

Preliminary program

3-5 October 2023

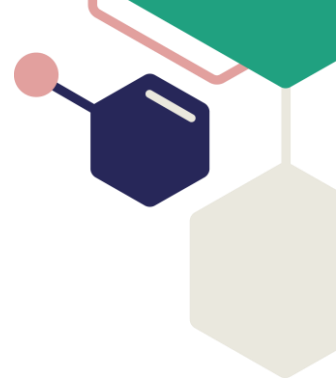
Stockholm/Online

# Biologics drug development

3 day course

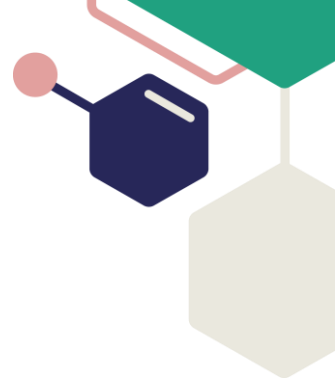
## Tuesday, October 3

- 08:30 Registration
- 09:00 **Introduction**  
*Olga Björklund, BioArctic*
- 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*
- 15:20 Coffee
- 15:50 **The Regulatory Environment in EU and US for Advanced Therapy Medicinal Products (ATMP)/Regenerative Medicine Advanced Therapy (RMAT)**  
*Björn Carlsson, NDA Group*
- 16:35-  
17:20 **Translational Sciences/Biomarkers**  
*Karin von Wachenfeldt, Truly Translational*



## Wednesday, October 4

- 09:00 **Patent/IP**  
*Johanna Bergh, AWA*
- 09:50 **Regulatory Strategies in Biologics Drug Development**  
*Erika Spens och Linda Nord, SDS*
- 10:40 Coffee
- 11:10 **Manufacturing of Clinical Material for Biopharmaceuticals and Analysis and Formulation of Biologics**  
*Soren Jevtic, BioInvent*
- 11:55 Lunch
- 13:10 **Safety Evaluation in manufacturing of biologics including virus validation**  
*Amir Jabari, BioInvent*
- 13:55 **Biosimilars – Non-Clinical and Clinical Aspects**  
*Dina Jurman, Xbrane Biopharma*
- 14:40 Coffee
- 15:10 **Clinical Trials**  
*Gunilla Andrew-Nielsen, Läkemedelsverket*
- 15:45-  
16:20 **Applications for Clinical Trials**  
*Gunilla Andrew-Nielsen, Läkemedelsverket*



## Thursday, October 5

- 09:00 **Financing**  
*Jonas Brambeck, Industrifonden*
- 09:45 *Coffee*
- 10:15 **Health economics and reimbursement**  
*Per Boström, Stockholm*
- 11:00 **Business Development**  
*Katarina Jansson, Jansson AK Consulting*
- 11:45 *Lunch*
- 13:15 **Partnering with Big Pharma**  
*Kay Brickmann, AstraZeneca*
- 14:00 *Coffee*
- 14:30 **Pharmacovigilance**  
*Staffan Dahlgren, PharmaRelations*
- 15:15-  
16:00 **Taking a project from idea to a late stage clinical development and beyond**  
*Siavash Bashiri, Xbrane Biopharma*