Product Information

Qualification of ZwickRoell Testing Systems - DQ IQ OQ PQ

Statutory requirements and regulations

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 subjected 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 (operator) must 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 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**.

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.

Since 2015, regulated undertakings have been required to produce 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.

The basic documentation includes the following documents and tests:

DQ	▪ Specification of the testing system ▪ Design Specification (DS) including FDS/ HDS/ SDS
IQ	▪ Scope of delivery ▪ Safety devices ▪ Installation
OQ	▪ Safety devices, power failure, data storage, function test and user administration ▪ If part of the order: Traceability and electronic signature

Test items within the scope of the qualification

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

PI 762 2.0921

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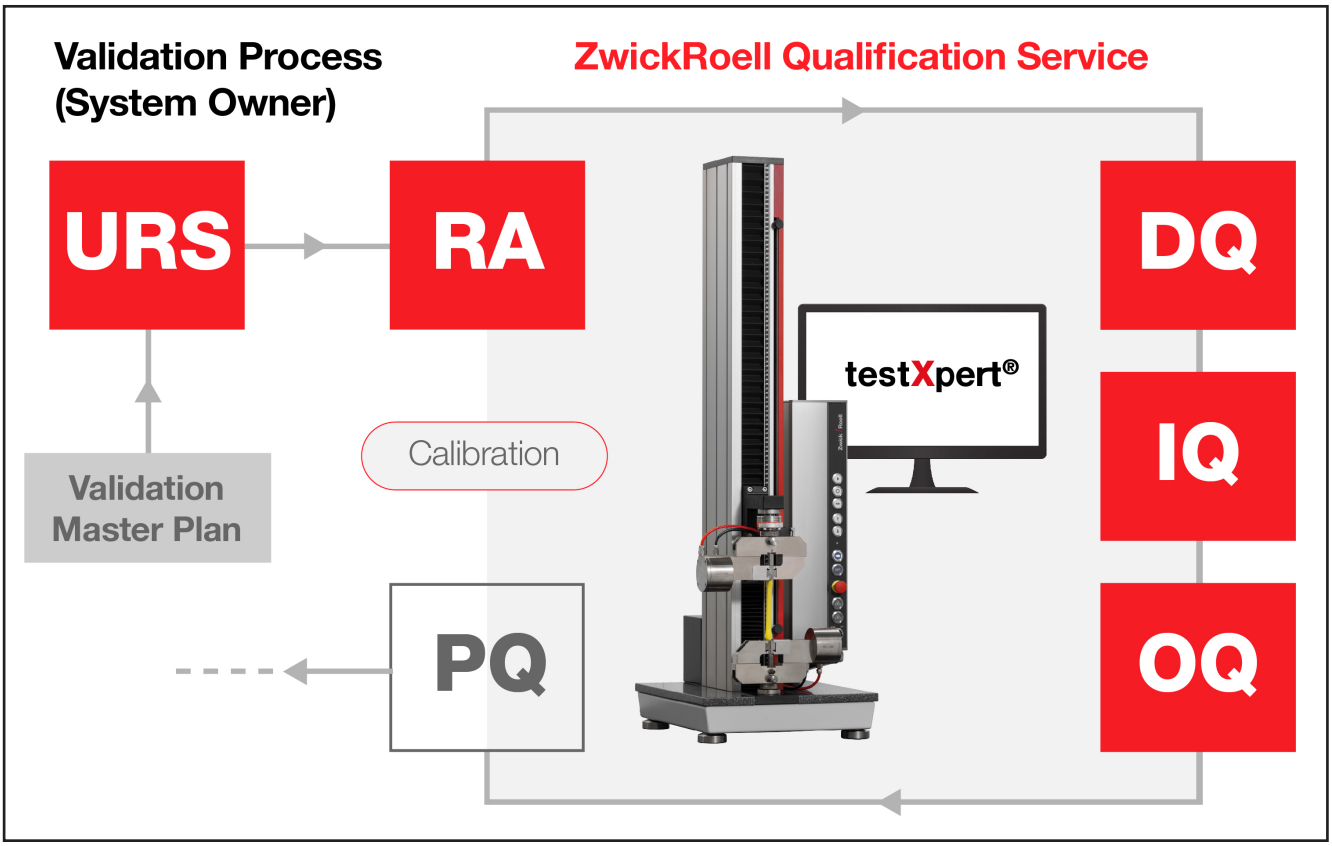

Schematic sequence of a validation

Qualification process at ZwickRoell

- Generation of the specification of the testing system
- Generation of Risk Analysis (RA) based on testing system specification. The RA serves as a traceability matrix
- Review of the design defined in the specification of the testing system within the Design Specification (DS)
- Verification of correct delivery, installation, and documentation of the system within the scope of Installation Qualification (IQ)
- Verification that the testing machine and software can perform their basic operations correctly during Operational Qualification (OQ)

Modular qualification solutions

In addition to the basic package, ZwickRoell can also provide individually tailored and periodic qualification.

In the case of an individually tailored qualification, the additional requirements resulting from the URS are integrated into the basic documentation.

The basic package includes comprehensive documentation consisting of the testing system specification, an RA, DS, IQ, and OQ.

All documents will be made available to you for review and authorization before qualification takes place.

Qualification will be performed on-site at your premises by specially trained ZwickRoell service technicians.

We can provide the creation and performance of a PQ as an individual service.

PI 762 2.0921

Product Information

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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 testXpert II or testXpert III testing software.

Qualifiable testing systems

ZwickRoell offers qualification service for all static testing systems, including torsion testing systems and testing systems for autoinjectors.

For ZwickRoell testing systems such as hardness testers, extrusion plastometers, LTMs, pendulum impact testers, electromechanical testing actuators, etc., we will gladly verify the option of a qualification upon request.

Traceability option

For testXpert III, and testXpert II as of version 3.4, the Traceability option together with organizational measures and procedure instructions for each individual undertaking, provides the necessary requirements to meet the *FDA 21 CFR Part 11* criteria.

testControl

testControl II

Qualification Service

Product Availability

	testControl	testControl II
zwickiLine	AVAILABLE	AVAILABLE
ProLine	AVAILABLE	AVAILABLE
AllroundLine	AVAILABLE	AVAILABLE
Other testing systems	ON REQUEST	ON REQUEST

PI 762 2.0921

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ZwickRoell qualification service - your benefits

Time and cost savings

Your resources are not tied up in preparing and implementing qualification. The modular document structure enables quick project implementation

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 1,500 successful qualifications–both nationally and internationally.

Bottom-up document structure

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 which has already been installed is also possible

Expert consulting

ZwickRoell possesses the expertise required to provide competent consulting.

Flexibility

The scope of the qualification can be expanded on the basis of the basic documentation.

We will also be happy to produce a completely individually tailored qualification based on your User Requirements Specifications (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.

PI 762 2.0921