Legal requirements
Extremely high demands are placed on quality assurance in the medical and pharmaceutical industries. National and international laws and directives such as the German Medicine Act (MPG) and the US Food and Drug Authority’s Code of Federal Regulations (CFR) require that all processes and computer-controlled systems directly related to product manufacture must be subject to validation. Observation of these guidelines is verified in an audit. This requires the appropriate documentation and supervision of all activities.

The responsibility for validation lies with the regulated undertaking (system owner), which must establish guidelines and procedures in order to comply with the legal requirements. Good Automated Manufacturing Practice (GAMP) serves here as a globally recognized code of practice for validation. It describes the tasks and duties of the supplier and the end user, together with the validation process. A significant element of validation is the technical inspection of individual systems and devices. This section is designated Qualification.

Diagram of validation process
- Planning phase, derived from the performance specifications or the user requirement specification (URS)
- Risk analysis RA
- Definition of the technical specifications, with verification in Design Qualification DQ
- Verifying correct delivery, installation, and documentation of the system as part of Installation Qualification IQ
- Verifying correct basic operation during Operational Qualification OQ
- Verifying reproducibility of specified sequences or parameters in Performance Qualification PQ

The regulated undertaking must check whether the Zwick testing systems used in the medical engineering and pharmaceutical industries are subject to the legal requirements so that qualification is necessary.

The operator of the system is required to maintain the valid status of the system throughout its lifetime.

We reserve the right to make technical changes in the course of ongoing development.
Zwick offers support with intelligent standardized solutions

The standard package includes comprehensive DQ/ IQ/ OQ documentation.

The individual documents are separated from the performance specifications and are based on risks identified by Zwick regarding the Zwick testing system and testing software. These risks are checked in the tests as part of the IQ and OQ processes.

We provide you with all documents before qualification takes place so you can check and approve them.

The standard documentation includes the following documents and tests:

- **DQ**
  - mode of operation
  - hardware, software, mechanical, electrical
  - electronic data and interfaces
  - non-operational properties (incl. risk assessment)

- **IQ**
  - scope of delivery
  - safety devices
  - installation

- **OQ**
  - safety devices and power loss
  - data storage, function test and user management
  - if included in contract: traceability and electronic signature

Test points during the qualification

Experienced, specially trained service technicians carry out the qualification step-by-step at your site using the qualification documents previously generated.

Each IQ and OQ test successfully completed is signed off by the qualifier and operator. The IQ and OQ report, as well as the final report, summarize the results of the IQ and OQ.

The Zwick documentation can be customized at any time upon request. Individual qualifications are also possible upon request.

**Operator responsibility**

The performance specifications, risk analysis according to GMP guidelines, the traceability matrix, FAT and SAT test reports and the performance qualification (PQ) are created by the operator.

The operator adds any missing items to the standard documentation after purchase.

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Qualification service with Zwick – your benefits

Cost and time savings
No resources needed to prepare and execute qualification
Standardized document layout enables rapid project implementation

Expert advice
Zwick offers expertise and knowledgeable consultancy on the scope of qualification required.

Know-how
Skilled service technicians work with you to complete qualification after commissioning and calibration at your site. Qualification of an installed Zwick testing system is also possible.

Guaranteed success
Qualification is performed on-site at your premises by a specialist in the hardware and software of the Zwick testing system.

You benefit from our wealth of experience
The content of the documents is based on years of experience in the qualification of testing machines. The documents are continually updated to conform with new rules and information.

Flexibility
Customized expansion of the standard Zwick documentation is possible whenever required.

Quality
Zwick is EN ISO/IEC 17025 accredited and can provide skilled and traceable calibration of testing systems in addition to qualification from one source.

We reserve the right to make technical changes in the course of ongoing development.
Product Information
Qualification of Zwick Testing Systems (DQ/ IQ/ OQ)

Overview of qualification service availability

Basic requirement
To qualify for this service the Zwick testing system must be completely operational with testXpert II or testXpert III. We do not currently offer qualification services for testXpert R.

Expanded Traceability option
Expanded Traceability is available with testXpert III and testXpert II Version 3.4 and above. It uses organizational measures and procedure instructions defined by the company to help fulfill requirements according to FDA 21 CFR Part 11.

Qualifiable testing systems
Zwick offers qualification services for all static testing machines with either the standard electronics (DUPS/MOPS) or our testControl or testControl II electronics. The qualification portfolio also includes the electromechanical testing actuator with testControl electronics and torsion test machines and autoinjectors. We are happy to provide you with an assessment of the feasibility of qualification services for Zwick testing instruments such as hardness testers, extrusion plastometers, the LTM, pendulum impact testers etc.

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* only with testXpert III

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