

Product Information

Qualification of ZwickRoell Testing Systems - DQ IQ OQ PQ



Qualification service for new and existing testing systems

ZwickRoell qualification documents are brought together in a basic package covering the basic equipment of the testing system.

Regulated undertakings are required to create user requirements specifications (URS) (*EU GMP Annex 15*). We therefore provide support in the form of a specification document* specifically tailored to our testing systems. This can assist you in the creation of your URS.

The individual specifications are transferred to the Risk Analysis (RA) and assessed there for relevance to GMP and occupational health and safety. All specifications classified as relevant to RA and GMP and occupational health and safety are channeled into the Design and Test documents and are reviewed during qualification.

Traceability is ensured throughout, from the specification of the testing system to the RA to the design and test documents.

In addition to the qualification plan and final report, the basic documentation includes the following documents and tests:

Statutory requirements and guidelines

Extremely high demands are placed on quality assurance in the medical and pharmaceutical industries.

National and international laws and regulations require that all processes and computer-aided systems directly related to product manufacturing must be subject to validation.

Compliance with these regulations is verified in an audit. This results in the need for appropriate documentation and supervision of all activities throughout the entire life cycle in order to minimize risks and guarantee patient safety.

The responsibility for validation lies with the regulated undertaking

The regulated undertaking (system owner) should establish policies and procedures to satisfy the legal GMP requirements. *Good Automated Manufacturing Practice (GAMP5)* can be applied here as globally recognized guidelines 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/instruments. This section is designated **Qualification**.

RA	<ul style="list-style-type: none"> ■ Examination of the risks associated with the testing system from the manufacturer's perspective ■ Serves as Traceability Matrix
DQ	<ul style="list-style-type: none"> ■ If part of the order: <ul style="list-style-type: none"> ■ Specification of the testing system (URS) ■ Design Specification (DS) including FDS/ HDS/ SDS
IQ	<ul style="list-style-type: none"> ■ Scope of delivery ■ Safety devices ■ Installation
OQ	<ul style="list-style-type: none"> ■ Safety devices, power failure, data storage, function test and user administration ■ If part of the order: <ul style="list-style-type: none"> ■ Traceability and electronic signature

Scope of the basic qualification

* available for testControl II with testXpert III V1.5 or higher

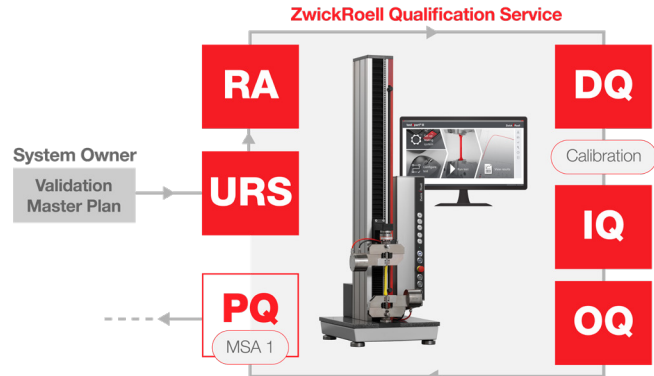
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Qualification process at ZwickRoell

- ZwickRoell creates the qualification document in the ordered scope.
- All documents are made available to the system owner in advance for review and approval.
- ZwickRoell signs the qualification documents and sends the originals to the system owner.
- Qualification will be performed on-site by a GMP-trained ZwickRoell service technician.

Validation Process



Schematic sequence of a validation

ZwickRoell qualification service - your benefits

Time and cost savings

Your resources are not tied up in preparing and implementing qualification. The modular document structure allows you to quickly implement the project.

Experience

The content of the documents is based on years of experience in the qualification of testing systems. The documents are continually updated to conform with new rules and new insights derived from the market.

ZwickRoell has already performed over 2,500 successful qualifications - both nationally and internationally.

Know-how

Experienced, specially trained service technicians carry out the qualification step by step following commissioning and calibration at your premises. Qualification of a ZwickRoell testing system that has already been installed is also possible.

Expert advice

ZwickRoell possesses the expertise required to provide competent advice.

Flexibility

The scope of the qualification can be individually expanded on the basis of the basic documentation, for example to include function tests for standard test programs or customized test programs.

We would be happy to create a completely individually tailored qualification based on the commonly agreed upon URS.

Quality

ZwickRoell is EN ISO/IEC 17025 accredited and can provide professional inspection and calibration of testing systems in addition to qualification, all from a single source.

Furthermore, ZwickRoell can offer support and advice during the PQ.

Your direct line to us

If you would like further information or have any questions, please feel free to contact our experts at: qualification@zwickroell.com

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Qualification portfolio	Document	Basic package	Optional and customizable services
URS DQ	URS	INCLUDED	POSSIBLE
	DS	INCLUDED	POSSIBLE
Calibration Calibration certificate			
RA	RA	INCLUDED	POSSIBLE
	IQ	INCLUDED	POSSIBLE
IQ OQ	OQ	INCLUDED	POSSIBLE
	Additional Function Test		POSSIBLE
PQ	MSA1 as part of PQ		POSSIBLE

Flexible qualification solutions

Our qualification portfolio consists of the packages DQ with URS and/or RA, IQ, and OQ. The ZwickRoell URS is included in the complete DQ, RA, IQ and OQ package.

In the case of a customized qualification, the additional requirements resulting from the commonly agreed upon URS will be integrated into the basic documentation. Furthermore, we offer customized function tests.

ZwickRoell can also provide support during the creation and performance of PQ based on a measuring system analysis (MSA).

	Scope of basic qualification	Customized scopes subject to review by the ZwickRoell Qualification Team
Risk analysis	ZwickRoell risk analysis <ul style="list-style-type: none"> • Items from the commonly agreed URS are not taken into consideration • Risk assessment with... <ul style="list-style-type: none"> • zwicki, ProLine, AllroundLine, TorsionLine and LTM: "GMP-critical" Yes/No • Autoinjector testing systems: two-stage FMEA • Workshop for risk analysis is not provided 	Risk analysis can be adapted: <ul style="list-style-type: none"> • Additional customer requirements • Expansion of the items of the commonly agreed upon URS • FMEA for zwicki, ProLine, AllroundLine, TorsionLine and devices/ instruments • Workshop for the risk analysis can be performed together with the customer
Test scopes	The general basic functions are described in the DQ and tested in the IQ and OQ as defined in the risk analysis <ul style="list-style-type: none"> • Axial testing system: standard tensile and compression test • Torsion testing system: Standard tensile and compression test with superimposed torsion • Autoinjector testing system (if applicable, with robot): standard autoinjector test • LTM: standard function test, dynamic 	Accessories and customized functions can be incorporated into the DQ & IQ & OQ: <ul style="list-style-type: none"> • Customer-specific additions in the DQ are possible, e.g. customized tooling • Customer-specific additions in the IQ, e.g. installation of customized accessories • Addition of customer-specific tests in the OQ are possible, e.g. additional negative tests and function tests
Function test	Function tests with regard to user management, traceability, and electronic signature are based on ZwickRoell standard settings. Any changes to this are not covered by the function test	Function tests with regard to user management, traceability, and electronic signature can be adapted to customized settings
Traceability Matrix	Traceability matrix is included in the risk analysis	Traceability matrix can be created separately according to customer requirements
Method validation/ PQ	Optional: Measurement system analysis 1 (MSA1) as basis for method validation/ PQ	Customer support with method validation and PQ

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Overview of the availability of the qualification service

Basic requirement

A key requirement for the qualification is the perfect technical condition of the ZwickRoell testing system in use with the testing software testXpert II, testXpert III, or testXpert Research version 6.0 and above.

Traceability option

For testXpert III, testXpert II as of version 3.4, and testXpert Research as of version 6.0, the traceability option together with organizational measures and procedure instructions for the respective undertaking, provides the necessary requirements to meet the *FDA 21 CFR Part 11* criteria in accordance with the testXpert ZwickRoell white paper.

Qualifiable testing systems

ZwickRoell offers qualification service for all static testing systems, including torsion testing systems and testing systems for autoinjectors as well as for dynamic LTMs.

For other ZwickRoell testing systems, we would be happy to examine the possibility of a qualification upon request.



testControl



testControl II

Qualification Service

Product Availability

	testControl	testControl II
zwickiLine	AVAILABLE	AVAILABLE
ProLine	AVAILABLE	AVAILABLE
AllroundLine	AVAILABLE	AVAILABLE
Autoinjector testing system		AVAILABLE
LTM		AVAILABLE
Other and automated testing systems	ON REQUEST	ON REQUEST