

# From regulatory requirements to strategic sustainability

## Xellia Pharmaceuticals ApS

Xellia Pharmaceuticals is an international pharmaceutical company which has developed and produced products for the pharmaceutical industry for over a century. The company is a market leader within active pharmaceutical ingredients (API) specialising in fermented antibiotics and injectable manufactured products.

The company's customers are national, international and global pharmaceutical companies and number around 700 customers in 70 countries. The company's 820 employees are distributed between 4 different production units in Denmark, Norway, Hungary and China.

### A regulatory requirement

Pharmaceutical companies like Xellia Pharmaceuticals are faced with strict requirements from government authorities as well as customers, which was the reason why the company invested in the maintenance system Sertica (or LOGI HOLD as it was called back then) in 1999.

It was essential to find a system that could document maintenance history and, more importantly, to find a system that the authorities could accept in relation to the regulatory requirements in the field.

Sertica was initially implemented in relation to maintenance in the manufactured products division, but now it is used extensively within the company – including for the calibration of machines and maintenance of buildings.

### Developments in maintenance procedures

From having started using Sertica solely for documentation in relation to the authorities and customers, the system has gradually been expanded with regard to function but also with regard to the number of users. In 1999 Xellia Pharmaceuticals started out with 10 users. In 2010 the number of users reached 55.



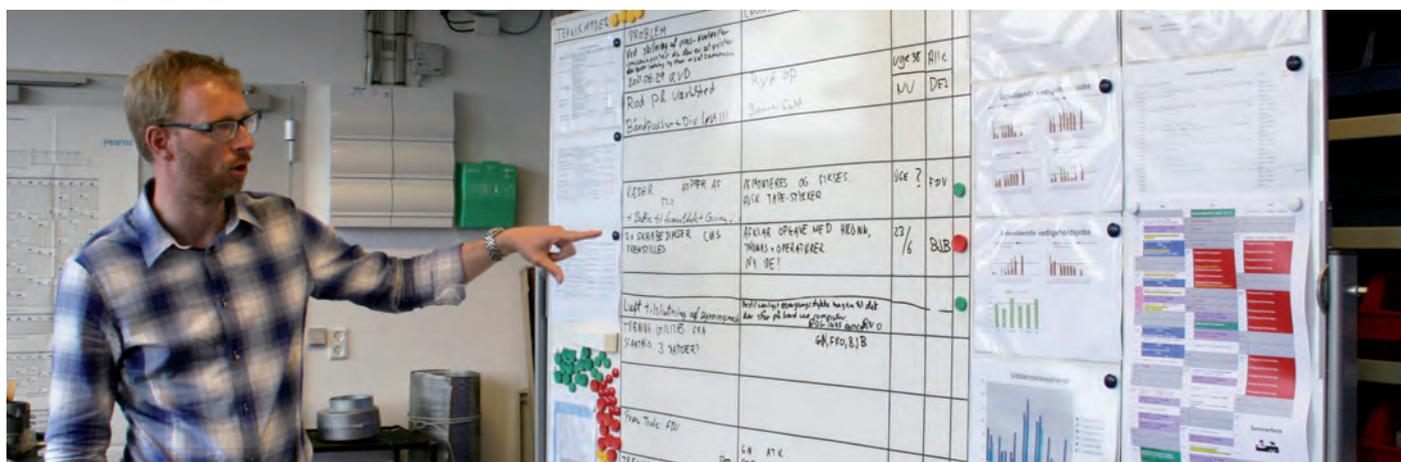
Xellia Pharmaceuticals has production units in Denmark, Norway, Hungary and China.

Xellia Pharmaceuticals uses Sertica widely throughout the organisation in Copenhagen, Denmark. At this location there are 15 people who function as users with regard to "ordinary maintenance", and an additional 40 peripheral users of the system – in total 55 users out of a total of 372 employees.

*It is important that the "machinery" runs optimally, as breakdowns can have a significant influence on production output.*

*Jakob Andersen, Maintenance Manager*

"We have chosen to implement the system as widely as possible within the company and to enable peripheral users to connect to the system, because they can perform maintenance tasks in relation to things like calibration of machines." Says Jakob Andersen, maintenance manager at Xellia Pharmaceuticals. It is thus very important to have a



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user-friendly maintenance system. The strategy Xellia Pharmaceuticals has chosen ensures flexibility, and at the same time this means fewer and shorter downtime periods in production.

Previously, the maintenance department carried out “summer holiday maintenance jobs” when large maintenance jobs required a production stop. Now maintenance jobs are carried out throughout the year. This ensures continuity of production throughout the year. It also makes it possible to carry out preventive maintenance.



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## A Strategy for the Future

Over the course of the past three years, there has been an intensification of strategic and practical use of the Sertica maintenance system and that development will continue.

The company is working towards using Sertica as a strategic tool to measure the effect of things like ongoing maintenance. This is done by looking at things like trends on the equipment.

Xellia Pharmaceuticals expects to take advantage of the job request module from Sertica, which replaces an old job requisition system based on spreadsheets – a system that is being used externally and in parallel with Sertica today. The goal is to achieve an insight into the statistics of error messages and job requests, and to be able to respond to and optimise resources according to these statistics.

Today there are a lot of users in the Xellia Pharmaceuticals organisation – in the future this will be optimised to that there will be Sertica super users in the company. This will be ensured by means of customised instruction, which will be carried out by teachers who are software experts from Logimatic.