

## 3 day Course in Biologics Drug Development

31 May- 2 June, 2022

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### Preliminary Program

#### Tuesday, 31 May

- 08:30 Registration
- 09:00 **Introduction**  
*Olga Björklund, BioInvent*
- 09:15 **Biopharmaceuticals - an introduction**  
*Patrik Strömberg, AnaCardio*
- 10:00 **Starting a Development Project/ TPP**  
*Sven Undeland, FHC Undeland*
- 10:30 Coffee
- 11:00 **Pharmacokinetics for biologicals**  
*Johan Wallin, BioInvent*
- 11:45 **In Vivo Pharmacology**  
*Joshua Gregory, Affibody*
- 12:30 Lunch
- 13:40 **Nonclinical Safety Studies**  
*Anneli Hällgren, Prekliniska byrån*
- 14:25 **Immunogenicity**  
*Melody Janssen, Sci Pot, Amsterdam*
- 15:10 Coffee
- 15:40 **Biosimilars – Non-Clinical and Clinical Aspects**  
*Siavash Bashiri, Xbrane Biopharma*
- 16:25-  
17:10 **Translational Sciences/Biomarkers**  
*Karin von Wachenfeldt, Truly Translational*

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#### Wednesday, 1 June

- 08:45 Coffee
- 09:00 **Patent/IP**  
*Johanna Bergh, AWA*
- 09:45 **Regulatory Strategies in Biologics Drug Development**  
*Malin Filler, SDS*
- 10:30 Coffee
- 11:00 **Manufacturing of Clinical Material for Biopharmaceuticals and Analysis and Formulation of Biologics**  
*Paula Salmikangas, NDA Group*
- 11:45 Lunch
- 13:00 **Safety Evaluation in manufacturing of biologics including virus validation**  
*Amir Jabari, BioInvent*
- 13:45 **The Regulatory Environment in EU and US for Advanced Therapy Medicinal Products (ATMP)/Regenerative Medicine Advanced Therapy (RMAT)**  
*Björn Carlsson, NDA Group*
- 14:30 Coffee
- 15:00- **Financing**  
15:45 *Jonas Brambeck, Industrifonden*

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#### Thursday, June 2

- 09:30 Coffee
- 09:45 **Health economics and reimbursement**  
*Per Boström, Stockholm*
- 10:30 Coffee
- 11:00 **Clinical Trials**  
*Gunilla Andrew-Nielsen, Läkemedelsverket*
- 11:35 **Applications for Clinical Trials**  
*Gunilla Andrew-Nielsen, Läkemedelsverket*
- 12:10 Lunch
- 13:15 **Business Development**  
*Katarina Jansson, Jansson AK Consulting*
- 14:00 **Partnering with Big Pharma**  
*Kay Brickmann, AstraZeneca*
- 14:45 Coffee
- 15:15 **Pharmacovigilance**  
*Lena Sundqvist, Vigiol*
- 16:00- **Taking a project from idea to a late stage clinical development and beyond**  
16:45 *Siavash Bashiri, Xbrane Biopharma*