

# Engineering for a healthier world

ENGLISH

nne pharmaplan®

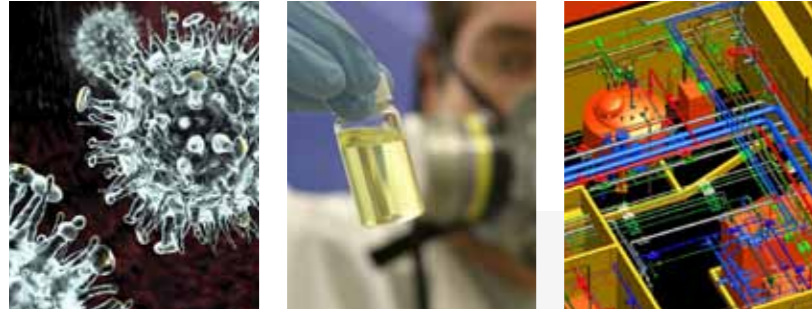


# Our reason for being

Through new and innovative products, the pharma and biotech industries make the world a healthier place. NNE Pharmaplan contributes to a healthier world through the services we provide to our customers. When we deliver consultancy or projects, we help bringing products faster to market, decreasing the overall cost of production and ensuring patient safety.

# Like a pharmaceutical company

NNE Pharmaplan is a lifelong partner to the pharmaceutical industry. We concentrate on providing services based on our pharma and biotech heritage, which we have built on for more than 80 years. In fact, we are the largest international engineering and consulting company that specialises in pharma and biotech. It is in our DNA...



**OUR COMPETENCIES.** We are born and raised with the process and production understanding of a pharma-biotech company. This is the foundation of our cross-technical teams of engineers, architects, chemists and pharmacists when they design, construct, validate and start up facilities. But it also enables us to support manufacturing operations with services within optimisation, product and process development, pilot plants and laboratories.

**DEDICATED TO THE INDUSTRY.** Our long history and deep engagement in the pharma and biotech industries are part of our dedication. Not only does more than 95% of our revenue come from these industries, but we are also recognised contributors in many of the organisations and groups that set pharmaceutical quality, manufacturing and engineering standards and guidelines. We contribute through ISPE, PDA, ASTM, ISA and ISO and have ongoing contact with regulatory agencies such as FDA, SFDA and WHO. As an example, our Senior Consultant Gert Moelgaard (pictured) is part of the team training FDA's investigators in the new FDA Process Validation Guideline.



**MAKING OUR EXPERIENCE COUNT.** NNE Pharmaplan combines expertise with passion to create results. When our experience and service philosophy form a synthesis, our customers gain a competitive advantage. We count almost 1,700 professionals with project experience and knowledge related to pharma and biotech. More than 200 have hands-on development or production experience and GMP knowledge. Our project execution and our staff embody 10,000 years of experience within pharma and biotech.



**INDUSTRY RECOGNITION.** We are proud - not least on behalf of our customers - when our joint results are recognised. And our customers have received many recognitions over the years: In 2009, two facilities designed and co-constructed by NNE Pharmaplan received ISPE's prestigious Facility of the Year Award: A new sterile production plant for hameln pharmaceuticals was awarded for Operational Excellence and a new R&D fill-finish pilot plant for CentoCor won the Facility Integration category. The same year, our DeltaV application for Pronova BioPharma's Kalomega plant was awarded the PlantWeb Excellence Award by Emerson. Novo Nordisk's facility for Factor VII haemophilia medicine (picture), designed and built by NNE Pharmaplan, was named Facility of the Year in 2005, and in 2004 another of Novo Nordisk's facilities, a 35,000 m<sup>2</sup> insulin bulk plant, was awarded IChemE's Haden Freeman Award for Engineering Excellence.

"Creative design within a super fast-track timeline for project execution, application of modular engineering for greater control and flexibility, and dramatic and pleasing architectural features throughout the facility". Statement by the nine-member ISPE Facility of the Year judging panel.



**OUR HERITAGE.** NNE Pharmaplan has roots in Danish Novo Nordisk and German Fresenius. Ever since these two and other early pharma companies started working with pharmaceuticals decades ago, we started building our competencies for providing engineering and consulting services. The picture illustrates a part of our heritage, an insulin production site in the early 1930s. At that time, many employees had diabetes or immediate family suffering from the disease. From the beginning, our heritage built on the appreciation of our impact on patient health. We have grown significantly since then. It has not always been easy, but we are proud of our achievements with our customers over the years and throughout the globe. That's why our tagline is "Engineering for a healthier world". NNE Pharmaplan was named Company of the Year in 2008 by ISPE.

# Closer to the customer



Global office locations make us unique. We have more than 25 offices in Europe, North America and Asia and plan to establish more. Our global network allows us to offshore some of our engineering production and to leverage different execution models like modular and turnkey for the benefit of our customers. It also allows us to be close to our customers, which is a key mantra of our organisation.

We employ close to 1,700 people, who together represent an impressive quantity of expertise, knowledge and hands-on experience – local as well as international. Our strong combination of global reach and local knowledge enables us to deliver tailored solutions to any customer.



# Contributing to world health

When patients share syringe needles, infections spread. In fact, reuse of needles contributes to more than 1 million deaths each year. Our engineers have developed an innovative auto-disabled syringe with a one-way valve that makes it impossible to reuse the syringe immediately after the liquid begins to leave the needle.

UNICEF recommends such solutions across the world and it is an example of how we apply our expertise to address global health issues.

# Inspired by innovation

Medicine plays a very important role in the history of mankind, and the pharmaceutical industry has known how to pursue opportunities for new drugs and treatments. More than ever, the market requires pharmaceutical companies to develop new products and get them to the market quickly - and to ensure a cost-effective and dynamic supply chain. We are proud to join our customers at the forefront of innovation.

**SINGLE-USE TECHNOLOGY.** The biopharmaceutical segment is undergoing a rapid process and technology development. Single-use equipment is a promising solution when combined with the right knowledge. The advantages are clear: Lower investments, increased flexibility, faster scalability and tech transfer, and lower contamination risk. Our project experience and strong supplier relations within single-use technology make us an attractive, vendor-independent partner who sets the optimal balance between single-use and stainless steel solutions.



**THE FDA'S NEW PROCESS VALIDATION GUIDE AND THE ASTM E2500 STANDARD.** A new process validation guideline from FDA combined with the ASTM E2500 standard for verification of pharma and biotech facilities enables a cost-effective alternative to the conventional DQ/IQ/OQ/PQ validation with more focus on product and process understanding. If implemented right, it saves money and time while improving quality and increasing focus on patient safety. NNE Pharmaplan has been deeply involved in setting the new standard and the follow-up industry guides, and our experts have helped several customers transform their traditional validation approaches to the new guidelines.

**QUALITY BY DESIGN (QBD) AND THE SCIENCE AND RISK-BASED APPROACH.** A new pharmaceutical quality paradigm based on science and risk-based principles paves the way for increased end product quality and efficiency. The new paradigm is headed towards broad scale implementation and regulatory harmonisation between the USA, Europe, Japan and others. NNE Pharmaplan is deeply involved in the preparation and implementation of these concepts and related practices. We assist customers throughout the world with training, consulting and implementation of projects that combine the benefits from cost-effective solutions and compliance with the future regulatory requirements.

**FAST TRACK.** Bringing new drugs fast to market benefits the patients. It also helps innovative companies gain a stronger market position and thus fuels development. Fast project execution also helps companies adapt better to changing market needs - and avoid over-investing. At NNE Pharmaplan, we address the need for fast project completion through an aggressive approach to fast-track work and we have built an impressive track record of fast-track projects.

**COST-EFFECTIVE PHARMACEUTICAL OPERATION.** Cost-effective manufacturing has become part of normal life in the pharmaceutical industry. With generic competition, patent expiry and cost-pressure on health care around the world, we expect the trend to continue. We follow the trends and opportunities of regulations, best practice industry standards and technology through our global network, to be able to help our customers deal with their global challenges. We assist with services within process optimisation, Lean, Six Sigma, operational excellence and business improvement projects - and with our global presence we can also assist in international roll-out of corporate operational excellence programmes.





#### PERSONALISED DRUGS AND TREATMENT.

The pharmaceutical industry of the future will be very different from the past, and the change is progressing right now. Small production volumes for orphan drugs and other treatments for rare diseases are part of the future agenda - and ultimately we will see personalised drugs and treatments on the market. With new treatments, diagnostics and combinational medicine taking shape, our customers are facing new manufacturing challenges. NNE Pharmaplan has already been involved in some projects concerning new facilities for advanced therapies and our experience tells us that such products require highly flexible and very robust solutions.

**TURNKEY FACILITIES.** NNE Pharmaplan's turnkey solutions represent a one-stop-shopping solution that spares our customers the trouble of dealing with the complexity of a facility project. We have built turnkey facilities throughout the world and take responsibility for dealing with suppliers and construction companies, ensuring that we meet the project goals in terms of time, cost and quality. We have standard concepts for basic vaccine, MAb and aseptic facilities which can be adapted to individual customer needs.



**AUTOMATION AND INDUSTRIAL IT.** The pharmaceutical industry's ability to advance in the global competition has become increasingly dependent on automation and IT. The integration of manufacturing data like electronic batch records MES and PAT, is becoming increasingly important in today's regulatory environment. Our capability to turn data into knowledge and regulatory compliance with statistical tools is thus key to our customers. Combining our long track record as a vendor-independent system integrator with our process and GMP expertise, we can help customers develop the best automation strategy for their specific production environment.

**MULTI-PRODUCT REVAMPS.** New manufacturing strategies from mergers, acquisitions and offshoring entail new roles for existing facilities. This often leads to critical revamp projects in fully operating plants. We increase capacity and flexibility with minimal interruptions in ongoing production or help turn old facilities into future business assets. Our revamp services include all activities from analysis to running production and ensure an exceptionally short production shutdown period followed by fast production ramp-up into guaranteed capacity.



The background of the entire image is a microscopic view of several green, spiky virus particles. These particles are spherical with numerous protruding spikes that resemble small, rounded heads on thin stalks. The lighting is dramatic, with some particles in sharp focus while others are blurred in the foreground and background, creating a sense of depth. The overall color palette is dominated by various shades of blue and green.

# Passion is key

Our investment in the industry and desire to transform knowledge into results are what fuel our passion. And we apply this passion in everything we do in order to improve our customers' business results and ultimately contribute to a healthier world.

# Committed to the full lifecycle

## DEVELOP

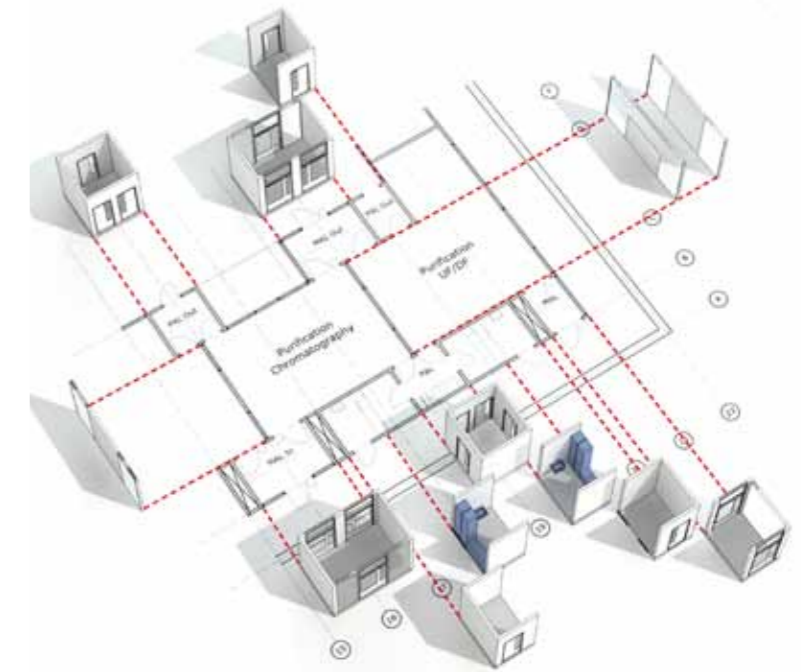
### THINKING OUT OF THE BOX – AND CREATING A HEALTHY DECISION PLATFORM.

By creatively applying both manufacturing sciences and our rich pool of industry experience NNE Pharmaplan helps customers devise strategies for supply chain, automation, technology selection, quality by design, site selection, technology transfer, etc. We have helped customers identify optimisation potential instead of investments, phased revamps to reduce impact on production and postpone investment, performed innovative reconfiguration of existing equipment enabling more capacity to be squeezed in, and used far less investment-heavy technologies such as single-use, RABS and isolators, due diligence of existing facilities and evaluation of outsourcing options.

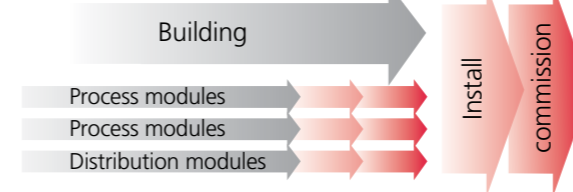


## ESTABLISH

**CUSTOMISED GMP SOLUTIONS THROUGH CLOSE COOPERATION.** NNE Pharmaplan's process and GMP experts are dedicated to ensuring that our design fits the specific requirements of our customers. But equally important to us is the close cooperation with our customers throughout a project. Our interactive 3D modelling tool enables us to model a facility in a few hours, using our standard library of 3D modules GMP reviews, preferably involving the user and user QA to ensure compliance and to create the most efficient solution.



### Modular



### Traditional



**SAFE & ROBUST PROJECT EXECUTION.** Reliable project execution requires a clear and consistent structure. NNE Pharmaplan has developed a global engineering model, Our Model, which serves as a common reference model for our entire organisation. It provides a common terminology and a common way of executing projects; and ensures that we work consistently with well-proven methods and best practices worldwide. Our aim is to give our customers the exact same services from beginning to end of a project, no matter where in world they meet us. Our project and construction management focuses on financial predictability, schedule, compliance and safety.

**FAST AND FLEXIBLE.** Fast project execution presents many benefits – not only to the individual company, but to the pharmaceutical industry as a whole. And it drives fast-to-market benefits to the patients. We complete projects within 12-20 months on a regular basis. We achieve fast and flexible projects by using a modular design methodology as our standard. Each module design is as self-contained as possible, including automation systems, installations, etc. This allows the modules to be designed and produced in parallel.

## IMPROVE

**REBUILD OR RETHINK?** The improvement of a facility is related to much more than the physical installation. Softer aspects such as work flows and regulatory compliance have significant impact on production efficiency and quality. Gap analysis, revision of SOPs and quality systems, operational excellence, design of experiments and advanced data analysis and automation are some of the tools we use to optimise production.





## NNE Pharmaplan offices

### CENTRAL EUROPE

#### Switzerland

NNE Pharmaplan  
Altkircherstrasse 8  
4054 Basel  
Phone: +41 61 307 9670  
Fax: +41 61 307 9680

NNE Pharmaplan  
Av. de Gilamont 52  
1800 Vevey  
Phone: +41 21 926 9700  
Fax: +41 21 926 9709

#### France

NNE Pharmaplan  
3 avenue Victor Hugo  
28000 Chartres  
Phone: +33 (0) 2 37 88 79 50  
Fax: +33 (0) 2 37 30 75 28

NNE Pharmaplan  
Immeuble SOLARIS - 3ème étage  
210 avenue Jean Jaurés  
69 007 Lyon  
Phone: +33 2 37 88 79 50  
Fax: +33 4 37 70 84 98

#### Germany

NNE Pharmaplan  
Siemensstr. 21  
61352 Bad Homburg  
Phone: +49 6172 8502-100  
Fax: +49 6172 8502-501

NNE Pharmaplan  
Werksgelände der Behring Werke /  
Hauptwerk  
Gebäude H6, 4. Stock  
Emil-von-Behring Str. 76  
35041 Marburg  
Phone: +49 6421 18679-40

#### Ireland

NNE Pharmaplan  
c/o Life Science Consultants  
Unit 8a, Kinsale Commercial Park  
Kinsale, Co. Cork.  
Phone: +353 21 477 7329  
Business Partner  
Kieran Coughlan

#### CHINA

NNE Pharmaplan  
17F, JinWan Mansion  
No. 358 Nanjing Road  
Tianjin 300100  
Phone: +86 22 2750 1730  
Fax: +86 22 2750 1745

TEDA office:  
Room 602, No. 5 Building,  
TEDA Service Outsourcing Park,  
No. 19 Xinhuan West Road, TEDA, Tianjin  
Phone: +86 22 59861090  
Fax: +86 22 59861097

Concept, text & design NNE Pharmaplan A/S

Photo Peter Sørensen (DAS BURO), Getty Images, iStock, NNE Pharmaplan

Print KLS Grafisk

Version September 2011

NNE Pharmaplan  
Room 1001, Tower A, Center Plaza  
No. 161 Lin He West Road  
Guangzhou 510620  
Phone: +86 20 3833 9386

NNE Pharmaplan  
Room 405, Man Po International Business  
Center  
No. 660 Xin Hua Road  
Shanghai 200052  
Phone: +86 21 6282 6077  
Fax: +86 21 6282 7194

### EMERGING MARKETS

#### India

NNE Pharmaplan  
A2/118, Safdarjung Enclave,  
New Delhi - 110029  
Phone: +91 11 26197251 / 52  
Fax: +91 11 26197253 / 26169248

NNE Pharmaplan  
B-15, Sector 2,  
Noida - 201301  
Phone: +91 120 4775100,  
Fax: +91 120 4775200 / 4775300

NNE Pharmaplan  
#14, Achiah Shetty Layout,  
RMV Extension, Sadashivnagar,  
Bangalore - 560080  
Phone: +91 80 23614415 / 23617234 / 35  
Fax: +91 80 23617240

NNE Pharmaplan  
703-704, Sagar Tech Plaza, A-Wing,  
Andheri Kurla Road, Sakinaka, Andheri  
(East)  
Mumbai - 400072  
Phone: +91 22 40647000  
Fax: +91 22 40647099

#### Malaysia

NNE Pharmaplan  
16, Jalan 51A/225  
46100 Petaling Jaya, Selangor  
Phone: +60 3 7862 3000  
Fax: +60 3 7862 3001

#### Russia

NNE Pharmaplan  
19 Leninskaya Sloboda  
115280 Moscow  
Russian Federation  
Phone: +7 499 270 0999  
Fax: +7 499 270 3399

NNE Pharmaplan  
191119, "Renaissance Plaza" BC,  
Littera "A"  
69-71 Marata Str.  
St. Petersburg  
Russian Federation  
Phone: +7 915 009 8716

### NORDIC

#### Denmark

NNE Pharmaplan  
Head Office  
Nybrovej 80-90  
2820 Gentofte  
Phone: +45 4444 7777  
Fax: +45 4444 3777

NNE Pharmaplan  
Brennum Park 25KP  
3400 Hillerød  
Phone: +45 4444 7777

#### NNE Pharmaplan

Hallas Alle  
4400 Kalundborg  
Phone: +45 4444 7777

#### Sweden

NNE Pharmaplan  
Sankt Eriksgratan 117  
SE-11343 Stockholm  
Phone: +46 8 59 49 60 00  
Fax: +46 8 59 49 60 99

NNE Pharmaplan  
World Trade Center  
Jungmansgatan 12  
211 19 Malmö  
Phone: +46 8 59 49 60 00

### NORTH AMERICA

#### United States

NNE Pharmaplan  
Perimeter Park ONE,  
3005 Carrington Mill Boulevard, Suite 380  
Morrisville, NC 27560  
Phone: +1 866 810 4073  
Fax: +1 919-763-1801

NNE Pharmaplan  
222 Third Street, Suite 2230  
Cambridge, Ma 02141  
Phone: +1 866 810 4073  
Fax: +1 617 621 7973

NNE Pharmaplan  
1055 Westlakes Drive  
Berwyn, PA 19312  
Phone: +1 866 810 4073  
Fax: +1 610 727 4360

NNE Pharmaplan  
150 Executive Park Boulevard, Suite 2300  
San Francisco, CA 94134  
Phone: +1 866 810 4073  
Fax: +1 415 656 1399

Email contact to all offices:  
[contact@nnepharmaplan.com](mailto:contact@nnepharmaplan.com)

