discussion among professionals from industry, academia and regulatory bodies involved in some of the practical aspects of quality management and quality assurance. The sessions will allow time for sharing of experience and for discussions between the speakers and the participants.

### **WHO SHOULD ATTEND?**

Quality assurance professionals, regulators, safety officers, laboratory management and study team members/personnel from both industry, contract research organisations and academia, who has interest and/or experience in the application of Good Practices and quality systems in research and development of biotechnological, chemical or pharmaceutical products.

### **Conference Programme**

A pre-final version of the conference programme is attached to this mail and can also be found on the web pages of DKG - <http://www.dkgqa.dk/> - and SARQA - <http://www.sarqa.com/>

Please notice that the presentations will be held in English.

## ***Registration***

Registration is made through faxing or emailing the attached registration form. Please note that registration will only be accepted after payment has been received. The fee is 3000 DKK (3750 SEK) on registration on or before 1 July 2006 (early bird deadline). The fee is 4000 DKK (5000 SEK) on registration after 1 July 2006.

### Attachments:

Pre-final programme  
Registration form

First announcement -May-2006

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Programme – 4 October 2006

09.00 – 12.00	<b>Registration Open</b>	
09.00 – 09.30	<b>Morning coffee</b>	
09.30 – 09.40	<b>Welcome by DKG and SARQA</b> Tony Jørgensen & Anders Wichman, DKG & SARQA Chairmen	
	<b>Plenary lectures: Current highlights in R &amp; D Quality</b>	
09.40 – 10.35	<b>Investigation of Scientific Misconduct</b> Speaker: Professor Anders Ekblom from Karolinska Sjukhuset in Stockholm	
10.35 – 11.30	<b>MHRA Pharmacovigilance Inspections</b> Speaker: Anya Sookoo, MHRA	
11.30 – 11.40	<b>Short break</b>	
<b>Parallel sessions</b>	<b>GCP/GMP: Pharmacovigilance</b>	<b>GLP: Multi-site studies</b>
11.40 – 12.50	<b>Initiating Danish Pharmacovigilance Inspections</b> Speaker: Hanne Kristensen & Claus Mortensen Danish Medicines Agency  <b>Experience from FDA Pharmacovigilance Inspection</b> Speaker: Mette Stockner, Executive Director, Ferring Pharmaceuticals <b>Panel discussion</b>	<b>Multi-site studies from a sponsor perspective</b> Speaker: Christina Olsen Sundelin, AstraZeneca  <b>Multi-site studies from a CRO perspective:</b> Speaker: Chris Clare, Director Quality Systems Covance Laboratories, Harrogate  <b>Panel discussion</b>
12.50 – 14.00	<b>Lunch</b>	
<b>Parallel sessions</b>	<b>GCP/GMP: Post marketing surveillance studies</b>	<b>GLP: Contamination of plasma samples</b>
14.00 – 16.00	<b>PMSS - The requirements from sponsor point of view</b> Speaker: Jens Peter Balling, H. Lundbeck A/S  <b>Requirements to IMP labelling &amp; distribution</b> Speaker: Karen Gram Larsen, Novo Nordisk <b>Panel discussion</b>	<b>Paper on contamination of plasma samples EMEA document - Authority perspective:</b> Speaker: Ragnar Hede, Medical Products Agency <b>Paper on contamination of plasma samples EMEA document - Industry perspective:</b> Speaker: to be announced <b>Panel discussion</b>
16.00 – 16.30	<b>Coffee, soft drinks</b>	
16.30 – 17.30	<b>Risk Management Ultra!</b>	
19.00 -	<b>Conference Dinner</b>	

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 Programme – 5 October 2006

09.00 – 09.05	Welcome to day 2
<b>Quality Management</b>	
09.05 – 09.50	<b>SQA Today - Promoting Quality Assurance around the Globe</b> Speaker: Ms Elliot Graham, Executive Director, Society of Quality Assurance, SQA
09.50 – 10.25	<b>GLP and/or ISO - experience from pharma industry</b> Speaker: Sonja Skotner, Novozymes
10.25 – 10.40	<b>Panel discussion</b>
10.40 – 11.10	<b>Coffee</b>
<b>Risk Management</b>	
11.10 – 11.45	<b>Risk Management GLP</b> Speaker: Marina Gottschalk GLP Federal Office, Coordination Quality Management
11.45 – 12.20	<b>Quality Risk Management in GCP: A Paradigm Change</b> Speaker: Dr. Peter Schiemann, Global Planning Manager, QRM Project Leader, F. Hoffmann - La Roche Ltd.
12.20 - 12.45	<b>Panel discussion</b>
12.45 – 14.00	<b>Lunch</b>
<b>News from Authorities</b> With focus on the Nordic area but also EU-Directive implementation and consequences	
14.00 - 14.25	<b>GLP - New GLP Consensus document concerning archiving</b> Speaker: Ragnar Hede, Medical Products Agency
14.25 – 14.50	<b>GCP</b> Speaker: Gunnar Danielsson, Medical Products Agency
14.50 – 15.10	<b>Coffee</b>
15.10 – 15.35	<b>GMP/GDP</b> Speaker: Danish Medicines Agency
15.35 - 16.00	<b>Panel discussions with inspectors</b>
16.00	<b>Closing remarks by DKG/SARQA Chairmen</b>

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## REGISTRATION FORM

Title: \_\_\_\_\_ / \_\_\_\_\_ Prof./\_\_\_\_\_ Dr./\_\_\_\_\_ Mr./\_\_\_\_\_ Ms.

Name: \_\_\_\_\_  
                    first                                    middle                                    last

Organisation: \_\_\_\_\_

Address: \_\_\_\_\_

Town/Country: \_\_\_\_\_

Phone No. \_\_\_\_\_ Fax No. \_\_\_\_\_

E-mail: \_\_\_\_\_

**I would like to attend the following workshops on day one:**

- **Pharmacovigilance (GMP/GCP):** \_\_\_\_\_
- **Multi-Site Studies (GLP):** \_\_\_\_\_
- **Post marketing surveillance studies (GMP/GCP):** \_\_\_\_\_
- **Contamination of plasma samples (GLP):** \_\_\_\_\_

## Practical information

The meeting will take place at the IDA Conference Centre, Kalvbod Brygge 31-33, Copenhagen. Please, see link for more information and map.

<http://ida.dk/Moedece/nter/>

A limited number of rooms are reserved on the night of 4-5 October at The Marriott Hotel, Copenhagen, at a special price of DKK 1395/night, including breakfast. The hotel is located very close to the IDA Conference Centre. Link to the hotel

<http://marriott.com/property/propertypage/CPHDK?groupCode=HLUHLUA&app=resvlink>

**For reservations, please contact the hotel directly on tel +45 88 33 99 00 or via the link above. Please state "DKG" as booking reference.**

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# Current Status of Quality in Research and Development

## Dietary requirements

Please specify any special diet requirements: \_\_\_\_\_

## Conference dinner

I plan to participate in the Conference Dinner on 4<sup>th</sup> October  Yes  No

## Method of Payment

Registration will only be accepted after payment has been received.

<b>Fee:</b>	Before 1 July 2006	<b>3000 DKK (3750 SEK)</b>
	After 1 July 2006	<b>4000 DKK (5000 SEK)</b>

Payment in Danish Crowns (DKR) should be made to DKG on **BG Bank Registration No. 0249 Account No. 10157587**. Please state “DKG/SARQA Conference 2006” on the paying-in form and also remember to write the name(s) for whom the fee covers.

Payment in Swedish Crowns (SEK) should be made to SARQA on **Bankgiro No. 5874-5100**. Please state “DKG/SARQA Conference 2006” on the paying-in form and also remember to write the name(s) for whom the fee covers.

Please send the completed form by e-mail or fax to:

Heidi Ulm, [hulm@lundbeck.com](mailto:hulm@lundbeck.com)

Fax No. +45 3643 8293