

Ensuring product quality with the testo Saveris 1



The customer

Pharma Stulln GmbH, based in the municipality of Stulln, Bavaria, produces sterile pharmaceuticals in line with the highest international quality standards.

With the support of state-of-the-art technology, 350 staff focus on eye drops, nasal sprays and inhalation solutions, which are sold on five continents. The company manufactures products to its own specifications for more than 50 prestigious customers from the pharmaceutical sector.

Pharma Stulln also performs stability tests in various temperature and climate zones in accordance with the ICH Guidelines. The owner-managed company has been operating for over 60 years. A new-build constructed in 2002 has since been extended several times.

Since 2015, Pharma Stulln has had a fully automated production and packing line. Sterile production in several GMP-compliant cleanrooms guarantees the highest quality and reliability from the development and testing stage to the manufacturing, filling and packing of the sales-ready product.

pharma **STULLN**



The challenge

Ensuring quality and complying with regulatory requirements – these two classic tasks formed the basis of the project that was conducted in cooperation with Pharma Stulln and involved the second and third generation of the testo Saveris 1. In Pharma Stulln GmbH's case, the challenge lay in installing a system that could record readings in various areas of the company, including in smaller rooms and warehouses. Refrigerators, heating cabinets and incubators also require continual monitoring. The alarm furthermore acts as a basis for the on-call staff's ability to immediately respond to emergencies, even outside standard working hours, for example.

The solution

In a nutshell, the task was about monitoring temperature and humidity, especially in the fields of warehouse logistics and laboratories. testo 150 TUC4 data loggers with a digital temperature and humidity probe were positioned at three different heights in the new warehouse area. testo 150 TUC4 data loggers with temperature cable probes and humidity probes were used to monitor incubators, refrigerators and freezers in the microbiology laboratory area, which is also new. In both cases, UltraRange long-range radio technology is used to monitor the premises and the instruments. At present, over a hundred testo Saveris 1 components are used.



In addition to the simple installation, Pharma Stulln also regarded the ease of integrating new components as a key benefit of the Testo solution. "As our company is growing and expanding, the focus lay on procuring an easily expandable system where the hardware, software and quick, reliable customer support all come from a single source", stated the Quality Assurance department. This challenge could be met as the individual components of the testo Saveris 1 are backwards compatible meaning even individual components can be replaced or combined without having to replace the entire system, which would otherwise be extremely costly.

Due to the generic expansion of the building, the measuring points at Pharma Stulln GmbH are a long way from each other, including in external logistics sites. The simple installation in an existing building was also seen as a plus point. This case is also an excellent example of how different data transfer techniques, specifically wireless and WLAN network technology, can come together.

Another aspect that must be particularly highlighted with regard to this case is the excellent, long-standing cooperation between Pharma Stulln, Testo Solutions GmbH and Testo Industrial Services GmbH. The latter is responsible for recalibrating and validating the testo Saveris 1 components and enables the user to receive the hardware, software and service activities as an all-in-one package. Furthermore, by using the testo Saveris 1, Pharma Stulln GmbH is able to offer its employees, customers and auditors easy-to-use software with graphical representations.

As a long-standing partner of Pharma Stulln GmbH, Testo Solutions GmbH is proud to have worked with a successful medium-sized enterprise from the pharmaceutical industry for so many years. One figure highlights that the customer appreciates the continuity too: Pharma Stulln GmbH has been using Testo software since 2013, i.e. for an entire decade.