

## Programme – 16 September 2009

<b>09.00 – 12.00</b>	<b>Registration Open</b>
<b>09.00 – 09.30</b>	<b>Morning coffee</b>
<b>09.30 – 09.40</b>	<b>Welcome by DKG and SARQA</b> DKG & SARQA Chairmen
<b>ICH Guidelines Q8, Q9, Q10</b>	
<b>09.40-10.15</b>	<b>ICH Q10 Quality System</b> Speaker: Lilian Hamilton AstraZeneca
<b>10.15-10.50</b>	<b>ICH Q8 Quality by Design</b> Speaker: Arne Torstensson, AstraZeneca
<b>15 min</b>	<b>Short break</b>
<b>11.05-11.40</b>	<b>ICH Q9 Risk Management</b> <b>Risk Management in Audit Planning</b> Speaker: Finn Ahlmann-Ohlsen, Novo Nordisk
<b>11.40-12.15</b>	<b>The Value of Risk Assessment in Quality Assurance</b> Speaker: Colin Brown, Charles River Laboratories
<b>12.30-13.30</b>	<b>Lunch</b>
<b>Authorities' Approach to Risk Management</b>	
<b>13.30-14.05</b>	<b>Challenges of Changes in legislation and Inspection (MHRA's GXP risk based inspection programme)</b> Speaker: Rebecca Harrison, MHRA
<b>14.05-14.40</b>	<b>Quality Risk Management – View of a German Authority</b> Speaker: Petra Rempe, GMP Inspector, Germany
<b>14.40-15.10</b>	<b>Coffee, soft drinks</b>
<b>15.10-15.45</b>	<b>Risk Management – the Danish approach in practice</b> Speaker: Marianne Bertelsen, LMS Denmark
<b>15.45-16.00</b>	<b>Panel discussion</b>
<b>Quality in Early Research</b>	
<b>16.00-16.35</b>	<b>Early Research from API to First Time in Man</b> Speaker: Not decided
<b>15 min</b>	<b>Q&amp;A</b>
<b>16.50-17.35</b>	<b>Entertaining</b> Speaker: Rune Larsson, Talarforum
<b>19.00</b>	<b>Conference Dinner</b>

## Programme – 17 September 2009

<b>09.00 – 09.05</b>	<b>Welcome to day 2</b> DKG & SARQA Chairmen		
<b>Outsourcing</b>			
<b>09.05-09.40</b>	<b>CRO Management within Pharmaceutical R&amp;D, from the Authority Approach – GMP</b> Speaker: Lana Karlmark, MPA Sweden		
<b>09.40-10.15</b>	<b>Outsourcing GMP/GCP</b> Speaker: Eva Giertz, AstraZeneca		
<b>10.15-10.30</b>	<b>Coffee</b>		
<b>10.30-11.05</b>	<b>Outsourcing GCP</b> Speaker: Jesper Nygaard Nissen, Novo Nordisk		
<b>11.05-11.40</b>	<b>Outsourcing from a Contractor point of view</b> Speaker: Thomas James Mc Cormack, Charles River Laboratories, USA		
<b>11.40-12.15</b>	<b>Outsourcing from a Market Company point of view</b> Speaker: Liselotte Larsson, Camurus AB		
<b>12.15-12.30</b>	<b>Panel discussion</b>		
<b>12.30-13.30</b>	<b>Lunch</b>		
<b>Parallel sessions</b>	<b>GMP Session The QP Role</b>	<b>GLP Session Interpretations of GLP</b>	<b>GCP Session</b>
<b>13.30-14.05</b>	<b>The QP Role from the Danish Authority point of view</b> Speaker: Maria Skiffard, LMS Denmark	<b>Differences in the Interpretations of GLP requirements by OECD: The point of view from Authorities</b> Speaker: Ragnar Hede, MPA Sweden	<b>Regulatory Compliance for Clinical Laboratories</b> Speaker: Samantha Atkinson, MHRA UK
<b>14.05-14.45</b>	<b>The QP Role from the QP point of view</b> Speaker: Ulla Stjernfelt, AstraZeneca	<b>Differences in the Interpretations of GLP requirements by OECD monitoring authorities: The point of view from the pharmaceutical industry</b> Speaker: Raymond Lowing, Sanofi-Aventis	<b>Human Biological Samples</b> Speaker: Östen Karlsson, AstraZeneca
<b>14.45-15.00</b>	<b>Panel discussion</b>	<b>Panel discussion</b>	<b>Panel discussion</b>
<b>15.00-15.30</b>	<b>Coffee, soft drinks</b>		
<b>Electronic Archiving</b>			
<b>15.30-16.05</b>	<b>Electronic Archiving</b> Speaker: Henrik Hounsgaard, Novo Nordisk		
<b>16.05-16.40</b>	Speaker: David Berglund, AstraZeneca		
<b>16.40-16.50</b>	<b>Q&amp;A</b>		
<b>16.50-17.00</b>	<b>Closing remarks by DKG/SARQA Chairmen</b>		