

NOVO NORDISK REGISTER IMPLEMENTATION

Novo Nordisk uses Register™ to improve regulatory tracking and batch release process

The pharmaceutical company Novo Nordisk has production facilities in several countries, and is constantly working to improve production processes, equipment, logistics and production flexibility.

Operating in the highly regulated pharmaceutical industry, Novo Nordisk must have every production improvement validated by regulatory authorities – not just in the country where they are developed, but in every country where the products are produced or sold. And this requires a huge amount of data.

Previously, Novo Nordisk used a home-made system to manage the process, but wanted to upgrade to an off-the-shelf solution. After an exhaustive search, Novo Nordisk settled on Register™ from Aris Global – and NNIT and Aris Global teamed up to create a system perfectly tailored to Novo Nordisk's internal processes.

THE CHALLENGE

Novo Nordisk manufactures and markets pharmaceutical products around the world – and LEAN production is an important consideration for the company. But all process changes have to be validated and approved by the regulatory authorities, and this can be extremely time-consuming. Previously, Novo Nordisk used three different systems for planning submissions, handling change requests from the authorities and storing product approval information. But the systems had become outdated, so the company decided to change to an off-the-shelf system.

After two rounds of investigation, Novo Nordisk chose Register from Aris Global. Peter Bonne Eriksen, Senior Vice President,

Regulatory Affairs, Novo Nordisk, explains, “We wanted a system that was robust, and was easy to update and support,” says Peter. “After looking around, we chose Register – it is the best on the market and the obvious choice.”

THE SOLUTION

Register is a web-based regulatory solution that provides a central repository for managing every aspect of products, registrations and submissions. For Novo Nordisk, it gives users around the world immediate access to up-to-date information, and speeds up the implementation of process changes. As with many companies, Novo Nordisk has its own specific work processes, and it used Register's unique configuration capabilities to meet its specific needs.

During implementation, NNIT worked with Novo Nordisk to specify the necessary configurations. NNIT also took charge of implementation, including data migration and validation, and helped with end-user training.

Peter explains, “The configurations required a lot of collaboration between NNIT and Aris Global. For example, our product and production reports have to include very specific data – so we had to create a different report and reporting structure. NNIT came up with a fantastic solution for structuring the reports, and set-up our servers to ensure that users could access the reports quickly.”

With such a huge shift in IT systems, organisational change management was also a big consideration. “Our people had been using the old system for years and they knew exactly how it worked,” says Peter.

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“The Register solution was a big change for them. We trained every user, and established a support team to handle issues – and NNIT’s help was invaluable. As well as preparing training materials and running workshops with users, NNIT set up a help desk and is now running 24/7 user support.”

THE RESULT

The Register implementation has proved a success for Novo Nordisk. “We had a number of key performance indicators at the start of the project,” says Peter. “One year on, we can already see that we’ve either fulfilled them, or are clearly moving in the right direction.”

By implementing Register, Novo Nordisk has replaced several manual processes, which is already speeding up its work. However, Peter knows further improvements are needed – increasing user friendliness, for example – to ensure Novo Nordisk reaps the full benefits of Register.



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**PETER BONNE ERIKSEN, SENIOR VICE PRESIDENT,
REGULATORY AFFAIRS AT NOVO NORDISK**

Register has already helped remove some of the risk Novo Nordisk faces when ensuring the compliance of its worldwide production network. With reliable data available around the world, Novo Nordisk has a clear overview of production improvements in each country, and can track the approval process, which reduces the risk of releasing the wrong batch in the wrong country. “Errors didn’t occur often with the old system,” says Peter. “But we are now even more confident in our process – and that has led to greater peace of mind.”

ABOUT NOVO NORDISK

Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. It is a world leader in diabetes care, and also works in areas such as haemostasis management and growth hormone therapy. With headquarters in Denmark, Novo Nordisk employs more than 27,000 employees in 81 countries.

ABOUT ARIS GLOBAL

For more than 20 years, Aris Global has been a trusted and reliable partner to many of the world’s leading pharmaceutical, device, biotechnology and clinical research organisations. More than 300 life sciences companies rely on its innovative solutions in pharmacovigilance and safety, regulatory affairs, clinical research and medical information.

ABOUT THE REGISTER PROJECT

Register™ is the market-leading solution for centrally managing products and tracking global registrations across each product’s entire lifecycle. In the project, NNIT:

- Ensured Register complied with Novo Nordisk’s business needs and GxP standards
- Designed and executed transfer of business critical data
- Tested and validated the system
- Ran training and change management activities
- Developed customised reports suited to Novo Nordisk’s specific needs
- Runs support and maintenance of Register

PREVIOUS PROJECTS FOR NOVO NORDISK

- ISOTrain, a system for creating and sharing SOPs
- Globeshare, an intranet system for sharing documents

FURTHER INFORMATION

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

ABOUT NNIT

NNIT is one of Europe’s leading consultancies in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it was our own, and of course, we meet the industry’s strictest requirements for quality. For over a decade, we have applied the latest advances in technology to make our clients’ software, business processes and communication more effective. NNIT employs nearly 1,300 people and in 2008, our turnover exceeded €185 million.