

NOVO NORDISK QUALITY CENTER APPLICATION

Validated Quality Center system speeds up IT testing by 30%

With more than 27,000 employees in around 80 countries, Novo Nordisk relies on IT systems to keep its business operating smoothly – and new systems and upgrades have to be thoroughly tested before roll-out. Back in 2004, Novo Nordisk was completing tests on paper, and storing the results in huge ring binders. This process was proving both time-consuming and inefficient.

Novo Nordisk knew that an off-the-shelf test management application was the answer; but the system still had to be validated and configured to ensure it met strict pharmaceutical regulatory requirements – so Novo Nordisk asked NNIT to help. As well as validation, NNIT now operates and maintains the system for Novo Nordisk.

With a fully validated test management application, Novo Nordisk has reduced the amount of time it takes to test IT systems by around 30 percent, and improved the quality of its testing procedure.

THE CHALLENGE

Novo Nordisk has a number of business critical IT systems – and before new systems or upgrades are rolled-out, they have to be thoroughly tested and all bugs removed. Back in 2004, Novo Nordisk was testing its IT systems manually. The results were stored in ring binders filled with printed screenshots and Word documents. But maintaining the

test documentation and running the tests was time-consuming, and the binders had to be flown around the world when testing global applications – an expensive process.

So Novo Nordisk decided to implement Test Director from Mercury Interactive in 2004. Test Director is a test lifecycle management tool that creates and manages test requirements and test cases, handles the defect workflow – and stores the test results. As a pharmaceutical company, Novo Nordisk's work has to meet strict regulatory requirements – and so Novo Nordisk worked with NNIT to validate the new system.

Hewlett Packard bought Mercury Interactive in 2006 – and the system continued to work smoothly for Novo Nordisk until Hewlett Packard upgraded Test Director 8.0 to Quality Center 9.2 in 2008. The new upgrade didn't include the Digital Signature add-on, which was an essential requirement for pharmaceutical approval.

THE SOLUTION

NNIT worked with Genilogix to develop a new Digital Signature add-on and ensure it met FDA requirements, as laid out in 21 CFR Part 11. At the same time, Novo Nordisk took the opportunity to refine its system. "The new Digital Signature add-on was very different," says Bo Vindberg, Product Delivery Manager at Novo Nordisk. "As a result, we had to re-think our entire testing procedure. But we had experience from using the previous version, and we worked with NNIT to refine and improve the process."

As well as working with validation and development, NNIT hosts and maintains Quality Center for Novo Nordisk, handling



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**PERNILLE BAEKGAARD, SYSTEM MANAGER,
NOVO NORDISK**

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all technical and functional support. "All requests and problems come directly to NNIT," says Carsten Mulvad, Principal Consultant at NNIT. "If there's anything we can't handle, we escalate it up to Hewlett Packard or Genilogix, so that Novo Nordisk has a system that works and has as little as possible to do with the backend.

So what exactly can Novo Nordisk do with Quality Center? And how does it improve the company's processes?

THE RESULT

Quality Center has completely removed ring binders from Novo Nordisk's testing procedures. All information is entered by computer and updated in real time – and, because the system is accessible online, users at Novo Nordisk sites around the globe can complete tests without having to ship ring binders overseas. According to Bo, this also means that outsourcing IT system support is simpler, as Novo Nordisk can monitor test procedures centrally, without having to travel to the external partner's office.

The system also functions as a library of tests, which gives Novo Nordisk two main advantages. "All test information is easy to find and present to regulatory authorities," says Bo. "And we can re-use old tests when testing systems again, and we can adapt existing tests when working on similar systems. All our users really like these two functions."

What does this all mean for Novo Nordisk's bottom line? Pernille Baekgaard, System Manager, who is now responsible for the system at Novo Nordisk, says, "It's all about time saving – and we've seen a significant improvement. It's hard to know for sure because we didn't document how long tests took using the old system. But we estimate it's sped-up our testing procedures by around 30 percent."

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 people in 81 countries.

ABOUT THE QUALITY CENTER PROJECT

- Validating the system
- Implementing a Digital Signature
- Operation and maintenance of the system
- Handling technical and functional support

PREVIOUS PROJECTS FOR NOVO NORDISK

- Two Quality Center upgrade projects
- Maintaining and operating Argus, an adverse event reporting system
- Implementing a Clinical Data Warehouse to store and retrieve clinical data

For further information

Please contact us at nnitcontact@nnit.com to learn more about the case or our support 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 nearly 1,400 people. In 2008, our turnover exceeded €185 million.