

# ARGUS APPLICATION MAINTENANCE AGREEMENT FOR LARGE PHARMACEUTICAL COMPANY

## Long-term partnership helps pharmaceutical company meet AE/SAE reporting regulations

For many pharmaceutical companies, finding employees with both advanced IT skills and pharmaceutical industry experience can be tough – and this can make it hard to assemble a team of support staff to maintain IT systems that fall under regulatory authority guidelines. For one large pharmaceutical company, the answer was a long-term application maintenance agreement with NNIT.

Since signing the agreement in 1999, NNIT has taken care of all technical support and maintenance of the customer's Argus system – an Enterprise Architecture for reporting adverse events to regulatory authorities. By outsourcing this task, the customer is able to concentrate its resources on business critical work.

### THE CHALLENGE

With more than 25,000 employees in over 80 countries, this pharmaceutical company relies on IT systems to ensure its contact with regulatory authorities remains smooth and meets regulatory requirements. One such application is Argus, a standard solution from Oracle. Argus manages Adverse Event (AE) and Serious Adverse Event (SAE) reporting for both clinical trials and marketed products.

Stringent rules are in place governing how and when AE/SAE information is submitted to various local authorities – and Argus Enterprise Architecture manages submis-

sion-format compliance and gives users an overview of the actions they need to take. But maintaining the system, and keeping it up to date with the latest regulatory standards, is time-consuming – and it requires a team of specialists with IT and pharmacovigilance skills as well as an in-depth understanding of quality requirements in the pharmaceutical industry.

Employees with this profile are few and far between, so the customer outsourced these responsibilities to NNIT.

### THE SOLUTION

NNIT's service level agreements cover system maintenance at several levels. As well as hosting the platform, both hardware and software, the NNIT team troubleshoots if any problems arise – and this requires a fast response. Dorte Lundberg, Argus Application Manager at NNIT, explains, "We call this second level support. For example, if a user submits an AE/SAE report but doesn't receive acknowledgement from the authorities for some reason, we step in to solve the issue. It's important that we understand the urgency involved in solving problems – often the AE/SAE must be reported to authorities within 24 or 48 hours, so we can't afford to waste time."

In another key aspect of the service, NNIT ensures the system stays up to date with regulatory standards. "This is where our insight into the pharma industry really pays off for the customer," says Dorte. "We perform the usual IT support roles – upgrades, new security updates, yearly reviews, etc. – but we are also proactive in following new regulations and we use the



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DORTE LUNDBERG, ARGUS APPLICATION MANAGER, NNIT

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knowledge we gain from other pharmaceutical companies. This means we can recommend how to react to changes in the regulations, and it's a huge advantage for the customer."

This aspect of the work also means that when the regulatory authorities perform an inspection, NNIT is ready to answer questions and provide documentation. "The customer is responsible for the overall compliance status of the system," explains Dorte. "But often it makes more sense for the authorities to speak directly to us about matters related to IT systems."

For basic user administration, NNIT uses Melody, an advanced user handling tool which provides an automated process for technical user management and manager approval. Daily operation is, therefore, handled directly via NNIT – and the customer does not waste time dealing with day-to-day system operation issues.

## THE RESULT

NNIT has its roots in the pharmaceutical industry, and its employees are well-versed in GxP standards and the Argus system. As a result, NNIT is an ideal implementation and hosting partner for all Argus maintenance – and ensures it complies with regulatory standards. NNIT is also active in the Oracle Argus user group – and according to Dorte, this helps improve the service tremendously. "We are in direct contact with other Argus users," she says. "So we learn from the experiences of other pharmaceutical companies – and share best practices directly with several Argus users."

All this means the customer can dedicate more resources to business critical work, confident in the knowledge that the Argus system will run smoothly, and will always be in compliance.

### ABOUT THE CUSTOMER

A large research-based pharmaceutical company, the customer employs more than 25,000 people in more than 80 countries. The company develops, produces and markets medicines in a number of therapeutic areas.

### ABOUT THE SUB-AREAS OF THE APPLICATION MAINTENANCE AGREEMENT

- Operation maintenance (GxP-compliant platform hosting including hardware and software)
- First line support (day-to-day running of the system including access management)
- Second line support (troubleshooting and problem solving)
- Upgrades, system updates and compliance issues
- Yearly configuration reviews, user access reviews and other regulatory system maintenance documentation

### FURTHER INFORMATION

Please contact us at [nnitcontact@nnit.com](mailto:nnitcontact@nnit.com) to learn more about the case or our application maintenance 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.