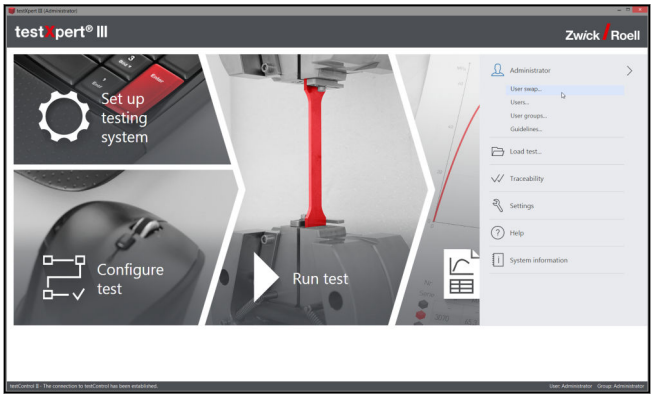
Product Information

testXpert III Option - Traceable and reliable test results in accordance with FDA 21 CFR Part 11

CTA: 129215 133338



Scope of services for traceability option

The testXpert III **Traceability option** can be applied to all safety-critical tests that place special requirements on traceability and documentation.

The **electronic records** function enables you to comprehensively document all actions and changes carried out in the testXpert III software so that they cannot be tampered with. Users define the degree to which the actions must be logged and possibly explained in accordance with their regulatory requirements (for example, changes to a test-relevant parameter such as test speed). This data is saved in the audit trail.

The **electronic signature** function makes it possible to document who is assuming responsibility and at the same time, makes the audit trail paperless. The signature on the test report can be replaced by the test program/test series digital signature by entering the user name and password in testXpert III. In the process, you can define exactly who the authorized individuals are and the number of signatures. Once signed, the test program and test series are protected from unauthorized changes.

Together with the standard testXpert III user management functions, the Traceability option offers all of the tools needed to fulfill the requirements of the FDA in 21 CFR Part 11 in terms of organizational measures and procedure instructions. ZwickRoell also offers qualification services (DQ/IQ/OQ) for validation support.

Guidelines for the regulated areas of the medical and pharmaceutical industry

The regulation **21 CFR Part 11**(Code of Federal Regulations) 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 on 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

- testXpert III enables logging of actions and changes before, during and after the test, making test results traceable and protecting them from tampering.
- The expanded traceability option can be configured as needed, and the degree of traceability can be defined. The administrator defines what must be logged and for which activities and events the user must enter a reason. In this manner, testXpert III offers the possibility of being individually adapted to the customer's QS regulations.
- The report entries are saved automatically and independently from the type in the system audit trail or in the respective test programs/series.
- The data is saved in binary coding and cannot be edited with Windows standard programs. Output can be generated in "readable" form (HTML / PDF) anytime in testXpert III.
- Report data is encoded when being archived.
- The optional reason is automatically added to the respective report input (with the old and the modified value).
- Comments can be inserted in the audit trail via a menu item.

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- The electronic signature function for the test program and/or test series can also be individually configured. This includes simple signature, the four eye principle, and multiple signatures by persons with various areas of responsibility.
- Once signed, the test report is provided with the series signatures and the corresponding time stamps (to the second) as standard.
- Signed test programs/test series can also be made available to a large group of people in order to make sure there is no tampering.

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 III's powerful integrated user management already included in the base package does exactly that. Choose from predefined user groups or define your own groups. For example, you can allow or block individual functions, standard actions (e.g. print report), or test programs, which helps to prevent input errors and tampering. User management also makes it possible to individually define password guidelines.

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Administrator view with all functions

Tester view with relevant functions

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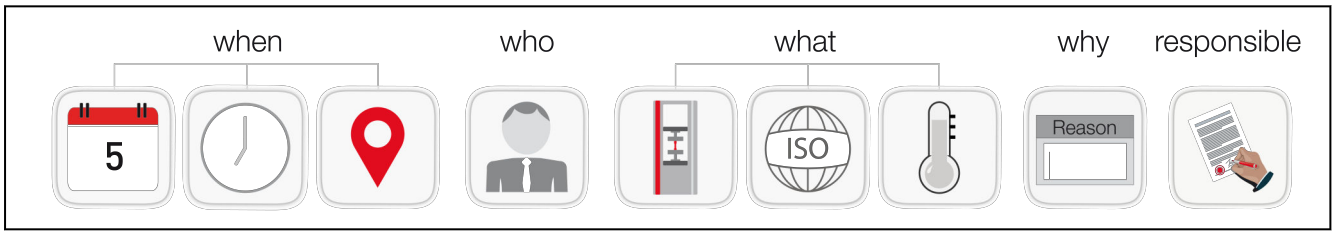

testXpert III logs all test- and system-relevant actions and settings.

All data at ambient temperature.

We reserve the right to make technical changes in the course of ongoing development.