

Environmental monitoring for the highest demands.

testo Saveris Pharma: Central monitoring of all audit-relevant environmental parameters for pharmaceutical applications – quickly, easily and efficiently.



Do you have all important environmental conditions in view at all times?

Compliance, transparency, efficiency and reliability are the four columns which support your daily work in the pharmaceutical sector. All four have just one objective: Quality assurance.

Compliance with all relevant norms and regulations.

Transparency of all quality-relevant processes in your company.

Efficiency in the implementation of the compliance requirements and the application of support systems. **Reliability** in the adherence to quality guidelines.

What do you think: How well does quality assurance work in your company?

Loads of data, not much benefit?

- ☐ Are your compliance-relevant environmental data being efficiently and reliably recorded?
- $\hfill\square$ Are the recorded data centrally and securely stored?
- ☐ Can you use the recorded quality data for analysis, and for improving your risk assessment?

High costs, low efficiency?

- ☐ Can you record your data without mountains of paper and according to FDA 21CFR Part 11 and EU GMP Annex 11?
- ☐ Can you carry out audits quickly and at low cost?
- ☐ Can you access your audit-relevant data at all times?

Lack of transparency?

- ☐ Do know exactly what's going on with the indoor climate in critical areas?
- ☐ When problems occur: Can critical parameters be identified quickly corrected at short notice?

Little control?

- ☐ Can you be sure that quality assurance is always working reliably?
- ☐ Can you react quickly to unexpected environmental influences?
- ☐ Are you relaxed about your next audit?

testo Saveris CFR software testo Saveris Pharma: In the testo Saveris CFR software, all measurement data are collected, visualized and documented without gaps. All information at a glance testo Saveris Base V 3.0 Compliance with 21 CFR Part 11 of the American FDA The testo Saveris Base V 3.0 is the "heart" of the and its European counterpart Annex 11 of the GMP system. The storage of the measurement values in with a single system. guideline is guaranteed by electronic signatures and triplicate in the Base, data loggers and database, avoids recording of the Audit Trail, and is additionally gaps in the documentation. complemented by maximum data integrity and user levels with different user rights. The complete solution testo Saveris was developed together with experts from the sector and more than 10 years' experience in Life Science environments. Highly precise measurement technology, intuitively operable software and comprehensive services help you to carry out your work quickly, efficiently and in accordance with GxP regulations. testo Saveris **CFR** software testo UltraRange radio technology With this technology, you use a self-sufficient radio network via encrypted, proprietary signals Cockpit with outstanding range and signal stability in testo UltraRange Customer's own WLAN testo Saveris closed rooms. access point Base V 3.0 Modular data loggers With the help of the different communication modules, the testo 150 data logger modules can be integrated into The web-based intuitive Cockpit of the testo Saveris any existing communication infrastructure (WLAN, LAN). testo UltraRange **WLAN** LAN/PoE CFR software makes it possible at any time to identify The optional testo UltraRange wireless technology alarms, initiate corrective steps and to acknowledge the allows the secure transfer of measurement values over alarms. Alarms are clearly presented in the Cockpit. long distances. Every alarm acknowledgement must be closed with a personalized, digital signature as well as a mandatory comment on the event. Digital probes with Plug & Play function The digital probes of the testo 150 data logger module series can be exchanged in seconds during continuing operation. There are no interruptions in the measurement. testo 150 testo 150 testo 150 testo 150 TUC4 DIN2 TC4 Measurement **Analog coupler** transmitter

Analog probes

The whole process at a glance.

- Minimize risks and reduce costs, in order to make your manufacturing processes more efficient.
- Access your data independently of platform, from anywhere and at any time.
- Use the recorded data for process analysis and optimization.

Achieve more efficiency.

Record the quality data for all important environmental parameters – digitally and paper-free.

Digital probes

- Record and document all relevant quality data for different applications.
- Access your data at any time and always be ready for your next audit.

Identify critical points.

- Identify errors early and intervene correctively.
- Use the intelligent alarm functions for fast action according to your CAPA system.
- Identify potential issues before they even occur.

Everything under control.

- Meet the high standards which apply to your application.
- Strengthen quality consciousness in your organization and with your partners.
- Gain full control over the quality of individual areas of responsibility.

And for your next audit: Be sure.

Be sure. testo

The testo Saveris performance promise.

testo Saveris Pharma supports you fourfold. The measuring data monitoring system records and analyzes your critical ambient data, provides immediate alarms when limit values are violated and can support you in the optimization of your processes. To do this, the complete solution uses three successful building blocks: Sensors, software and services.



Sensors:

Reliable recording of quality data.

Thanks to over 60 years' experience in the manufacture of measurement solutions and sensors, Testo offers you all the measuring instruments you need for the monitoring of environmental parameters. These include data loggers for the automatic recording of measurement values and alarm provision.



Software:

Audit-proof compliance for all GxP-relevant data.

The testo Saveris CFR software fulfils FDA requirements with regard to 21CFR Part 11as well as Annex 11 of the EU GMP guideline, with an audit-proof central data management platform which is accessible worldwide. The platform enables the comprehensive analysis and evaluation of all recorded measurement parameters – with the help of flexible alarms, different reporting functions and various database hosting options.



Services:

A competent partner worldwide.

Our specially GxP-trained service team accompanies you in all process steps in a customer-oriented and systematic way – from planning, documentation, system qualification and software validation, right up to service and support. Together with you, we define a tailored service concept in all project phases. You can rely on us during operation, too. We take care of your system and its maintenance, calibration and validation.

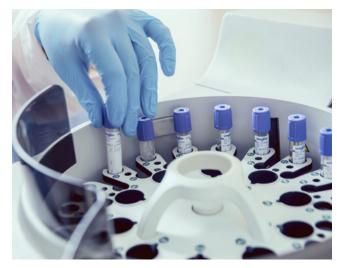
Our pharma expertise:

Solutions for R&D, production, logistics and healthcare.

Testo has been a reliable partner for the pharmaceutical industry for many years. Hardly any other sector is regulated more strictly and monitored so restrictively. Because in the end, it is the well-being and health of people which is in focus here. We give you the certainty of always being on the safe side when monitoring your important parameters – in research and development, production, storage and logistics as well as in all healthcare applications.

The close exchange with our customers shows: In a globally networked and dynamic world, it is not enough simply to measure accurately. It is more about the comprehensive management of all relevant quality parameters with a single, intelligent system that makes your daily work easier, more efficient and more reliable. And that's why we developed testo Saveris Pharma: **Environmental monitoring for the highest demands – easy, efficient and reliable.**

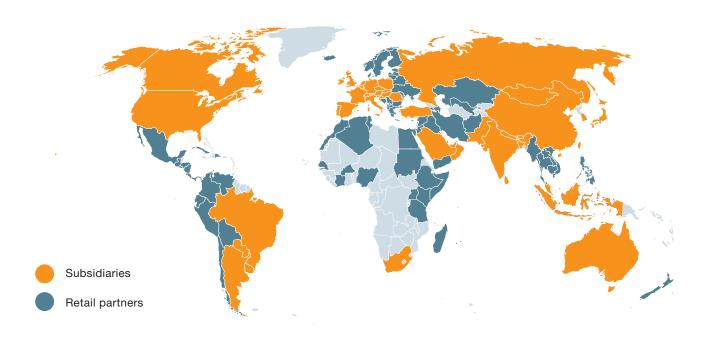








High-tech from southern Germany.



For over 60 years, Testo has stood for innovative measuring solutions made in Germany. As a world market leader in portable and stationary measuring technology, we support our customers in saving time and resources, in protecting the environment and human health and in increasing the quality of goods and services.

Over 3000 employees work in research, development, production and marketing for the high-tech company in 34 subsidiaries all around the world. Testo impresses more

than 1 million customers all over the world with high-precision measuring instruments and innovative solutions for the measurement data management of tomorrow. An average annual growth of over 10% since the company's foundation in 1957 and a current turnover of just short of 300 million Euros impressively demonstrate that southern Germany and high-tech systems go perfectly together. The above-average investments in the future of the company are also a part of Testo's recipe for success. Testo invests about a tenth of annual turnover in research and development.