**”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. | | |