

LUNDBECK QUALITY CENTER APPLICATION

Pharma-ready version of Quality Center brings Lundbeck's IT systems online fast

Operating in the strictly regulated pharmaceutical industry can be tough – and all work has to meet regulations, not only research, development and production, but also IT systems.

For a number of years, Lundbeck had wanted to use a test management system from Hewlett Packard called Quality Center to speed up its IT system testing processes. But the system had to be validated to ensure it meets regulatory requirements – and this was prohibitively expensive. Until, that is, NNIT offered a version of Quality Center that was prepared for pharmaceutical validation.

Lundbeck is now using Quality Center to test a range of IT systems from vendors, such as SAP and EMC. It's made documentation to regulatory authorities considerably easier, improved testing quality, and significantly reduced the time it takes Lundbeck to bring a new IT system online.

THE CHALLENGE

A research-based pharmaceutical company with around 5,500 employees across the globe, Lundbeck relies on IT systems to keep its operations running smoothly. This means that every new IT system and upgrade has to be thoroughly checked and tested before it's rolled out. In addition, Lundbeck has to document to medical authorities that its IT systems – especially those directly connected to drug development and production – meet regulatory guidelines.

Lundbeck was completing this testing and documenting process manually – and the results were stored in massive ring binders, stuffed with printed screenshots, Word documents and hand-written notes.

According to Mikael May Yde, Head of IT Compliance in Corporate IT at Lundbeck, the entire process was proving extremely time-consuming. “We were running a lot of IT projects, including an SAP implementation, and we were spending a lot of hours on testing. We printed out Word files, and filled in the results in pencil. It worked and we got approval from authorities – but it wasn't very efficient.”

Lundbeck wanted to implement Quality Center, a test lifecycle management system from Hewlett Packard. But the system was not set up for pharmaceutical companies, and validating it to meet regulatory approval would be expensive. The solution came when NNIT offered a version of Quality Center that was prepared for pharmaceutical validation, which would make the validation process much easier, and cheaper, for Lundbeck.

THE SOLUTION

The system supplied by NNIT included a Digital Signature add-on that was essential for meeting FDA requirements as laid out in 21 CFR Part 11. In essence, the Digital Signature allows people to approve and ‘sign’ documents, like signing their name at the bottom of a piece of paper, so authorities can see that the tests have been carried out.

Now, NNIT also operates and maintains Quality Center for Lundbeck. “Essentially, we run first and second line support,” explains Carsten Mulvad, Principal Consultant at NNIT. “If there's a problem, it comes to us and we solve it. If we can't solve it for some reason, we escalate it up to Hewlett Packard. The idea is that Lundbeck has as little to do with running the system as possible.”



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MIKAEL MAY YDE, HEAD OF IT COMPLIANCE IN CORPORATE IT, LUNDBECK

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NNIT also handles setting up new users using a flexible licensing system. Lundbeck has a total of 25 concurrent licenses. The licenses are unnamed, so anyone in Lundbeck can use the system, and 25 people can be logged into Quality Center at any one time. In all, around 400 Lundbeck employees are trained in using Quality Center, and if Lundbeck has a large project running, NNIT simply supplies more licenses for a limited period.

THE RESULT

Has the system improved Lundbeck's IT testing processes? "When you develop or implement a new IT system, you want it to get up and running quickly so you can reap the benefits as soon as possible," says Mikael. "Quality Center has certainly helped make projects run faster. We haven't run a full business case, so I don't have the figures, but I guess it has reduced testing time by anything from 30 to 50 percent. There would certainly be a lot of unhappy people if we went back to the old system."

The cut in testing time is due to a number of factors. Lundbeck no longer uses printed paper, pencil notations or ring binders in its IT testing process. Instead, Quality Center manages the process. The information can be accessed by another user in real-time, even if that user is on the other side of the world. And because Quality Center acts as a library of tests, Lundbeck can re-use old tests when re-testing systems, and can adapt existing tests when working on similar systems – vastly improving efficiency.

But perhaps more importantly for Mikael, Quality Center has helped improve test quality. "It gives us a complete overview of what tests we've run – and when we run a test, we get a status report. And the defect tracking function helps us find and eliminate bugs and errors. All-in-all, we have more control of the testing process, which means we always know where we are. It's also made documentation to authorities much simpler and faster. In the old days, we had to find the ring binder and pull out the right piece of paper. Now we can get the right documentation with one click."

ABOUT LUNDBECK

Lundbeck is a research-based company dedicated to finding new drugs for the treatment of CNS disorders, including depression, schizophrenia, Alzheimer's disease, Parkinson's disease and insomnia. The company's goal is to improve the quality of life for people with a psychiatric or neurological disorder. Based in Denmark, Lundbeck employs around 5,500 people worldwide.

PREVIOUS PROJECTS FOR LUNDBECK

- Business Intelligence migration
- General SAP operation of the Lundbeck SAP platform

ABOUT QUALITY CENTER FOR THE PHARMA INDUSTRY

- NNIT's version of Quality Center is pre-prepared for pharmaceutical validation
- Validated Digital Signature meets FDA requirements
- Offers complete overview of testing process
- Existing tests can be re-used or adapted
- Documentation for regulatory authorities is fast and simple to find

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.