

3 day course in Biologics Drug Development

May 28-30, 2018, Stockholm

Preliminary Program

Day 1

- 08:45 Registration
- 09:00 **Introduction**
Chair: *Olga Björklund, NDA Group*
- 09:15 **Biopharmaceuticals - an introduction**
Patrik Strömberg, Sobi, Stockholm
- 10:00 **Starting a Development Project/ TPP**
Lena Jendeberg, Wilson Therapeutics, Stockholm
- 10:30 Coffee
- 10:50 **Pharmacokinetics for biologicals**
Annsöfi Nihlén, PKxpert, Stockholm
- 11:35 **In Vivo Pharmacology**
Johanna Fälting, BioArctic, Stockholm
- 12:20 Lunch
- 13:30 **Nonclinical Safety Studies**
Anneli Hällgren, Prekliniska byrån, Huddinge
- 14:15 **Immunogenicity**
Paul Chamberlain, NDA Group, Upplands Väsby
- 15:00 Coffee
- 15:20 **Translational Sciences/Biomarkers**
Karin von Wachenfeldt, Truly Translational, Lund
- 16:05- **Patent/IP**
16:50 *Tomas Lundquist, Groth, Stockholm*

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Day 2

- 09:00 **Regulatory Strategies in Biologics Drug Development**
Katarina Mercer, SDS, Stockholm
- 09:45 **Manufacturing of Clinical Material for Biopharmaceuticals**
Martin Selander, Cobra Biologics, Södertälje
- 10:30 Coffee
- 10:50 **Analysis and Formulation of Biologics**
Patrick Merky, Cobra Biologics, Södertälje
- 11:35 **Safety Evaluation in manufacturing of biologics including virus validation**
Susanne Wood, Sobi, Stockholm
- 12:20 Lunch
- 13:30 **Pharmaceutical product development of biological drugs: Getting the product on the market**
Jonas Fransson, Sobi, Stockholm
- 14:15 **Biosimilars – preclinical and clinical aspects**
Ira Palminger Hallen, NDA Group, Upplands Väsby
- 15:00 Coffee
- 15:20 **The Regulatory Environment in EU and US for Advanced Therapy Medicinal Products (ATMP)/Regenerative Medicine Advanced Therapy (RMAT)”**
Terese Johansson, NDA Group, Upplands Väsby
- 16:05-
16:50 **Financing**
Jonas Brambeck, Industrifonden and Kennert Johansson, EUSMESupport, Stockholm

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Day 3

- 09:00 **Health economics and reimbursement**
Per Boström, Stockholm
- 09:45 **Clinical Trials**
Gunilla Andrew-Nielsen, Läkemedelsverket, Stockholm
- 10:15 Coffee
- 10:35 **Applications for Clinical Trials**
Gunilla Andrew-Nielsen, Läkemedelsverket, Stockholm
- 11:05 **Business Development**
Henrik Krook, DeLiSci, Stockholm
- 11:50 Lunch
- 13:00 **Licensing Strategies among Big Pharma**
Kay Brickmann, AstraZeneca, Mölndal
- 13:45 **Pharmacovigilance**
Lena Sundqvist, Linde Healthcare, Stockholm
- 14:30 Coffee
- 14:50-
15:35 **Market, Phase IV & post reg. phase**
Charlotta Liljebris, XSpray Pharma, Uppsala