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Reference GDP-compliant deep-freeze storage of pharmaceutical products

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GDP-compliant deep-freeze storage of pharmaceutical products

at Simon Hegele Gesellschaft für Logistik und Service mbH in Karlsruhe, Germany

Simon Hegele was founded in 1920 and is today an internationally active, highly specialized logistics and service provider with over 50 locations worldwide. The company offers customized logistics services for customers in the pharmaceutical, healthcare, industrial and retail sectors.

The project

A warehouse at the Karlsruhe site was to be converted to meet GSP/GDP requirements for customers from the pharmaceutical industry. A special conversion such as this requires a great deal of GMP expertise. This was a new field of activity for Simon Hegele, so the company looked for experienced partners: Testo Solutions and Testo Industrial Services.

The key data of the project

- Total investment in the seven-figure range
- Project duration until first use 3 months, approx. 12 months in total
- Compliance with the GDP standard
- Testo Solution: Fast implementation time at the customer's premises of 16 weeks from the start of commissioning to completion of validation
- Testo Industrial Services: Calibration of the sensors within just 4 weeks and installation in 1,700 UTK freezers
- Summer and winter mapping of the warehouse
- Testo Solution: Implementation of the monitoring system for the warehouse and freezers
- Testo Industrial Services: Qualification of all equipment & validation of the monitoring system

The focus was on compliance with the requirements in GDP-regulated areas to ensure the quality of the stored products.

Testo Solutions GmbH provided the hardware and software for the project. As a service provider for quality assurance, Testo Industrial Services GmbH provided the experts for the calibration/qualification.

The collaboration between the customer, Testo Solutions and Testo Industrial Services ran smoothly. Communication was clearly structured via a central contact person for each company and any questions that arose could be resolved quickly.



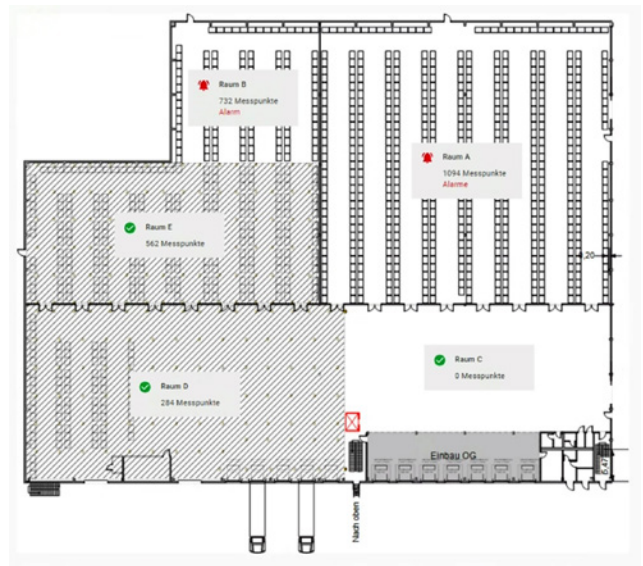
Goal & course of the project

The aim of this project was the rapid conversion of an existing warehouse with the implementation of all relevant quality assurance measures into an air freight and GDP-compliant area for the deep-freeze storage and worldwide distribution of pharmaceutical products.

Key activities included the commissioning of four storage areas, the implementation of warehouse qualification with the necessary metrological services, the installation and calibration of the monitoring system and its validation.

In addition to the new warehouse areas and the newly procured freezers, the testo Saveris 1 monitoring system was also to be used to monitor the transportation of the pharmaceutical product outside the freezers. Special transport carts were integrated into the Saveris system for this purpose.

For Simon Hegele, a smooth process was particularly important, especially in the event of last-minute changes to the timeline. The clear definition of responsibilities and a limited number of contact persons on the part of the service provider/manufacturer was essential in order to keep communication costs to a minimum, as the stocks of existing customers were to be repositioned during ongoing operations in the final phase.



Service provided by Testo Industrial Services

- Conceptual design and consulting on GDP-relevant topics such as calibration, qualification and validation
- Flexible and efficient GxP services team on site
- Comprehensive project management taking into account initial calibration, warehouse qualification and computer system validation
- Coordination and implementation of the initial calibration of 1,700 sensors over a period of 4 weeks
- Preparation of qualification documentation from risk analysis onwards
- Implementation of the installation qualification of the warehouse areas including the ventilation system
- Carrying out warehouse qualification including empty chamber mappings (OQ mappings) and mappings in summer and winter in loaded condition (PQ mappings)
- Conceptual design of a recalibration strategy for the built-in sensors
- Introduction of the holistic test equipment management system PRIMAS

Ambient monitoring in freezers & warehouses

with the testo Saveris monitoring system 1

The compliant deep-freeze storage of pharmaceutical products in the 1,700 UTK freezers at Simon Hegele is constantly checked by the testo Saveris 1 monitoring system. The optimum temperature for the products is $-75\text{ }^{\circ}\text{C}$, with a temperature corridor between $-85.4\text{ }^{\circ}\text{C}$ and $-45\text{ }^{\circ}\text{C}$.

The specialists from Testo Solutions installed the system on site. The components are one sensor per freezer, one base station and the appropriate software. Live monitoring of the temperature and technical conditions is supported by an alarm system and automatic monthly reporting including user-specific report generation. The testo Saveris 1 detects technical faults, as well as temperature undershoots/overshoots, and issues an alarm message. The system also monitors the indoor climate in the warehouse with constant recording of temperature and humidity values. A radio network was set up in the warehouse specifically for the transmission of messages, via which gateways and loggers, for example, communicate.

The experts from Testo Industrial Services took over the calibration of the 1,700 sensors as well as the prescribed summer and winter mappings in the warehouse to determine the standard-compliant limit values for the qualification.

The team then carried out the qualification of the warehouse and validated the monitoring system, including the sensors. Together with Simon Hegele's contact person, the experts also defined customized alarm and escalation levels for the messages from the monitoring system and configured the system.



Services provided by Testo Solutions

- Close consultation and coordination: Technical project planning and design of the monitoring system and advice on the technical infrastructure such as servers, IT and load simulations
- Before the purchase decision: Installation of a pilot system to demonstrate the functionality to the customer
- Installation and commissioning of the complete hardware of the monitoring system and the configuration of the software system
- Final acceptance of the system by means of a site acceptance test based on the customer's specifications
- User training tailored to the customer
- Comprehensive individual support concept including help desk, hotline and technical maintenance





"A high level of commitment to the project on the part of all those involved, as well as a broad range of specialist expertise, flexibility, speed and trustful cooperation on an equal footing were the basis for the very successful project implementation and achievement of objectives. We are therefore happy to continue this collaboration."



Markus Henn
Head of Central Project Management
Simon Hegele Gesellschaft für Logistik & Service mbH

Your advantage: Our expertise

- Ensuring continuous quality control and constant monitoring of storage conditions
- Process optimization through optimized layouts, use of automation technology and efficient air conditioning systems = rationalization and increased productivity
- Comprehensive support through validation expertise throughout the entire process reorganization
- Know-how transfer to the customer to ensure processes and QM standards even after project completion
- Comprehensive GDP consulting services and competent project management ensure smooth processes and low costs for the customer
- Maximum care in complying with GDP guidelines to ensure product quality and audit security
- Transformation of the warehouse during business operations & adherence to the tight schedule



