

Therapeutic proteins – focus on analysis and formulations

February 5-6, 2019, Stockholm, Sweden

Program

Tuesday, February 5

09.45 Registration with coffee/tea and sandwich

10.20 **Introduction**

Session 1: Novel techniques and methods for therapeutic proteins

10.30 **Advances in the analysis of protein biopharmaceuticals through application of contemporary 2D-LC coupled to UV- and Q-TOFMS.**

Sandra Koen, Research Institute for Chromatography, Kortrijk, Belgium

11.15 **New perspectives on formulation analysis and its implications**

Sebastian Hansson, Solve, Sweden

11.45 **Stability testing of pharmaceutical proteins. Overview of stability indicating methods and regulatory requirements.**

Christine Lagerquist Hägglund, Sobi, Sweden

12.15 **Novel excipients for peptides and proteins**

Stefan Ulvenlund, Enza Biotech, Sweden

12.45 **Lunch, poster session, exhibition**

Session 2: Purity determinations

14.00 **Glycoprotein and Antibody analysis: from CE-MS to CE-CE-MS**

Christian Neusüss, University of Aalen, Germany

14.30 **Glycoanalysis of therapeutic proteins – Challenges and possibilities using current analytical approaches**

Margareta Ramström, Medical Product Agency, Sweden

15.00 **Intermission, poster session, exhibition and coffee/tea**

Session 3: Registration aspects

- 15.30 **Views on registration of therapeutic proteins by the authorities**
Mats Welin, Medical Product Agency, Sweden

Session 4: Biophysical characterization

- 16.00 **Formulation of biological drugs; effect of protein and excipient interactions on product stability**
Helen Sjögren, Ferring, Denmark

- 16.30 **Deeper numerical characterization of cell-based biosensor data**
Torgny Fornstedt, Karlstad University, Sweden

17.00-17.45 **Poster presentations**

Application of triple quadrupole MS for drug-to-antibody ratio and molecular weight determination of antibody-drug conjugates
Malin Källsten, Uppsala University, Sweden

Distribution and physical structure of the components in a freeze-dried protein formulation
Maria Badal Tejedor, RISE Research Institutes of Sweden

2D-NMR characterization for the higher order structure assessment of biologics and biosimilars
Björn Walse, SARomics Biostructures

17.45-18.15 **Exhibition / Poster session**

18.15 – Dinner

Wednesday, February 6

- 09.15 **Characterization of therapeutic proteins – analysis of protein conjugates and MABs using light scattering coupled to column chromatography and field flow fractionation.**
Arthur Porfetye, Wyatt Technologies, Germany

Session 6: Stability and aggregation studies

- 09.45 **Profiling and optimization of protein stability using calorimetric approaches.**
Natalia Markova, Microcal, Malvern Instruments Ltd, Sweden

- 10.15 **Avoiding problems with protein aggregation in formulation studies**
Jonas Fransson, Sobi, Sweden

- 10.45 **Intermission, Posters and coffee/tea**
- 11.15 **Presentation of a new center for protein formulations: NextBioForm**
Anna Millqvist Fureby, Research Institutes of Sweden, NextBioForm
- 11.30 **Novel analytical approaches for mechanistic understanding of protein aggregation**
Ulla Elofsson, Research Institutes of Sweden
- 12.00 **Novel methods to study effects of moisture and formulation on the stability of lyophilized proteins**
Anna Millqvist Fureby, Research Institutes of Sweden, NextBioForm
- 12.30 Concluding remarks
- 12.45-13.45 Lunch

Exhibitors

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