**”Quality Complexity - Navigating International Challenges”**

**The 8th Scandinavian SARQA/DKG Quality Assurance Conference**

**DATE: November 15th, 2018**

**VENUE: Malmö Arena Hotel, Hyllie (Malmö)**

The language of this conference is English

Conference fee 1400 DKK/1900 SEK

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| 08.30-09.15 | Registration/Coffee – breakfast buffet |
| 09.15-09.30 | Welcome – joint presentation SARQA and DKG |
| 09.30-10:45 | **BREXIT and international collaboration between regulatory agencies****UK Perspective on BREXIT***Title and presenter awaiting confirmation***International collaboration between regulatory agencies***Title and presenter awaiting confirmation* |
| 10:45-11:00 | Morning Break Coffee Tea |
| 11:00-12:15 | **Data Integrity****MHRA GxP Data Integrity Guideline***Title and presenter awaiting confirmation***Data Governance from an industry perspective***Robert Fjæstad Gustafsson, AstraZeneca AB* |
| 12.15-13.30 | Lunch |
| 13.30-15.00 | STREAM: **GCP/PV****Trends in pharmaco-vigilance inspection deviations***Thorsten Frank Jørgensen, Leo Pharma***TBD***Title and presenter to be defined* | STREAM: **GLP****OECD Advisory no. 19 on the Management, Characterization and Use of Test Items***Sophie Svensson, SWEDAC***Registration of pesticides***Jesper Yngvesson, Agrolab* | STREAM: **GMP/GDP/Device****The New Annex 1 - When, What and Why?***Matts Ramstorp, BioTekPro***Stand-alone GMP for ATMP – an overview***Anna Lundén, Key2Compliance AB* |
| 15.00-15.30 | Coffee/Tea/Refreshments |
| 15.30-17.20 | **Risk-based approach - practical aspects****Efficient QC procedures – how?***Charlotte Høgsted, Key2Q***Audit trail review – what trails to select for review?***Mogens Høgsbro Østergaard, Novo Nordisk*  |
| 17.20-17.30 | Closing remarks |
| 17.30- | Post Conference Networking Event – finger food, beer, wine and non-alcoholic drinks.An opportunity to talk and network with your colleagues at the end of the conference. |