

ARGUS APPLICATION UPGRADE PROJECT FOR NOVO NORDISK

Critical IT system upgrade completed in just 72 hours

A major upgrade to a critical IT system can be a daunting prospect for any company. Success depends on detailed preparation, domain knowledge, comprehensive IT skills and careful contingency planning. This was the challenge facing Novo Nordisk when they decided to upgrade their Argus application – and they asked NNIT to help.

The Argus system is an Enterprise solution for handling and reporting Adverse Events and medical events of special interest to regulatory authorities. It covers drugs in clinical trials and already marketed products – and falls under strict regulatory guidelines. As a consequence, the Argus system can only be out of operation for a maximum of three days, giving Novo Nordisk only 72 hours to switch from the old system to the new.

Novo Nordisk worked closely with NNIT and Oracle (the system vendor) on the project – and completed the upgrade with eight hours to spare.

THE CHALLENGE:

Completing a full upgrade in just 72 hours

Novo Nordisk has to meet strict regulatory requirements, including reporting any Adverse Events and Serious Adverse Events in products and developmental drugs within 72 hours. To manage submission-format compliance and ensure reporting is done on time, Novo Nordisk uses Argus, a standard solution from Oracle.



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MARTIN HOLM-PETERSEN
DIRECTOR, IT & QUALITY COORDINATION, NOVO NORDISK

Novo Nordisk began using the Argus system in 1998. But in 2008, the vendor discontinued support of the implemented version. Novo Nordisk had to upgrade – and chose to switch from a client-server-based version to a new web-based system in order to benefit from new functionality, better performance and easier user access.

Novo Nordisk asked NNIT to help. “The Argus system falls under CRF 21 part 11 and is heavily controlled by regulatory authorities,” explains Martin Holm-Petersen, Director of IT & Quality Coordination at Novo Nordisk. “So we needed a supplier who understood the documentation and validation requirements in the pharmaceutical industry. NNIT was already helping us with system maintenance, so they were the obvious choice.”

But there was one critical constraint in the project. Due to regulatory requirements, the upgrade had to be completed without shutting down the system for more than 72 hours.

THE SOLUTION:

Laying the groundwork for a smooth switch

NNIT began working with Novo Nordisk and Oracle six months before the go-live date, redesigning Argus’ system documentation and specifications together with Oracle to match Novo Nordisk’s requirements.

“This was a very complex area of the project,” says Martin. “The documentation proves that the system functions according to guidelines, and we can expect inspections on Argus from the regulatory authorities a couple of times a year, so we need to have it in place. In the end, this proved much harder than expected – especially for the customisations.”

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NNIT supplied extra IT personnel with validation experience to write test cases for the operational qualification – and assist with the installation and performance qualification. “This is one of NNIT’s biggest strengths and their help was invaluable,” says Martin. “Even if they aren’t able to provide people with the right skills first time, they’re very good at adapting and if we had a problem they were very quick to solve it.”

Once the system and documentation was ready, NNIT set up the servers and new database. NNIT then modified other system interfaces, such as a new reporting system and customer complaint system, to ensure Argus would integrate smoothly with Novo Nordisk’s IT infrastructure.

With everything ready, there was just one more task – to complete the upgrade within the 72-hour window.

THE RESULT:

Project complete with six hours to spare

“72 hours is not a long period of time,” says Steen Jørgensen, Project Manager at NNIT. “So we planned every minute of the shut-down window and did dry runs of each process to make sure everything would go like clockwork. We even built in a number of fall-back positions in case anything went wrong.”

In the end, nothing went wrong. “Thanks to NNIT’s planning and practice, we actually completed the upgrade with six hours to spare,” says Martin. “That’s quite a feat for an upgrade of this scale.”

And three months on, has the project been a success? “We haven’t had all the user feedback as yet,” says Martin. “But yes, it’s definitely been a success. We turned what could have been a very difficult situation into a successful one.”

ABOUT NOVO NORDISK

Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. A world leader in diabetes care, Novo Nordisk also works in areas such as haemostasis management and growth hormone therapy. With headquarters in Denmark, Novo Nordisk employs more than 29,000 people in 81 countries.

ABOUT THE ARGUS UPGRADE PROJECT

- System customisation, including a customer-specific reporting tool and customer complaint tool
- Server and database set up
- External system integration
- Installation, operation and performance validation
- Switch to new system in less than 72 hours

For further information

Please contact us at nnitcontact@nnit.com to learn more about the case or our upgrade and validation services.

ABOUT NNIT

NNIT is an international IT service provider offering IT consulting and the development, implementation and outsourcing of IT services for regulated industries. We create value for our clients by treating their IT as if it were our own. We use IT to support our clients’ daily operations and help them achieve their business goals. Owned by Novo Nordisk, NNIT employs about 1400 people. In 2009 the turnover exceeded €213 million.