

CASE STUDY

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*—Bo Memhave
NNE Business Director
and CIO*



COMPANY PROFILE

- NNE A/S (Novo Nordisk Engineering A/S)
- Engineering consulting/Software support
- Headquarters in Copenhagen, Denmark
- Subsidiaries in China, France, Switzerland, Sweden, United States
- <http://www.nne.biz/>
- Product Purchased - Citadon CW



EXECUTIVE SUMMARY

After safety and effectiveness, time to market trumps all else in the high-stakes pharmaceutical and biotechnological industries. And when being first — or getting to market at all — requires building a new, state-of-the-art facility, the world’s leading pharma and biotech companies turn to NNE, a pioneer in “fast track” design and building methods.

Focusing on quality and tight working relationships with clients and strategic partners, NNE turns in one record-breaking performance after another. The company has steadily reduced the time necessary to take a plant from design detail to fully operational, culminating in its current 11¹/₂-month production standard — less than one-third the previous industry average.

Instrumental to the company’s success is its reliance and global standardization on Citadon CW® (Collaboration Workspaces), Citadon’s secure, centralized electronic collaboration and document management platform. Citadon CW enables NNE to manage workflows and approvals, complete with an audit trail and built-in tracking capabilities. And the company, as well as its partners and clients, can post, store, access, and comment on the latest critical project documents — knowing that the information is protected by Citadon CW’s physical, application, and functional security controls. Without Citadon CW, NNE wouldn’t be as efficient at what it does best: designing and building flawless life sciences facilities fast.

THE COMPANY

NNE is a leading supplier of engineering and construction services to the worldwide pharmaceutical and biotechnological industries. The company’s technical competencies span engineering, construction, validation, start-up and optimization, and reconstruction for product development and production plants, laboratories, and more. A subsidiary of Novo

Nordisk A/S, NNE has functioned independently since 1991 and is headquartered in Denmark with subsidiaries in China, France, Switzerland, Sweden, and the United States. The company gained ISO 9001 certification in 1997. Its 150,000-square-foot NovoSeven pharmaceutical plant, in Hillerød, Denmark, earned the International Society for Pharmaceutical Engineering “2005 Facility of the Year Award.”

THE CHALLENGE

In 2001, NNE set a goal of becoming the first engineering firm to build biotechnological and pharmaceutical factories in 12 months or less, from order to occupancy. This timeframe, a stunning reduction from the 36 months typical of its competitors, would be certain to enshrine the company as a world leader in fast-track building. To make it a reality, NNE carefully nurtured select, rock-solid strategic partnerships, rather than relying on a loose constellation of vendors and suppliers, any one of whom may or may not deliver when needed. And it developed a range of innovative, exceptionally effective processes that the company felt certain could elevate its operations to the level it wished to occupy.

But before NNE could run construction projects the way it believed they could be run, the company needed the right enabling technology: a strong, project-centric document and collaboration system. One that could provide overarching control capabilities, integrate processes with partners and customers, make current information available everywhere at once, and fully integrate with the company’s existing enterprise resource planning (ERP) systems. NNE needed to ensure its engineers were making their best designs available to everyone who could use them. And the company needed a system that would be easy to use and offer quick, obvious benefits; otherwise, adoption would lag. NNE had tried in-house solutions but decided the total cost of ownership — including maintenance, support, etc. — was too great. Still, the company wanted a flexible system it could customize as required.

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THE SOLUTION

NNE uses modular engineering practices and Citadon CW to great effect.

Breaking Projects Into Pieces...

NNE systematically breaks down its fast-track projects into discrete, recognizable modules — both from a process perspective and a physical perspective. The company’s modular design process divides huge construction projects into small segments that can be expedited as required using repeatable, best-practice solutions.

Just as important, NNE’s modular engineering breaks down physical plants into plug-and-play sections that can be independently manufactured and tested off-site. The on-site arrival of the modules is tightly orchestrated to accommodate their designed placement in the facility. Individual modules are so self-contained that the final, on-site assembly process involves only the mating of simple interfaces via pipes, wires, drains, etc.

This approach takes advantage of the deeper and more-flexible resources available beyond the worksite. And it avoids many of the constraints typically imposed by construction sites — such as limited access to qualified test personnel and quality-assurance resources — that add time to a project.

Modular engineering also means future expansion can be planned during the initial construction, and implemented later in the same efficient way.

Thanks to fast track engineering, NNE can begin construction in earnest before the final process design is complete. As the functional modules are being manufactured, concrete is being poured; meanwhile, NNE engineers are still designing the facility’s control systems.

...Then Pulling Them All Together

“In many ways, Citadon CW makes it possible for us to do what we do,” says Bo Memhave, NNE business director and CIO. “It’s an excellent tool that really gives us the advantages we need, and enables us to take on the kind of projects we want to take on.”

Citadon CW gives NNE an up-to-the-minute design and construction overview of what needs to be done, and ties together all the individual phases and participants.

“Citadon CW has proven to be the ideal tool to help us collaborate with our partners and bring new pharmaceutical products to market faster than ever before,” says Memhave. “By creating reusable processes, we can build collaboration solutions on demand, and Citadon CW’s easy-to-use Windows interface makes it easy to bring in new partners with little or no training.”

NNE uses Citadon CW to efficiently and safely distribute documents from its United Kingdom data center to design teams across time zones and around the world. CW workflows enable project managers to solicit comments on documents from partners and clients and to assess project status.

“In the old days,” says Memhave, “you’d send out a lot of information in all directions and hope it got to the right people at the right time, and to none of the wrong people. With CW, by contrast,



the project manager just checks the task list for one, single view of how we’re doing. And the information is totally secure.”

NNE also takes advantage of Citadon CW’s open and published API.

“We customize the software to simplify ongoing project support and administration,” says Memhave. “For example, if you lose your password, we’ve configured CW so you can go directly to our website, press one button, and immediately receive a new password. Our goal is to eliminate wasted time whenever possible.”

Another example: NNE can add new projects to Citadon CW as easily as filling in some form fields and pressing a button. “It generates a whole new workspace entirely in CW and rolls in our standard layouts in just a few seconds,” says Memhave.

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The Right Personnel

Everyone on an NNE project can access the documents necessary to perform their jobs via Citadon CW, but when it comes to input, the company manages the process with dedicated “document supporters.”

“We don’t want hundreds of engineers inundating CW with information,” says Memhave. NNE document supporters act as gatekeepers, filtering the information to be published. That’s because, according to Memhave, “Every minor calculation is not relevant, and if anyone could post anything, the result might be more detrimental than beneficial.”

“Our customers are happy to pay for document support service because they know our gatekeepers will classify documents appropriately,” says Memhave. The gatekeeper function is especially critical when there are numerous subcontractors on each job, some of whom may not be familiar with NNE’s way of doing business. “It just saves everybody an enormous headache,” says Memhave.

Document supporters rely on the software’s Binder tool, which enables them to create a special repository (binder) for bringing together related documents, such as a series of build plans related to a specific area of the building, or a specific discipline. It’s then possible to restrict individual subcontractors to particular Citadon CW binders — so the subs know where to find the information they need but can’t wander into areas that don’t concern them. The files can even remain in the original folder structure, where they can be accessed and updated according to the privileges assigned.

Obviously, in a fast-track design and construction environment, space management is critical. Space managers encompass all the engineering disciplines — mechanical, instrumentation, HVAC, etc. — to make sure everything will fit. So, in addition to document supporters, NNE supplies at least one space manager for every large project.

How Low Can It Go?

NNE’s modular engineering techniques, especially well-suited to fast-track projects, were fully implemented for the first time on the NovoSeven pharmaceutical facility, which, built in only 18 months, won ISPE’s “2005 Facility of the Year Award.” NNE later built a 97,000-square-foot, state-of-the-art vaccine production facility for the Bavarian Nordic biopharmaceutical company in a once-unthinkable 11¹/₂ months from detail design to operational qualification.

“Citadon CW has helped us go from 36 months to 11¹/₂ months,” says Memhave. He acknowledges there are physical limitations to how fast plants can be built — “you know, the concrete still needs to dry” — but says “we’re still squeezing additional days out of the process now, and my personal feeling is we can go below ten months.”



Summary

NNE employs a modular engineering approach, innovative project management practices, tight interaction with clients and partners, and Citadon CW to design and build pharmaceutical and biotechnological facilities two or three times as fast as its competitors.

When NNE chose to standardize on Citadon CW for its worldwide operations in 2001, many in the company were reluctant to get on board. As Memhave points out, the most important thing was to change people’s minds about the processes the company wanted to implement. “Changing minds is critical — and CW has been instrumental in changing the minds at NNE,” says Memhave. “Without it, we wouldn’t have implemented the processes that have gotten us to our current, sub-year production time.”

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About Citadon

Founded in 1996, Citadon is the award-winning provider of on-demand Collaboration and Business Process Management solutions for distributed and project-oriented organizations. Citadon provides Web-based solutions that enable customers and their constituents to seamlessly share and manage a wide variety of document types, automate complex business processes, collaborate, and communicate without barriers, while providing a secure mechanism for capturing and leveraging knowledge.

Citadon automates and streamlines business processes and communications within and across enterprises, resulting in faster turnaround, increased accountability, reduced risk, and cost savings. More than 65,000 subscribers in over 60 countries rely on Citadon everyday to deliver business-critical automation and management.

Citadon solutions are available worldwide directly from Citadon or through an international network of sales partners. For more information, please visit: www.citadon.com.

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