Testo
Application example

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Highly efficient validation of the sterilization of pharmaceutical products with the CFR data logger system testo 190.

In order to ensure security in the manufacture of medicaments in autoclaves, the sterilization of pharmaceutical products has to meet high GxP requirements and be CFR 21 Part 11-compliant. These critical processes must be validated at regular intervals. For this purpose, cabled and wireless systems are today in use for measuring temperature and pressure. 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 temperature and pressure in sterilization 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 sterilization is to kill off germs and microorganisms contained in the manufactured medicaments to the defined residual content. In order to ensure that the prescribed targets are met, the production processes must be regularly validated according to strict GxP guidelines. Several cost and time-consuming steps are necessary for this validation:

1. Positioning measurement technology in the plant
In order to obtain reliable measurement values, the temperature and pressure sensors have to be attached in the plant or to the product using adhesive tape or other aids. The correct set-up in an average plant can take several hours.

2. Evaluation of the measurement values
Several 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. Calculations
In order to determine the success of a validation measurement, the factor by which germs are destroyed, also known as the lethality or F-value, must be calculated. In sterilization processes with humid heat too, the quality of the saturated steam is crucial. The calculation of this critical parameter is as a rule currently carried out using supporting tables or Excel lists, which on the one hand involves the risk of an input error, and on the other hand is very time-consuming.

4. Image documentation
In validation, 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.

5. Reporting
The requirements placed on the contents of a validation 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 a highly efficient validation of the sterilization of pharmaceutical products. 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