



2005 Facility of the Year:

Novo Nordisk NovoSeven® Manufacturing Facility Employs Groundbreaking Modular Design

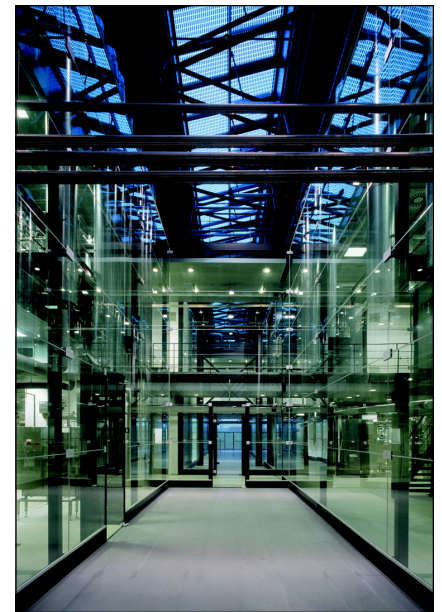
In 2000, Danish pharmaceutical company Novo Nordisk had an enviable problem: how to expand production as rapidly as possible in order to meet increased demand for its lifesaving NovoSeven® hemophilia drug. To build a new, dedicated NovoSeven manufacturing plant, Novo Nordisk set an aggressive delivery schedule that would have been impossible to meet, using conventional facility design/construction methods. Instead, the company embraced a revolutionary solution: modular design and engineering.

By going modular, Novo Nordisk was able to take delivery on the project after a fast-tracked 18 months – and the sleek new facility in Hillerød, Denmark is a powerful proof of the modular concept for the project's design, engineering and construction firm, NNE. The 14,000-square-meter plant is an integrated facility for mammalian cell fermentation, recovery, and

purification, with a large, open hall supporting independent production modules. The modular design will enable easy expansion as product demand increases into the future.

“The NovoSeven facility represents an industry milestone, by establishing modular engineering as an effective and powerful tool for rapid design and execution of pharmaceutical facilities,” said Kjeld Bjerregaard, NovoSeven Facility Manager. “The finished product is a thoughtfully organized building that demonstrates the result of modular thinking in the architectural design and construction, and in providing a safe and positive working experience for employees.”

This groundbreaking implementation of modular design and construction, and its use to accelerate construction and enable the company to respond rapidly to a pressing business need, has earned Novo Nordisk a cov-



The high tech appearance of the production area signals its critical function as the heart of NovoSeven® production.



The working environment is bright and open with many varied views to the outside from different places within the facility.

eted new distinction: 2005 Facility of the Year. The NovoSeven facility was chosen from an outstanding field of 28 global entries, each with powerful merits and award-winning attributes in its own right. Novo Nordisk was presented the Facility of the Year Award during the Plenary Session of the 2005 INTERPHEX exhibition, held in New York in April.

“The NovoSeven facility is an outstanding example of the high-quality, creative approaches pharmaceutical companies are taking to address key business challenges,” said Peter Bigelow, Chairman of the Facility of the Year Judging Panel. “Novo Nordisk deserves this recognition for several reasons: creative design within a super fast-track timeline for project execution, application of modular engineering for greater control and flex-

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ibility, and dramatic and pleasing architectural features throughout the facility.”

A Modular Design/ Engineering Approach

From its initial stages, project design for the new NovoSeven® plant was driven by the requirement to reduce execution time as much as possible. “Even with everyone working as fast as possible, the schedule would not have been met through the traditional approach of executing major project components in series, by first constructing a building and then installing the equipment inside,” said Bjerregaard. Rather, the project team constructed process modules in parallel at offsite locations, where commissioning and qualification of each system could be conducted without the usual dependencies on adjacent upstream and downstream equipment.

Modules were divided into five subgroups: cell fermentation, chromato-

graphic separation, raw materials and buffers, clean utilities, and facility utilities. Each group of modules was purchased from a supplier with expertise in the specific type of equipment. The modules were ordered as complete functional and operational units, including instrumentation and power panels. A module for a purified water system, for instance, would be built and qualified to the requisite capacity on a skid, complete with instrumentation and control systems, and then be delivered to the site as a self-contained unit.

Meanwhile, the building was designed and constructed in independent sections, each planned to accom-



At this stage in construction, piping in the basement was already completed.

modate delivery and then meet the specific operating requirements of its respective process module. For the main production hall, mounting of equipment was particularly challenging due to the large number of modules and their close proximity on each other. The solution was to first construct the large hall and close the building for weather protection, and then afterwards to transport

all the process equipment into the hall and stage it in its proper place on the ground floor or first floor.

Distribution piping between modules (product, CIP/SIP, solvents and utilities, collection of waste, etc.) was a critical path issue for the modular design since it had to be installed and ready to connect as each module arrived onsite. Piping installation could not impede module delivery, and it needed to allow for adjustment in the event of



The third production area is open and ready for use if an expansion of the production capacity of NovoSeven® should be needed.



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unavoidable inaccuracies in the building design. To meet these needs, NNE installed the bulk of the distribution piping in the basement, which was completed and closed first to enable construction above ground.

Once modules arrived at the site, all that remained was to verify that off-site testing had not been invalidated in transit, to connect piping, power, and automation network cable, and to perform necessary on-site testing.

Facility as Art

Not only is the new Novo Seven manufacturing facility a living case study of modular design and engineering, but it's also an architectural gem. The beautiful structure was specifically designed to create an open, positive, and easily-navigated work environment, while remaining true to its core mission as a functional and expandable production facility. “Novo Nordisk used architecture and engineering to create a work of art – a building that is not only functional, but should bring great satisfaction to its employees,” said Facility of the Year Judge Ulrich Rudow.

The NovoSeven facility consists of four different components, each of which has a distinct structure and specific demands for surroundings, surfaces and HVAC. The four sections include the classified production area, a utility area for supporting processes and buildings, an energy center supplying power to the entire facility, and a common administration building with offices, laboratories, and employee canteen. “We wanted each area to ‘explain itself’ through the chosen materials and finishes. Glass and steel, for instance,



To create a feeling of unity and purpose among the employees, the offices and meeting rooms in the common building offer lots of views of the production area.

imply cutting-edge technology and smooth, sterile, and easy-to-clean surfaces – so they created an appropriate identity for the production area,” said NNE architect Charlotte Andersson.

While the four building sections were constructed independently and are designed as self-contained structures, glass corridors connect each section and provide cohesion among the different plant functions. Visiting inspectors often appreciate the corridors’ transparency, which provide them with a clear view of the production area. Furthermore, the clear layout of the corridors provides the staff with well-defined escape routes that are easy to navigate. Offices and meeting rooms in the administration building offer plenty of views of the production area, helping tie all employees

into the plant’s singular mission of producing NovoSeven®. “The goal is to make each person working in the facility feel part of a unified whole,” said Bjerregaard.

The glass and steel design of the large production hall and its supporting units is meant to visually connect the classified production area with the rest of the facility. The spacious walkways within the production hall played a valuable role during construction by facilitating the installation of modules and equipment. The production area’s high-tech appearance clearly signals its mission-critical function to staff and visitors, and its open and transparent construction helps employees gain a coherent picture of the whole facility and its many processes. At the same time, the transparent design supports requirements



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The production facility at night.

for worker safety by enabling employees to overview a large area and detect danger signals early enough to take corrective action.

One Plant, One Product

At the time of Novo Nordisk's decision to build a new manufacturing plant for NovoSeven® in 2000, the drug was approved for treating hemophilia and other congenital bleeding disorders – but it was also being investigated in clinical trials to determine whether it could be used as a general hemostatic agent. This opened the door to a wide range of potential new applications and indications for NovoSeven® and made its real market potential difficult to pinpoint, as well as the timeframe that would be required for future clinical trials, regulatory approvals, and market penetration. As a result, Novo Nordisk had no clear projections of the future production capacity that would be required of the new facility.


Therefore, planning for the future had a two-fold objective: to expand production capacity as quickly as possible for the approved indication of NovoSeven®, and to build in the flexibility and expandability to accommodate future indications as they are approved. By offering this flexibility and enabling fast-track delivery of the plant in only 18 months, modular design and engineering provided the solution. “Flexibility is a key word when designing a production facility today,” said Klaus Illum, NNE's Engineering Director. “It is critical that the facility is able to change and adapt over time. New production capabilities must be integrated easily and cost-effectively as product and business requirements evolve.”

To accommodate future expansion, the NovoSeven facility's production area consists of three production units opening onto the main hall. At the time of handover, two units were operational; the third is a construction

shell that can be built out to accommodate future surges in NovoSeven® production. Looking even further ahead, the facility's repeatable design will simplify construction of a reflected duplicate of the entire plant, should product demand require it. In designing a facility that could accommodate the range of possibilities for future demand and indications of a single product, Novo Nordisk and NNE fulfilled their vision of “One Plant – One Product.”

Proving the Modular Concept

Handover of the NovoSeven facility in November of 2002 may have marked the completion of a successful project for Novo Nordisk, but it signaled an exciting new beginning for NNE. As the starting point and proof of concept for the design/engineering firm's modular engineering principles, the new facility provided invaluable knowledge to help NNE continue refining its principles and working methods. More significantly, the project gave NNE the impetus to continue working toward its strategic goal of building a greenfield pharmaceutical facility (from start of detailed design to start of performance qualification) in only 12 months. In fact, the experience gained from the NovoSeven® project enabled NNE to complete a subsequent facility in 14½ months.

“By delivering a facility in 18 rather than the standard 30 months, we took a huge step toward our goal of a 12-month facility,” said Illum. “But, just as important, the NovoSeven facility was a groundbreaking project that helped demonstrate the feasibility of modular design, not only for fast-track delivery, but for the inherent flexibility that modularity provides.” 



For comprehensive information about the 2006 Facility of the Year Award competition, visit

www.facilityoftheyear.org