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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 to R&D innovation in the Nordic Biologics Industry

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

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Bernt Nilsson, *Director Process Industry Centre,* **Lund University, Denmark**

Lene Grejs-Peterson, *Senior Advisor (Clinical Trials),* **Danish Medicines Agency, Denmark**

Ivan Horak, *Chief Scientific Officer and Chief Medical Officer,* **Symphogen, Denmark**

Alois Jungbaer, *Professor,* **University of Natural Resources and Life Sciences, Vienna**

Kai Touw, *Process Development Consultant,* **Sartorius Stedim Biotech, Netherlands**

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 from Astrazeneca, Statens Serum Institut, Bavarian Nordic& Alligator Bioscience
- Gain insights into Sweden's biologics future direction with Ministry of Sweden

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ATTENDEE PROFILE FOR BIOLOGICS WORLD NORDIC 2018

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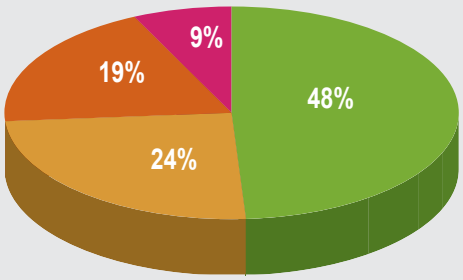
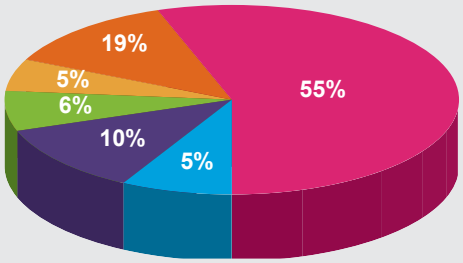


- USA
- Nordic Region
- Rest of Europe
- Asia

INDUSTRY BREAKDOWN



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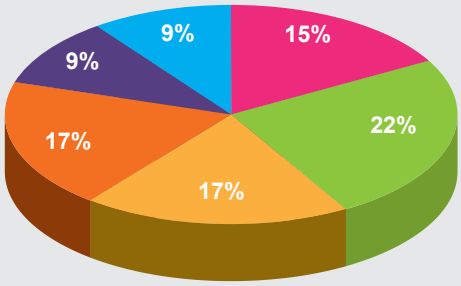
- Government/Regulators
- Solution Providers
- Big Pharma
- Others

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 And Future Direction	Next – Gen Biomanufacturing Technologies
NETWORKING BREAK	
Commercialisation, Investments And Partnership For Nordic Biopharma	Future Of Manufactuing For Nordic Biopharmas And Operational Excellence
NETWORKING LUNCH	
Nordic Innovation Highlights Showcase	Process Development Best Practices & Cell Line Engineering
NETWORKING BREAK	
Round Table Discussions On Nordic Biopharma Challenges	Regulatory Landscape And Market Entry Barriers
COCKTAIL RECEPTION	CONFERENCE ENDS

For Speaking opportunities, contact

Aishwarya Pattanshetti
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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 AND FUTURE DIRECTION

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,* **Norwegian Medicines Agency, Norway**

9:25 A look into Sweden's Biologics Industries' Current State and Future Direction

- Nordic Government's Initiatives in supporting the biologics industry
- Creating regional and international alliances to spur growth
- The rise of Medicon Valley as Europe's Strongest Life Science Cluster

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

9:50 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, Norway**

10:15 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**
Rasmus Beedholm Ebsen, *Senior Advisor-Life Sciences,* **Invest in Denmark, Ministry of Foreign Affairs, Denmark**
Soren Nielson, *Chief Executive Officer,* **2A Pharma, Denmark**

11:00 SPEED NETWORKING BREAK & REFRESHMENTS

COMMERCIALISATION, INVESTMENTS AND PARTNERSHIPs FOR NORDIC BIOPHARMA

11:45 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, Sweden**

12:10 Round Table Discussions on Nordic Biopharma Challenges

Roundtable 1 - REGULATION: Be prepared for the Clinical Trial Regulations and Ethical Review in the Nordic Countries
Lene Grejs Petersen, *Senior Adviser,* **Danish Medicines Agency, Denmark**

Roundtable 2 - Clinical Trials: How to select and use the RIGHT technology, and for that technology to gain the acceptance of patients, healthcare professionals and regulators

Roundtable 3 - Investment: How to bring in more investments for Nordic Biopharmas

Roundtable 4 - Partnerships: Criteria for selecting the Right Partner

Roundtable 5 - International Market Entry Barriers

12:50 Key Takeaways by Round Table Leaders

13:00 **NETWORKING LUNCH**

NORDIC INNOVATION HIGHLIGHTS SHOWCASE

14:10 **Translational Vaccine Research Moving from Mouse to Man and Back**

- Identify Vaccine Formulation
- Produce Vaccine
- Clinical Test Vaccine
- Lessons Learnt – Back to New Vaccine Formulation?

Ingrid Kroman, *Director- Vaccine Development,* **Statens Serum Institut, Denmark**

14:35 **Case Study:**

Epigenetics of Heart Failutre & Underlying Molecular Mechanisms

- A brief overview of heart failure
- A brief introduction into epigenetics
- Genome wide coverage of 5 methyl-cytosine and 5 hydroxy-methyl-cytosine
- Whole RNA seq / single cell RNA seq
- The effects of different types of genomic DNA methylation on gene expression and how these events underly heart failure.

Ralph Knoll, *Chief Scientist,* **Astrazeneca, Sweden**

15:00 **Case Study:**

ATOR-1015, A Next Generation, Bispecific CTLA-4-OX40 Targeting Antibody For Tumor Directed Immunotherapy Of Cancer

- Discussion on design & pharmacodynamics properties of ATOR-1015
- Exploring biochemical and manufacturing aspects
- Taking ATOR from research to Pre-Clinical Development for Clinical Trials

Peter Ellmark, *Principal Scientist,* **Alligator Bioscience, Sweden**

15:25 **Case Study:**

Developing a Safe & Scalable Cell Therapy for Type 1 Diabetes

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

15:50 **NETWORKING BREAK**

NORDIC INNOVATION HIGHLIGHTS:CLINICAL DEVELOPMENT OF VACCINES FOR CANCER

16:15 **Case Study:**

Using Artificial Intelligence to Discover therapeutic antibodies and vaccines

Jens Kringelum, *Head of Bioinformations,* **Evaxion Biotech, Denmark**

16:40 **Case Study :**

Development Of 2A Pharma's Novel Vaccines Platform From Clinical Stage

- Exploring novel vaccine platform
- Focus on novel HPV vaccine to cover more strains of HPV for better coverage thus reducing risk for malignancies
- Potential as therapeutic vaccines in areas of cancer and infectious diseases
- Strong development plan and commercialization

Soren Nielson, *Chief Executive Officer,* **2A Pharma, Denmark**

17:05 **Case Study :**

Clinical Development Of PROSTVAC®, A Vaccine For The Treatment Of Metastatic Castration-Resistant Prostrate Cancer (MCRPC)

- Therapeutic overview (vaccine construct, basic principles of vaccines in oncology)
- Phase 1 and 2 data with PROSTVAC
- Phase 3 design, outcome, lessons learned
- Next steps, risk mitigation, implications for other programs

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

17:30 Chairman's Closing Remarks

17:40 Cocktail Reception

Day – 2 [1st March 2018]

8:30	Registration
8:50	IMAPAC 's Opening Remarks
8:55	Chairman's Opening Remarks

NEXT – GEN BIOMANUFACTURING TECHNOLOGIES

9:00 **Case Study by Symphogen:**

Moving from Clinical Discovery to Commercial Scale Manufacturing in a Fast Way

- Achieving IND approval in the shortest way possible : Lessons learnt

Frank Nygaard, *CMC Project Director,* **Symphogen, Denmark**

9:25 **Next Generation Factory to reduce Cost of Goods 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, *Deputy Department Manager, API Process Development,* **Chugai Pharmaceuticals, Japan**

9:50 **Scalable Technologies For Process Intensification In The Factories Of The Future**

- Smaller facilities, reduced scale-up risk, consistent product quality and higher throughputs through continuous and intensified bioprocessing
- Discussion on the latest solutions for challenges implementing intensified and continuous bioprocessing
- Exploring SUBs designed for extreme cell densities at scale

Kai Touw, *Process Development Consultant,* **Sartorius Stedim Biotech, Netherlands**

10:15 **NETWORKING BREAK**

FUTURE OF MANUFACTUING FOR NORDIC BIOPHARMAS AND OPERATIONAL EXCELLENCE

11:00 **Developing scalable manufacturing platforms that would adapt to future demands**

- Key factors to consider in facility design and its impact on patient safety
- Implementing a standardized quality system
- Overcoming scale-up challenges and achieving operational excellence

Rudiger Mechsner, *Director,* **Biotecs, Switzerland**

11:25 **Critical Considerations About Biosimilars Development**

- Exploring platforms for production and analytical Characterization of Biosimilar Development
- Demonstrating Efficient and Accurate Biosimilarity Testing
- Discussion of Successful Case Studies overcoming Key challenges

Lauren Lu, *Senior Scientist,* **Genscript, China**

11:50 **Panel Discussion:**

Transitioning into the Manufacturing Space for Nordic Biopharmas by 2020

- Discussion on the challenges & opportunities in the transition from R&D to commercialization including an evaluation of the manufacturing process, bio analytics and mitigation strategies.
- Collaboration strategies with global CROs and CMOs to maintain quality & uphold timelines
- Future Developments to improve transition from bench research to commercialization

Panelists:

Lars Petersen, *Site Head,* **Biogen, Denmark**

Frank Nygaard, *CMC Project Director,* **Symphogen, Denmark**

12:35	**NETWORKING LUNCH**
	PROCESS DEVELOPMENT BEST PRACTICES & CELL LINE ENGINEERING
13:45	**Engineering the Next Generation CHO Cell Lines for the Production of Recombinant Proteins** • Building the next generation of protein production platforms • Engineering CHO Cell Lines to fit the purpose • Generating CHO Cell Lines for new proteinbased therapeutics **Bjorn Voldborg,** *Director of CHO Core,* **Novo Nordisk Foundation Center for Biosustainability, Denmark**
14:10	**Integrating Downstream Processing of Biologics** • Design and optimization of integrated downstream processes • Advanced control of multiple separation steps • General platform for integrated DSP in lab-scale **Bernt Nilsson,** *Director Process Industry Centre,* **Lund University, Denmark**
14:35	**Impact of Biomarkers in Early Drug Development** • What kind of Biomarkers are important • What can biomarkers do for you? **Birgitte Sogaard,** *Director of Clinical and Quantitative Pharmacology,* **Lundbeck, Denmark**
15:00	**Preparative Chromatography for Separation of Proteins** **Arne Staby,** *Scientific Director of CMC Project Planning & Mangagement,* **Novo Nordisk, Denmark**
15:25	**NETWORKING BREAK**
	REGULATORY LANDSCAPE AND MARKET ENTRY BARRIERS
16:10	**What Is Needed For Nordics Biologics Drug To Enter The European/International Market?** • Regulatory Strategies On Increasing Clinical Trials Efficiency In EU • How will Brexit impact the market access for Nordic Biopharmas • Key Regulatory Guidelines for Clinical Development of Biologics and Vaccine • What are the key challenges faced by Nordic biopharma **Gunilla Andrew-Nielsen,** *Head Of Department Of Clinical Trials And Special Permissions,* **Medical Product Agency, Sweden**
16:35	**Taking a drug candidate to IND : New Rules in the EU Implemented on Clinical Trials Application (CTA)** • New drug approvals – regulatory hurdles vs HTA assessment and payment for innovative medicines • How do we ensure uptake of new innovative medicines? • What are the relevant clinical criteria for use vs regulatory approval? • How do we help life science industry launch meaningful new drugs for patients in need **Nikolai Brun,** *Director of Division-Medical Evaluation & Biostatistics,* **Danish Medicines Agency, Denmark**
17:00	**Closing Regulatory Forum** **Challenges faced By Nordic Biopharmas in Navigating the Regulatory Maze** • Overcoming International Market Entry Barriers • Adjusting to the new changes post Brexit : Do's and Don'ts • Case Studies of Nordic Biopharma Successes **Nikolai Brun,** *Director of Divions, Medical Evaluation & Biostatistics,* **Danish Medicines Agency, Denmark** **Steinar Madsen,** *Medical Director,* **Norweigan Medicines Agency, Norway** **Gunilla Andrew-Nielsen,** *Head of Department of Clinical Trials and Special Permissions,* **Medical Products Agency, Sweden**
17:45	Chairman's Closing Remarks
17:50	End of Conference

Biologics World Nordic 2018
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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:

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Project Manager
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Companies expected to attend Biologics World Nordic 2018

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- CMC Biologics
- Statens Serum Institute
- Alvotech
- Alligator Bioscience
- Desentum
- Paras Biopharmaceuticals
- Faran Pharmaceuticals
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- 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
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- Tikomed
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2- Days Conference Pass	LIMITED SUPER (By 17 Nov)	LIMITED SPECIAL (By 15 Dec)	EARLY BIRD (By 26 Jan)	STANDARD PRICE
General Public Including: Solution Providers, Big Pharmas, International Biopharmas European Biologics Companies, European Academics	**€ 2099** (USD 2495)	**€ 2299** (USD 2695)	**€ 2499** (USD 2895)	**€ 2699** (USD 3095)
Nordic Biologics Companies & Nordic Academics **(BUY 2 GET 3, BUY 3 GET 5)**	**€ 799** (USD 995)	**€ 899** (USD 1095)	**€ 999** (USD 1195)	**€ 1099** (USD 1295)

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Biologics World Nordic 2018

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Copenhagen, Denmark

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