Product Information

testXpert R Option - Traceable and Reliable Test Results in Accordance with FDA 21 CFR Part 11

CTA: 282711 282206

Traceability option

The testXpert R traceability option can be applied to all safety-critical tests that have special traceability and documentation requirements. This applies to both dynamic and static test sequences. With the standard user management feature integrated in testXpert R, we ensure that your report data is tamper-proof at all times. The traceability option, together with organizational methods, therefore offers all the technical prerequisites to meet regulatory requirements such as those of the FDA.

Electronic records provide the user with a view of all testing and system related actions and changes in the audit trail. Various filter functions allow for quick and targeted record searches.

The Reasoning function prompts the user to provide justification for defined processes and events, for example, when changing a test related parameter such as the testing frequency.

The Electronic Signature function documents who is assuming responsibility and at the same time, makes the audit trail paperless. For selected processes, the user is required to provide an electronic signature by entering the respective user ID and password in testXpert R.

Furthermore, ZwickRoell offers comprehensive qualification service (DQ / IQ / OQ).

Guidelines for the regulated areas of the medical and pharmaceutical industry

The regulation 21 CFR Part 11 on electronic records and electronic signatures of the United States Food and Drug Administration (FDA) defines acceptance criteria for the use of electronic records and electronic signatures in place of records in paper form and handwritten signatures on paper. These electronic documents must be handled with as much confidentiality, be just as authoritative, and hold the same value as the paper documents. Compliance with regulations FDA 21 CFR Part 11 and EU GMP guidelines Annex 11 is required for use with electronic records and signatures in a regulated environment. It is still possible to use conventional paper documents and handwritten signatures.

Advantages and features

- With testXpert R you can log actions and changes before, during and after the test, making test results traceable and protecting them from tampering.
- The traceability option can be configured as needed. The responsible party shall determine for which of the logged operations and events the user must provide a reason. With a simple click, the system can also be set to require an electronic signature for these actions. In this manner, testXpert R provides the option to be customized according to QA regulations.
- The reasoning and signature are automatically added to the relevant log entry (with both old and amended values).
- The report view offers helpful filtering options for quick entry searches.
- The report data is securely stored and cannot be changed with standard Windows programs. Output can be generated in readable form (HTML) from testXpert R at any time.
- For documentation purposes, the traceability configuration can also be output in HTML format.

Comprehensive user management / LDAP connection

Should users be able to carry out functions only within a defined area of responsibility? Or would you like to make life easier for users by hiding unneeded functions? testXpert R's powerful integrated user management function already included in the base package does exactly that. You can choose predefined user

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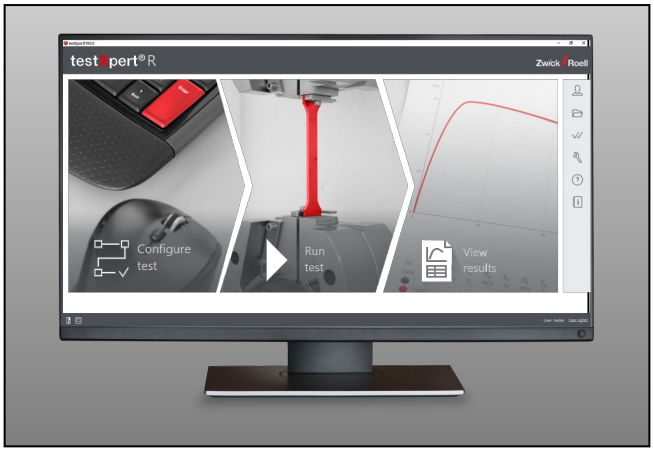
roles, define new customized roles or connect your own Windows user management (LDAP) system: this makes it possible to allow or disallow functions (e.g. testing system or controller setup) or test specifications, which helps to prevent input errors and tampering.

Description	ArticleNumber
testXpert R traceability option	**1094291**

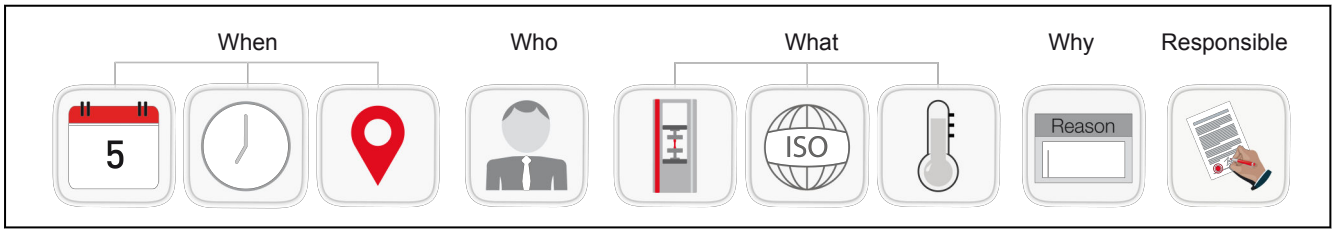
CTA: 282685 282764

Administrator view with full functionalities



User optimized view

CTA: 133299



testXpert R logs all test related and system related actions and settings.

All data at ambient temperature.

Subject to change in the course of further development.