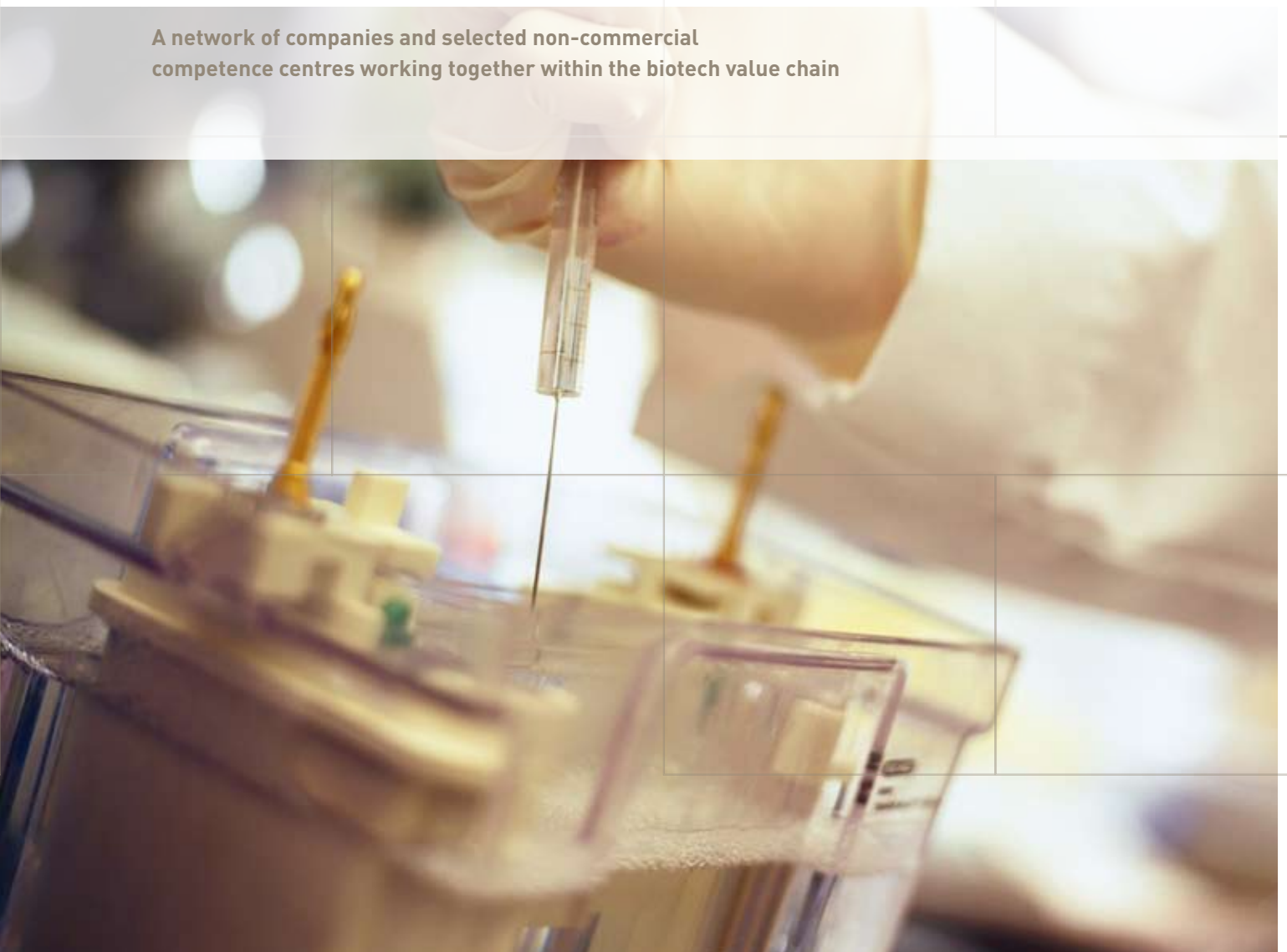


02051

January 2006

NbiNet Bioprocess Technology Network

A network of companies and selected non-commercial
competence centres working together within the biotech value chain



Participating organisations:

3H Biomedical AB (SE)

AgroFerm A/S (DK)

Alpharma AS (NO)

Alsiano A/S (DK)

BD Diagnostics (SE)

Belach Bioteknik AB (SE)

Bioevaluation

Uppsala-Stockholm HB (SE)

Biora AB (SE)

Biosentrum AS (NO)

Biotech-IgG AB (SE)

BiotekNet (DK)

Bioteknologisk institut (DK)

Biotechvalley.nu (SE)

BioThema AB (SE)

Biovitrum AB (SE)

**Center for Surface
Biotechnology** (SE)

Core Competence AB (SE)

Danisco Sugar Oy (SF)

EPT Teknik (SE)

Fagrell Consulting AB (SE)

Galilaeus Oy (SF)

GE Healthcare (SE)

Hydrios Biotechnology (SF)

Magellan Instruments (SE)

Medipolis GMP Oy Ltd (SF)

Norferm AS (NO)

Novozymes A/S (DK)

Novozymes Biopharma AB (SE)

ORF Genetics (IS)

PE Bioprocess Consulting AB (SE)

Quattromed AS (ES)

Roal Oy (SF)

SBL Vaccines (SE)

SIK (SE)

SINTEF (NO)

UniTargeting Research AS (NO)

Unizyme Laboratories A/S (DK)

Validation

& Inspection Europe AB (SE)

VTT (SF)

+ individual participation representing additionally 55 companies and 14 R&D environments except for the organisations mentioned above.

Affiliated

Governmental Organisations

VINNOVA (SE)

TEKES (SF)

VTU (DK)

NFR (NO)

Rannis (IS)

Title: NbiNet - The Nordic Network on Bioprocess Technology		
Nordic Innovation Centre project number: 02051		
Author(s): Gunnar Hörnsten		
Institution(s): SIK The Swedish Institute for Food and Biotechnology		
<p>Abstract: NbiNet has during a three year period established a self-sustained Industrial Network on Biomanufacturing in the Nordic region. The network integrates different types of competence needed in developing Biomanufacturing industry. The Industry in itself, customers to Biomanufacturing contract producers, R&D and process developers, supply and services companies and academic environments are of particular interest. Also governmental organisations in the Nordic region with a responsibility for development of the national innovation systems have taken part in this work.</p> <p>The project is a combined networking and innovation systems project and its primary result is the making of new contacts of a high quality within the industry on a Nordic scale. As primary means to achieve this close interaction and gathering of people, a number of workshop activities was organised across. These workshops have differed in character. Two primary work flows have concerned technologies and marked development. On technology development some meetings have been oriented to present experience on novel technologies and to disseminate technical competence of a more generic nature, some have a process perspective and gives comparative information on different systems and solutions. On market development, some efforts were directed to enhance internal knowledge on market demands and customers needs, other aspects were to present Biomanufacturing competence to the general public at meetings organised fully by NbiNet or in collaboration with others.</p> <p>The project associated a reference group of national research supporting governmental organisations already from the start. The reference group followed the project and a very valuable flow of information has thereby been made possible. Biomanufacturing is now more clearly entered on-the map of national agendas in the Nordic region, with the important values it contributes within the development of Health, Better Life & Well-being, Growth & Sustainability, Jobs & Innovation Policy and Globalisation.</p>		
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Executive summary

Main objectives

NbiNet is a Network of Stakeholders within industrial use of Biomanufacturing competencies, businesses and technologies. It aims at facilitating knowledge transfer and networking in between companies, R&D environments and public organisations strongly involved in Production, Research or Development using Lab-, Small or Large-scale Cultivation as a key technology.

Around the Core group of participants described above, NbiNet does also aim at Strategic Interaction with Biotech Supply companies and companies that needs to acquire or develop Cultivation Capabilities or Cultivation Based Products (for laboratory test, test production or clinical studies).

The most pronounced role of NbiNet is to act in creating contacts between different types of competencies among the Stakeholders, be it by innovation system, technology, knowledge or business driven motives. NbiNet deals with an entire very complex innovation system structure not only in the sense of the “triple helix”, but also in the sense that we work on integration also “within the individual three helixes” in themselves. NbiNet deals with the intricacies of developing contacts where people start to look upon each other as partners and not only as players.

NbiNet has during the three year starting up period (2002-2005) focussed on:

- Involving Biotech supply companies, with the intention to acquire knowledge on new emerging technologies as rapid as possible
- Involving leading University and Institute R&D groups in sharing experience and new technological possibilities in bioproduction
- Promoting the industrial development among biotech supply companies via addressing new types of technologies now at the University Research Stage and spread knowledge on their motivation within bioprocess industry
- Serving as a motor for industrial “need based innovation” within the University and Institute Sector
- Serving as an introduction to bioproduction among small research based companies in need of increased volumes of test material
- Marketing a Nordic Solution to local production of potential new products e.g. aid in the choice of production system for new types of products
- Helping in the development of new test production through teaching of companies in need of external bioproduction to -pose the right questions, when in contact with the bioprocess industry

Method/implementation

NbiNet is a Network of Stakeholders within industrial use of Biomanufacturing competencies, businesses and technologies. As such, the primary methods used are related to bringing select people together. This has been done on various scales, e.g. at small meetings 2-20 persons and smaller workshops and seminars. To promote conditions where high quality contacts are easily achieved, the latter meetings aimed for 30-75 participants.

Complementary to these meetings, general presentations of NbiNet issues have been made also e.g. to general convention audiences exemplified by the formally announced “Open Stage Program” at the Scandinavian BIOTECHFORUM in 2005.

A Steering committee has managed NbiNet. The group consisted of:

Einar Jonsbu, ALpharma AS
Lotta Ljungqvist, Biovitrum AB
Robert Wahren, Core Competence AB
Håkan Gros, Danisco Sugar
Kim Hansen, Novozymes A/S
Liselotte Larsson, Novozymes Biopharma AB
Einar Mäntylä, ORF Genetics
Gunnar Hörnsten, SIK AB

The role of the Steering committee has been general management. The Steering committee has refined and developed the Strategies of NbiNet over the three year period.

At the start-up of NbiNet, two key types of environments for networking were defined. The first environment was found within the Øresund Contract ETIF on Enabling Technologies for Industrial Fermentation. It primarily dealt with Technology development, dissemination and implementation. The second environment defined “Value chain-dependencies” and people known by the Steering group members were a natural starting point. Combined these environments contained critical mass in networking on making use of bioprocess technologies in Biobusiness.

Already at an early stage in development of the concept of NbiNet it was recognised that the conditions for developing this industry differed between the Nordic countries. A reference group of professionals working at key governmental organisations in the Nordic countries was established. The starting-up ambition with the group was to disseminate knowledge on the innovation systems in the respective country, the ways the financing agencies worked and to take things from there.

The following persons represented their respective organisations within the work of the reference group at one or more occasions over the project period: Tronn Hansen (NFR), Oddur Már Gunnarsson, Laila Törnroos and Sigridur Thormodsdottir (NICE), Thorstein Tómasson (Research Council of Island), Oddur Már Gunnarsson (Rannis), Teppo Tuomikoski (TEKES), Margareta Danielsson and Maria Landgren (VINNOVA) and Johannes Lundin Brockdorff (VTU).

Two operational task groups (later named work flows) were set-up treating different aspects of NbiNet. These work flows became the beacons that helped us to navigate in an economy and technology driven industrial business development.

The role of the market oriented task group gradually developed into a work flow to develop our understanding of the financial, business development and market driven motivations for NbiNet. The second task group deals with the “hardware”, expanded to define the needs for further technical support and development. Long term many demands are to be met in order to maintain competitiveness among Biomanufacturing companies in the Nordic region.

The project manager, Gunnar Hörnsten at SIK, The Swedish Institute for Food and Biotechnology, has co-ordinated activities and managed NbiNet in-between the formal meetings with the Steering committee.

Communication tools

Interactive communication over the internet/email in-between meetings have been complementary to internal meetings/workshop/seminar activities. A key tool in defining the concepts that NbiNet should give priority to is a Mind mapping tool (MindManager from Mindjet).

Concrete results and conclusions

A selection of 13 meetings can be singled out as the central events of NbiNet and are descriptive for the types of activities and motivations that NbiNet deals with. It is shown in the headings that NbiNet acts both on a more technical level as well as on a Value chain oriented level. NbiNet also sets out to define and further develop a market understanding in the Nordic region on how Biomanufacturing competences are set into work.

- Metabolic engineering in different production organisms. 12 May 2003, Snekkersten, Denmark (Publicly announced seminar)
- How to Add Value in the Biotech Value Chain, 15 May 2003, Lund, Sweden (Publicly announced seminar and workshop)
- What you need to know to develop cultivation for your new molecular products, 14-15 October 2003, Stockholm, Sweden (Publicly announced workshop)
- Industrial fermentations and molecular techniques – Sweden and Denmark bridging the gaps. April 27, 2004, Lund, Sweden (Publicly announced seminar)
- Substrates, in process chemicals and PAT in bioproduction. May 13, 2004, Copenhagen, Denmark (Publicly announced seminar)
- Financing of Industrially relevant R&D in the Nordic Region. September 11, 2004, Reykjavik, Iceland (Internally announced)
- Suppliers meet bioprocess R&D and bioproduction. 23-24 November 2004, Helsinki, Finland (Publicly announced workshop)
- Biotech Bioprocess Industry and its potential to help its customers, 1 December 2004, Stockholm. (Internally announced workshop)
- Exemplifying Process Analytical Technologies, 11 May 2005, Stockholm, Sweden (Internally announced workshop)
- Creating Successful Business in Life Sciences, 13-14 September 2005, Uppsala, Sweden (Publicly announced workshop)
- Icelandic biotech industry presents itself, 29 September 2005 Reykjavik, Iceland (Publicly announced seminar)
- Novelties in bioproduction and downstream processing, 30 September, Reykjavik, Iceland (Publicly announced workshop)
- Consultancy cultivation (CRO's and CMO's) – important contacts at an early stage in product development. Open Stage Program at BIOTECHFORUM, 12 October 2005, Stockholm, Sweden. (Publicly announced seminar)
- NbiNet partnering meeting on contract research, technology implementation, development of processes and biomanufacturing. 13 October 2005, Stockholm, Sweden. (Publicly announced seminar)

The primary beneficiaries of NbiNet are in total 241 individuals of which 172 persons represented 88 companies, 51 persons represented select top 20 academic/institute environments and 18 individuals represented government agencies, e.g. public financing R&D organisations in the Nordic region. These numbers on persons and organisations, exclude most meetings of a strictly bilateral nature that followed on earlier NbiNet activities.

Apart from formal NbiNet meetings, NbiNet has also taken part in an additional 10 meetings. At the latter meetings some thousands of individuals had the opportunity to listen to presentations relating to NbiNet. Also posters have been shown on select meetings. The persons taking part at these latter meetings are excluded in the statistics from NbiNet.

Journalistically, NbiNet has been presented in 10 articles. Additional administrative information on NbiNet is available in the Final report sent to NICE. The webpage <http://www.sik.se/nbinet> also includes more information on NbiNet e.g. detailed programmes of public activities.

Conclusions

The Nordic region at large contain sufficient critical mass to motivate the further development of this industry nationally and within the framework of the EU.

A necessary part of a viable Life Science industry

Biomanufacturing is an industrial basis for production of a range of different products. Large scale productions of high value products are found within pharmaceuticals (e.g. growth hormone and insulin; Swedish and Danish industry were world leading in developing modern manufacturing of these products). Lower value and large scale productions are exemplified by traditional antibiotics, industrial enzymes, feed additives and starter cultures/bakers yeast. Danish, Norwegian and Finish industries include good examples of world leading companies in these areas. Traditionally biomanufacturing have been made in bioprocess industries in large tanks. Among novel large scale productions we also find agricultural biotech where e.g. high value products produced in plants are refined to diagnostics or pharmaceuticals. Iceland, Sweden and Finland have on-going pioneering industrial work in this field. Smaller scale productions are also common, primarily for production of research chemicals needed in medicines and diagnostics development. Another example of importance is interaction studies with materials, chemicals, physical conditions and instruments that demand high quality small scale production of biologicals. The Nordic region as a whole contains many facilities for these types of productions, but only a few are independent consultancy facilities working within e.g. FDA approved regulatory/GMP conditions.

Down-stream of the production process, biomanufacturing purifies the product to the qualities needed for different applications. Also within this area we find a world leading company with its roots in the Nordic region.

Both large scale and small scale segments are viable business areas where one cannot replace the other.

We should be aware of that the Nordic Industry within Life Sciences is fragmented in various ways and that the larger Nordic region as a whole, is a much better geographical area on which to base policy decisions than the individual countries alone. This is stated with the full respect of that National agendas should be based on National priorities. However, within Biomanufacturing the markets and the value chains in which the companies and research

environments in the Nordic countries work, are mostly local (incl. smaller regions) or “global” (incl. the major countries and unions). All Nordic Countries share values as are shown in listing the key agenda concepts that NbiNet defined working with the reference group on National innovation systems. Those are: Health, Better Life and Well-being; Growth and Sustainability; Jobs and Innovation Policy; and Globalisation. Biomanufacturing is a needed tool for these demands to be met within Life Science industry as a whole.

Biomanufacturing industry is under a global pressure! Conditions that promote Nordic industries in competing with the rest of the world are not widely in place in the Nordic region.

Recommendations

Four of the Nordic countries have joined forces within a large European ERA-Net initiative on Industrial Biotechnology (ERA-IB). Denmark acts as a participant partner and Norway, Sweden and Finland are present as observers. ERA-IB is approved for support and is currently being negotiated with the commission.

NbiNet will have a representative (Gunnar Hörnsten, SIK AB) on the External Advisory Board of ERA-IB. It is therefore possible to maintain and further develop the contacts with the Nordic Stakeholders of ERA-IB.

NbiNet combined with ERA-IB are natural contact points between the National organisations and biomanufacturing industries in the Nordic region.

The strengths and weaknesses that are present in the Nordic Innovation Systems on Biomanufacturing deserves more attention since manufacturing capacity and expertise is of central importance for Life Science industry at large.

There are many crucial and complex strategic bottle-necks that needs to be dealt with to secure the competitiveness of this industry in the Nordic region on the longer time scale. The active involvement of high ranking policy makers and leading governmental officials are a prerequisite for the balanced allocation of means for being successful in this work.



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Nordic Innovation Centre

Nordic Innovation Centre

The Nordic Innovation Centre initiates and finances activities that enhance innovation collaboration and develop and maintain a smoothly functioning market in the Nordic region.

The Centre works primarily with small and medium-sized companies (SMEs) in the Nordic countries. Other important partners are those most closely involved with innovation and market surveillance, such as industrial organisations and interest groups, research institutions and public authorities.

The Nordic Innovation Centre is an institution under the Nordic Council of Ministers. Its secretariat is in Oslo.

For more information: www.nordicinnovation.net