

## 3 day Course in Biologics Drug Development

November 16-18, 2021

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### Program

#### Tuesday, November 16

- 08:30 Registration
- 09:00 **Introduction**  
*Chair: Olga Björklund, BioInvent, Stockholm*
- 09:15 **Biopharmaceuticals - an introduction**  
*Patrik Strömberg, Sobi, Stockholm*
- 10:00 **Starting a Development Project/ TPP**  
*Sven Undeland, FHC Undeland, Stockholm*
- 10:30 Coffee
- 11:00 **Pharmacokinetics for biologicals**  
*Johan Wallin, BioInvent, Stockholm*
- 11:45 **In Vivo Pharmacology**  
*Joshua Gregory, Affibody, Stockholm*
- 12:30 Lunch
- 13:40 **Nonclinical Safety Studies**  
*Anneli Hällgren, Prekliniska byrån, Huddinge*
- 14:25 **Immunogenicity**  
*Melody Janssen, Sci Pot, Amsterdam*
- 15:10 Coffee
- 15:40 **Biosimilars – preclinical and clinical aspects**  
*Speaker to be announced*
- 16:25-  
17:10 **Translational Sciences/Biomarkers**  
*Karin von Wachenfeldt, Truly Translational, Lund*

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#### Wednesday, November 17

- 08:30 Coffee
- 09:00 **Patent/IP**  
*Ulrika Munter, Sobi, Stockholm*
- 09:45 **Regulatory Strategies in Biologics Drug Development**  
*Katarina Mercer, SDS, Stockholm*
- 10:30 Coffee
- 11:00 **Manufacturing of Clinical Material for Biopharmaceuticals and Analysis and Formulation of Biologics**  
*Laura Salazar, NDA Group, Finland*
- 11:45 Lunch
- 13:00 **Safety Evaluation in manufacturing of biologics including virus validation**  
*Amir Jabari, BioInvent, Lund*
- 13:45 **Pharmaceutical product development of biological drugs: Getting the product on the market**  
*Speaker to be announced*
- 14:30 Coffee
- 15:00-15:45 **The Regulatory Environment in EU and US for Advanced Therapy Medicinal Products (ATMP)/Regenerative Medicine Advanced Therapy (RMAT)**  
*Laura Salazar, NDA Group, Finland*

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#### Thursday, November 18

- 08:30 Coffee
- 08:45 **Financing**  
*Jonas Brambeck, Industrifonden, Stockholm*  
*EUSMESupport*
- 09:45 **Health economics and reimbursement**  
*Per Boström, Stockholm*
- 10:30 Coffee
- 11:00 **Clinical Trials**  
*Gunilla Andrew-Nielsen, Läkemedelsverket, Uppsala*
- 11:35 **Applications for Clinical Trials**  
*Gunilla Andrew-Nielsen, Läkemedelsverket, Uppsala*
- 12:10 Lunch
- 13:15 **Business Development**  
*Henrik Krook, DeLiSci, Stockholm*
- 14:00 **Licensing Strategies among Big Pharma**  
*Kay Brickmann, AstraZeneca, Mölndal*
- 14:45 Coffee
- 15:15 **Pharmacovigilance**  
*Lena Sundqvist, Vigiowl, Huddinge*
- 16:00-  
16:45 **Oncopeptides, Taking a project from idea to a late stage clinical development and beyond**  
*Eva Nordström, Oncopeptides, Stockholm*