

Highly efficient qualification of a freeze-drying plant with the CFR data logger system testo 190.



In order to ensure security in the manufacture of active pharmaceutical ingredients in freeze-drying plants, high GxP requirements have to be met. More often than not, a cabled system is currently required to provide proof of adherence to these requirements. When using these systems, Excel lists with complex calculations are frequently used as standard-compliant documentation.

The testo 190 CFR data logger system is the intelligent solution for the monitoring and documentation of the temperature curve in freeze-drying processes. The smart all-in-one solution, comprising hardware, software and service, enables you to monitor production processes more efficiently and optimize them sustainably.

This means you reliably adhere to quality standards and save time and money.

The challenge

The objective of freeze-drying is to prolong the shelf life of products such as infusions or injections as well as to make them easier to transport and store, by withdrawing water. In order to ensure that the prescribed targets are met, the production plants must be regularly qualified according to strict GxP guidelines.

1. Positioning measurement technology in the plant

The temperature sensors must be stably positioned on the cooling/heating plates in the freeze-drying plant with home-made additional weights. The correct set-up in an average freeze-drying plant with 40 measurement points can take several hours.

2. Evaluation of the measurement values

Several hundred A4 pages of recorded measurement values are not unusual in this kind of measurement, representing a considerable challenge in terms of time for the staff member evaluating the measurement data. Since the measurement data have to be completely checked and prepared as tables and graphs, it is almost impossible to process them quickly using standard programmes.

3. Image documentation

For the purposes of qualifying a freeze-drying plant, the measurement set-up has to be documented with images. This is necessary in order to be able to reproduce the exact positioning of the temperature sensors during the measurement. In view of the fact that there are 40 or more measurement points, image documentation of this kind can sometimes be a matter of several hours.

4. Reporting

The requirements placed on the contents of a qualification report are very high, and often present companies with a great challenge. These reports must contain tables, graphs, information on measurement technology, image documentation and much more. In order to present this collated information clearly in a report, several programmes are often needed, which is very time-consuming for the processing staff member.



The solution



Data loggers

Software

Multifunction case

The testo 190 CFR data logger system allows the highly efficient qualification of a freeze-drying plant. The system consists of robust, durable and reliable **CFR data loggers** in four temperature and one pressure version; **a multifunction case**, which serves the programming and readout of the loggers as well as their storage and safe transport; and the unique **testo 190 CFR software** which enables full, audit-relevant documentation with just the click of a mouse button.

In the development of the 21 CFR Part 11-compliant software, special attention was paid to intuitive operation. The user is guided safely step by step through the qualification process, and receives warnings at critical points. The software is therefore equally suitable for experts and beginners.

Using the CFR software, up to 8 data loggers, which can be time or temperature controlled, are programmed, and after the measurement procedure also read out, via a connection cable between the multifunction case and the laptop/computer. In the context of the data analysis, the calculations for the holding phases are automatically carried out and checked against the defined acceptance criteria. In addition to this, the software enables fast and easy creation of image documentation. And the best part is: there is no effort for assembling the whole documentation, because it can be simply created with a mouseclick.

Overview of advantages:

- Large measurement data memory
- Fast and reliable overview of the measurement results
- Less effort and lower error potential
- No data export to other systems needed
- Compliant with GxP and 21 CFR Part 11
- 1-click report
- Integration of up to 254 measurement points per validation process into the software possible