LIMITED SUPER OFFER

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Biologics World Nordic 2018

28 February - 1 March, 2018
Copenhagen, Denmark

- **100+** High level decision makers from the different Biologics Manufacturers
- **25+** Speakers from Sweden, Denmark, Norway, Finland, UK as well as rest of Europe and the World
- **18+** Hours of Networking
- **10+** Case studies from Nordic Biopharmas & Big Pharmas on Biologics R&D and Process Development
- **3+** Technology Presentations
- **2** Dedicated sessions on partnerships and investments in the Nordics Biologics Industry

DISTINGUISHED PANEL OF SPEAKERS

Steinar Madsen, *Medical Director,* **Norweigan Medicines Agency, Norway**

Oystein Soug, *CEO,* **Targovax, Norway**

Ashesh Kumar, *CEO,* **Paras Biopharmaceuticals., Finland Oy, Finland**

Gunilla Andrew-Nielsen, *Head of Department of Clinical Trials and Special Permissions,* **Medical Products Agency, Sweden**

Anders Lonnberg, *Science Coordinator,* **National Life Swedish Government**

Ingrid Kromann, *Director of Vaccine Development,* **Statens Serum Institute, Denmark**

Jacqueline Ameri, *CEO,* **PanCryos, Denmark**

Dr. Peter Ellmark, *Principal Scientist,* **Alligator Life Sciences, Sweden**

Hidenari Yamada, *Deputy Department Manager,* **Chugai Pharmaceuticals, Japan**

Marcel Francowiack, *Innovation Manager,* **Cell Therapy, RISE Research Institute, Denmark**

Christopher Heery, *Chief Medical Officer,* **Bavarian Nordic, USA**

WHY SHOULD YOU ATTEND BIOLOGICS WORLD NORDIC 2018?

- Meet big pharmas and international pharmas from Nordic region, Europe and Rest of the World.
- Complete networking for Nordic region biologic companies looking for partnerships and technical collaboration opportunities.
- Debate growth strategies when Nordic Biologics are entering Clinical Phase II and III
- Explore the latest biologics developments with the best Case Studies from Merz, Symphogen, Bavarian Nordic, AbbVie and Alligator Biosciences
- Gain insights into Sweden's biologics future direction with Ministry of Sweden
- Hear about Novo Nordisk Foundation's journey from discovery to Commercial Application

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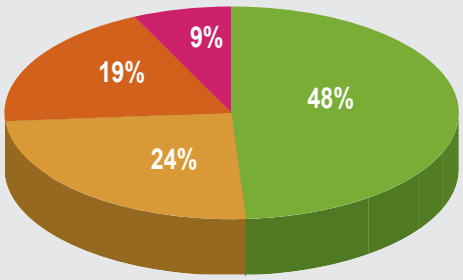
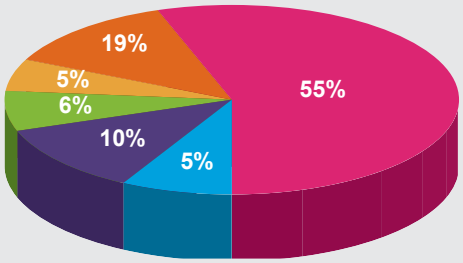
ATTENDEE PROFILE FOR BIOLOGICS WORLD NORDIC 2018

GEOGRAPHY



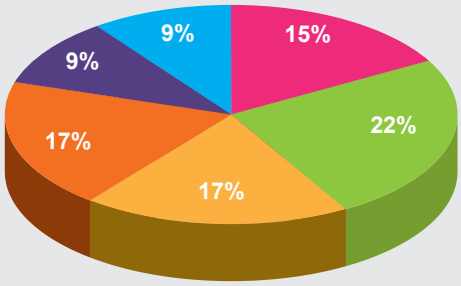
- USA
- Nordic Region
- Asia
- Rest of Europe

INDUSTRY BREAKDOWN



- Biopharma/Biotech
- Academia
- Government/Regulators
- Solution Providers
- Big Pharma
- Others

JOB TITLES



- CEO/GM/MD
- VP/Directors/Department heads
- R&D Managers
- Manufacturing
- Business Development Marketing
- Ministry/Regulators

AGENDA AT A GLANCE

CONFERENCE DAY 1 - 28 February	CONFERENCE DAY 2 - 1 March
NORDICS BIOLOGICS INDUSTRY LANDSCAPE	TRANSITIONING BIOLOGICS FROM BENCH TO PROOF OF CONCEPT TO COMMERCIALIZATION
NETWORKING BREAK	
PARTNERSHIPS, LICENSING & INVESTMENTS	PRE-CLINICAL AND CLINICAL TRIAL CASE STUDIES
NETWORKING LUNCH	
ANALYTICAL DEVELOPMENT & QUALITY CONTROL	NORDICS INNOVATION HIGHLIGHTS – CELL THERAPY & ONCOLOGY CASE STUDIES
NETWORKING BREAK	
PROCESS DEVELOPMENT & SCALE-UP BEST PRACTICES	FUTURE OF THE NORDIC BIOPHARMACEUTICAL INDUSTRY
COCKTAIL RECEPTION	**CONFERENCE ENDS**

For Speaking opportunities, contact

Aishwarya Pattanshetti

at +65 3109 0124 or aishwarya.pattanshetti@imapac.com

Conference Program

Day - 1 [28th February 2018]

8:00	Registration
8:50	IMAPAC's Opening Remarks
8:55	Chairman's Opening Remarks

NORDICS BIOLOGICS INDUSTRY LANDSCAPE

9:00 **KEYNOTE PRESENTATION**

Positioning Nordic Biologics Industry on a Global Map

- Current opportunities and challenges in development and manufacturing of biologics in Nordic?
- How to maximize the advantages in R&D and realize academic- industry cooperation to fast track innovation in the Nordic region.
- How can the Nordic region leverage its advantages to be an important player in global environment?

Oystein Soug, *CEO,* **Targovax**

9:25 **Technology Presentation: Reserved for technology and solution providers**

9:50 **A look into Sweden's Biologics Industries' Current State and Future Direction**

Anders Lonnberg, *National Life Science Coordinator,* **Sweden Government**

10:15 **What Is Needed For Nordics Biologics Drug To Enter The European/International Market?**

- Regulatory Strategies On Increasing Clinical Trials Efficiency In EU

Gunilla Andrew-Nielsen, *Head Of Dept Of Clinical Trials And Special Permissions,* **Medical Product Agency, Sweden**

10:40 **SPEED NETWORKING BREAK & REFRESHMENTS**

PARTNERSHIPS, LICENSING & INVESTMENTS

11:20 **Road to Successful Out-licensing: How to Get on Big Pharma's Radar?**

- Choosing right partners – from big pha rma's perspective
- Technical and business considerations in identifying the best match for partnership
- Turning the agreement into a living partnership – how to avoid potential pitfalls in the negotiations.
- Successful Strategic Alliance for the Development and Commercialization of XofigoTM for the treatment of prostate cancer

11:45 **Reserved for Technology Presentation by Sartorius**

12:10 **What Big Pharma want? Understanding Their partnership criteria, licensing pathways and portfolio needs**

- Selection criteria and matrix for licensing partners
- Case studies of successful partnerships with small to medium biotech companies in Asia
- Managing partnerships with biotechs: lessons learnt and best practices

12:35 **Panel Discussion:**

Attracting foreign investment & bringing international firms to the Nordic Region.

- Business development strategies & Identification of potential global markets
- Case study of successful tie-ups between international and local companies.
- Successful Strategic Tie Up in Technology Licensing for Biosimilars Developments

Panelists:

Ashesh Kumar, *Chief Executive Officer,* **Paras Biopharmaceuticals., Finland Oy**

13:20 **NETWORKING LUNCH**

ANALYTICAL DEVELOPMENT & QUALITY CONTROL

14:30 **High Throughput Methods for Analytical Development of Biologics**

- Evolving importance of analytics with in biologic products developmental and manufacturing life cycle
- How is analytical instrumentation changing to support new products and challenges accompanying them
- How to attain meaningful analytical results for low concentration

14:55	**Technology Slot: Analyzing Charge Variants for Characterizing and Monitoring Quality Attributes of Proteins** • Comparative analysis of IEC, IEF, CIEF and iCIEF • Different considerations in charge variants analysis across the manufacturing process • Applications of iCEF in QC and product characterization
15:20	**Case Study on Protein Characterization and Analytical Challenges faced Developing Desentum's Immunotherapeutic Hypoallergen**
15:45	**NETWORKING BREAK**
	PROCESS DEVELOPMENT & SCALE-UP BEST PRACTICES
16:25	**Realizing large scale production – from pilot to commercial scale**
16:50	**Technology Presentation: Economics of adopting single-use technologies in Nordics 's bioprocessing scenario** • Pros and cons of using disposable systems in upstream and downstream, small and large-scale processing • Consideration factors in switching to disposable system- economy, validation and limitations • Impact of changing production equipment from stainless steel to single-use on current manufacturing process • Case study on the successful implementation of disposable technology to existing antibody production • Choosing the right bioreactor combination for your single-use facility
17:15	**Next Generation Factory to reduce Cost of Gods of Monoclonal Antibody API** • Concept of next generation factory reducing CoGs of Mab API from several hundred dollars to several ten dollars. • How to increase start-up speed and flexibility in manufacturing at the facility • Key features of the facility being "small footprint" and "highly automated" • Enabling Technologies such as End-to-End Continuous Manufacturing, In-Line Monitoring, Real Time Release, and Internet of Things **Hidenari Yamada,** *API Process Development,* **Chugai Pharmaceuticals**
17:40	**Panel Discussion:** **The Criteria for Selecting the Right CMO- A Discussion to Understand the Internal Capabilities and Needs before Selecting the Right Candidate** • What different internal capabilities and strengths to evaluate to ensure you outsource to the right CMO • The regulatory landscape local and global to keep in mind when choosing the CMO • How to manage the costs and quality is maintained when you outsource manufacturing. • Evaluating the different factors to increase capacity or outsource.
18:25	Chairman's Closing Remarks
18:30	Cocktail Reception

Day – 2 [1st March 2018]

8:00	Registration
8:50	IMAPAC 's Opening Remarks
8:55	Chairman's Opening Remarks

TRANSITIONING BIOLOGICS FROM BENCH TO PROOF OF CONCEPT TO COMMERCIALIZATION

9:00 Handling the Biosimilars Patent Expiry and Meeting the Market Demand

- How can the Nordic biopharma's handle the issue of running out of time to meet the market demand?
- Status of the patents expiring in 2019 for biosimilar products.
- How to secure more funding to push the products

Steinar Madsen, *Medical Director,* **Norweigan Medicines Agency**

9:25 Striking a strategic balance to achieve biologics business sustainability for middle-sized biotech companies in the Nordic Region

- Biosimilars, biobetters, or novel drugs: Laying down the evaluation criteria in determining portfolio focus
- Insights and approaches to market prioritization and future expansion
- Business models and strategies to thrive in an ever-shifting competitive environment

9:50 Taking a drug candidate to IND : Current Clinical Trial Regulations and Ethical Review in the Nordic Countries

- Planning of preclinical safety studies : know your biology, know your chemistry
- Manufacturing of biologics: CMC is the game.

10:15 Novo Nordisk Foundation: Bridging the Gap from Biologics Discovery to Commercial Application

10:40 NETWORKING BREAK

PRE-CLINICAL AND CLINICAL TRIAL CASE STUDIES

11:25 Translational Vaccine Research - Moving From Mouse To Man And Back

- Identifying Vaccine Formulation
- Producing And Testing New Vaccines In A Fast And Economical Way
- 5 Different Pre-Clincal Vaccine Antigen Production Processes For Clinical Trials
- Lessons Learned – Back To New Vaccine Formulation?

Ingrid Kromann, *Director Vaccine development department,* **Statens Serum Institut**

11:50 Technology Slot: Overcoming the Complexities of Conducting Bioequivalence Studies

- Understanding the importance of determining and creating a hierarchy of parameters for bioequivalence studies
- Demonstrating pharmacological equivalence via exploring and utilizing multiple compositions of PD markers
- Uncovering innovative approaches for accelerating trial cycles and approval.

12:15 Case Study:

Clinical Development of Sym004, an Engineered Monoclonal Antibody for the Treatment of Metastatic Colorectal Cancer

12:40 NETWORKING LUNCH

NORDICS INNOVATION HIGHLIGHTS – CELL THERAPY & ONCOLOGY CASE STUDIES

14:10 Developing a National Strategy Plan for Fostering the Commercialization of Advanced Therapy Medicinal Product Projects in Sweden

Marcel Frankowiack, *Innovation Manager Cell Therapy,* **Research Institutes of Sweden**

14:35 Case Study:

Developing a Safe & Scalable Cell Therapy for Type 1 Diabetes

Jacqueline Ameri, *Chief Executive Officer,* **PanCryos., Denmark**

15:00	**Case Study:** **Clinical Development Of CD40 Agonistic Immuno-Oncology Antibody, ADC-1013, An Antibody Intended For The Immunotherapy Of Cancer** **Dr Peter Ellmark,** *Principal Scientist,* **Alligator Bioscience**
15:25	**Case Study:** **Clinical Development Of PROSTVAC®, A Vaccine For The Treatment Of Metastatic Castration-Resistant Prostrate Cancer (Mcrpc)** **Christopher Heery,** *Chief Medical Officer,* **Bavarian Nordic**
15:50	**NETWORKING BREAK**

FUTURE OF NORDICS BIOPHARMACEUTICAL INDUSTRY

16:30	**Strategies For The Effective Transition From A SME To A MNC: Insights From The Success Story Of A Local Biopharmaceutical Leader** • Strategies to fast track biologic product commercialization for novel biologics. • Challenges & solutions to developing an effective technology transfer partnerships to ensure product quality, production scale up & market entry • Future developments for global expansion & future outlooks for market access in key markets including China, Europe, SEA, & USA.
16:55	**CLOSING PANEL DISCUSSION** **Panel discussion: Building a collaboration network between academia, small biotech and big pharma to fast track biologic product commercialization and market access** • Understanding small and medium biotech companies' strength and weakness in product development and commercialization • How to bridge the gap in translating good research into commercial opportunities • Successful case studies from the Nordic. • Building strategic alliance or merge to success?
17:40	Chairman's Closing Remarks
17:45	Cocktail Reception

Biologics World Nordic 2018
28 Feb - 1 March | Copenhagen, Denmark

WHY SHOULD YOU SPONSOR?

Biologics World Nordics will provide commercial organizations with the opportunity to:

- Educate the market about what you offer Raise brand awareness and position yourselves as leaders in your field
- Maximize your face time with key profiles from biologics manufacturers from the Nordics region regulators and national health organizations all in a single location
- Enjoy the option of privately arranged meetings and consultations with selected potential clients
- Hold face to face meetings with your target profile

WHO SHOULD SPONSOR?

If you provide any of the following solutions nothing should hold you back from being a part of this:

Sponsors include:

- Bioprocess Equipment
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- Filtration Equipment
- Contract Research
- Contract Manufacturing Organizations
- Facility Design Expertize
- Automation Equipment
- Cold Chain Logistics
- Fill and Finish
- Cell Lines
- Engineering
- Protein Analysis
- Protein Characterization
- Platform Technology
- Distributors
- Packaging Solution Providers
- Venture Capitalists
- Consultants

For more information on sponsorship and exhibition opportunities, contact:

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Companies expected to attend Biologics World Nordic 2018

- Astrazeneca
- CMC Biologics
- Statens Serum Institute
- Alvotech
- Alligator Bioscience
- Desentum
- Paras Biopharmaceuticals
- Faran Pharmaceuticals
- Orion
- Medix Biochemica
- Fit Biotech
- Hytest
- Xbrane Biopharma
- StrongBridge Biopharma
- Scandinavian Biopharma
- Novo Nordisk
- Symphogen
- DanDrit
- Ferring Biopharmaceuticals
- Orphazyme
- Zealand Pharma
- Sanofi Genzyme
- Bavarian Nordic
- Nsgene
- Allergan
- 2A Pharma
- Novahep
- Active Biotech
- Bioinvent
- Wnt Research
- Dilaforette
- Promore Pharma
- Athera Biotech
- Biolamina
- Diamyd Medical
- Octapharma
- Sobi
- Agrisera
- Tikomed
- Targovax
- Nordic Nanovector
- Pfizer
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- Genentech