

Validation and monitoring of a pharmaceuticals warehouse with measurement solutions and services from Testo.



The objective of the cooperation between Testo and Grieshaber Logistics Group AG was the creation and establishment of an overall GMP concept for a new warehouse in Rheinfelden, Germany. Testo working together with the subsidiary Testo Industrial Services, was responsible for the following tasks:

- Qualification of all warehouse areas and utilities
- Delivery, installation and commissioning of the validatable measurement data monitoring system testo Saveris
- Calibration of testo Saveris measurement probes
- Validation of overall process

All activities were be state-of-the-art, fulfil the relevant requirements in the field of EU-GMP legislation, and pass FDA audits.

Grieshaber Logistics Group AG

Grieshaber Logistics Group AG, with headquarters in Bad Säckingen, Germany, is an international contract logistics service provider with seven state-of-the-art sites in the EU and Switzerland, whose customers include many well-known companies from the pharmaceutical industry. With approx. 125,000 m² total warehousing area, 35 company-owned vehicles and 70 affiliated companies and partners, the firm fulfils all the requirements placed on innovative and high-quality logistics. The new site described in this reference offers the most modern GMP storage in three different temperature zones over approximately 25,000 m².



The challenge.

Due to its size and the technology involved, the new warehouse building was extremely demanding with regard to the GxP services to be provided. Apart from this, the timetable was very tight, making it necessary to begin with preparations and specifications even before the actual building phase.

The possibility of already being involved in the GMP-compliant design of a warehouse for pharmaceuticals during its construction also presented a further special challenge: All concepts and technologies needed to be designed and planned so flexibly as to be possible to react quickly to any unforeseen constructional changes to the warehouse.

The measurement data monitoring system to be installed needed to ensure a highly accurate overview of the temperature and humidity values in the warehouse, the refrigerated and the deep-freeze areas as well as the mezzanines, in order not only to guarantee a high level of storage and product quality, but also to fulfil the stringent GxP requirements.

Another challenge was presented by the extensive 25,000 m² massive metal and concrete shelving and storage area, whose radio coverage by the measurement data monitoring system was technically difficult.

The solution.

Analyzing risks

In order to implement the customer's requirements, risk analyses were initially made, and measures then defined for the minimization of those risks. Subsequently, Testo Industrial Services qualified the storage areas (DQ, IQ, OQ, PQ), integrating the document layout of the customer and taking the relevant SOPs and general quality assurance measures into account.

Creating a climate profile

After the risk analysis, a climate mapping of the warehouse was carried out – the basis for a reliable and precise climate monitoring. Before temperature and humidity could be monitored, the so-called critical control points (CCPs) had to be identified. Because although a warehouse's air conditioning system displays only a particular temperature, several different temperature zones still occur, which can negatively influence the quality of the stored pharmaceuticals. Typical examples are doors, skylights outer walls or the temperature differences in high-bay shelving between the cold air at floor level and the warm air in the vicinity of the ceiling. Since the climatic conditions within a warehouse are also considerably influenced by the respective outside temperatures, Testo Industrial Services carried out a summer and a winter mapping at Grieshaber.



Temperature and air humidity were recorded and documented over a longer period at a total of 563 measurement points. An overall climate profile of the warehouse was created from the collected data.

Installing and validating the measurement data monitoring system

The next steps in the process encompassed the planning, installation and commissioning of a suitable measurement data monitoring system, including the measurement of the wireless transmission distances. The measurement data monitoring system testo Saveris here proved to be especially suitable. Due to the combination of wireless and Ethernet components, it can be used to securely monitor extensive areas. Automatic alarms by SMS, e-mail or alarm relay, given out by the independently working base station, allow the responsible operative to react immediately in cases of limit value violations. Remote alarms can even be given when the system is not connected to a running PC. Data recording with testo Saveris continues to function without interruption, even in cases of power cuts. All recorded measurement data are furthermore centrally filed and archived in the validatable 21 CFR Part 11 software.

In total, 53 wireless temperature and humidity probes (°C/%RH) were installed over the entire warehouse and service area, for the monitoring of shelves and block storage as well as the mezzanines and server rooms. A further 13 wireless temperature probes were positioned in the refrigerated and deep-freeze areas.

In order to obtain a three-dimensional overview of the temperature and humidity values, four probes were fitted diagonally ascending over four levels in every third row. This allowed an uninterrupted profile of the warehouse to be created over its entire length as well as its entire height. In the area of block storage and in the refrigerated and deep-freeze rooms, the probes were fitted at the same level, as the differences in storage height are negligible here.

In order that the signals of all wireless probes could be securely transmitted to the testo Saveris base station, 25 testo Saveris extenders were installed on the mezzanine balustrade as well as centrally on the hall ceiling. They pick up the wireless signals from the probes and transfer them via the firm network to the base station of the measurement data monitoring system.

After the installation of testo Saveris, a Site Acceptance Test (SAT) was carried out, in which the full functionality of the system was again confirmed. All quality-relevant measurement sites were subsequently calibrated and the entire monitoring system validated GMP-compliantly, taking 21 CFR Part 11 requirements and the Annexe 11 of the EU GMP guideline into consideration.



The advantages.

During the progress of the project, the specialists from Testo and Testo Industrial Services GmbH continuously advised and accompanied the responsible people at Grieshaber Logistics Group AG, ensuring that deadlines for the GMP-compliant qualification, validation and monitoring of the new warehouse building were met.

Thanks to a definition of the measurement points based on summer and winter mapping, and the corresponding climate profile, the foundations were laid for a reliable and norm-compliant temperature and humidity monitoring with the measurement data monitoring system testo Saveris. The monitoring of all storage areas now takes place with 66 testo Saveris wireless probes which form a tight monitoring net, informing the operator, directly and via various channels, of potential risks, including in cases of power cuts.

testo Saveris was furthermore integrated flexibly and in a future-oriented way, so that nothing stands in the way of any extensions to the warehouse or the monitoring system, or a new positioning of the probes (for example in the course of rebuilding work in the warehouse).

"This project was extremely important to Grieshaber logistics Group AG, and Testo work has provided excellent support. In addition to the flexible, service-oriented and punctual implementation, we were impressed by the company's willingness to oblige us: Together, we were able to adapt the extent of the project during its implementation, allowing us to reduce costs without having to accept a loss of quality as a consequence."

Andreas Grieshaber
Market Management Grieshaber Logistics Group AG

More information.

For more information on the measuring data monitoring system testo Saveris and the service range of Testo Industrial Services, as well as answers to all your questions on GMP-compliant qualification, validation and monitoring of a warehouse for pharmaceuticals, go to www.testo.com