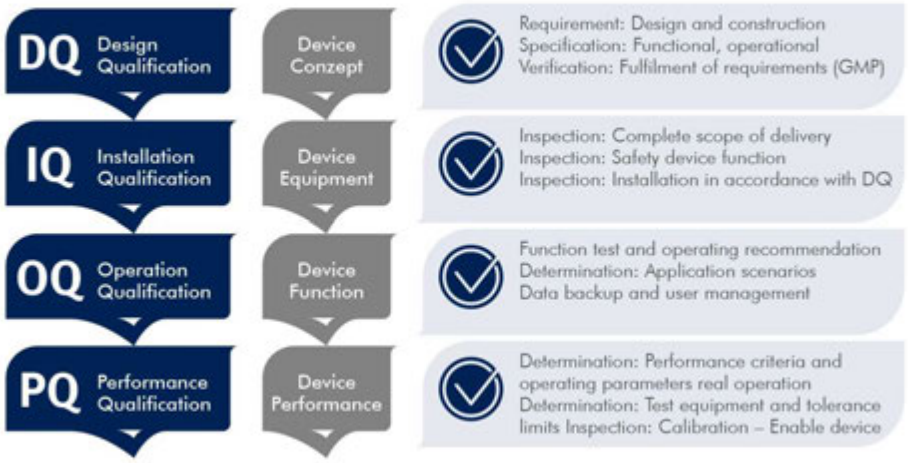
DQ, IQ, OQ, PQ - Instruments of quality assurance and an important required from a standards perspective.

In recent years, the demand for qualification with manufacturer support has intensified significantly. For us at A.KRÜSS, it was clear that we could only meet this challenge holistically with customer support throughout the entire qualification process.In the past qualification in the laboratory was comparatively manageable: the proof that a technical system works flawlessly should be planned and confirmed in written form. Today's stipulations are extremely high and elaborate. National and international laws and regulations, such as the German Act on Medical Devices (MPG) or the Code of Federal Regulations (CFR) of the American Food and Drug Administration (FDA), require qualifying for all processes, equipment and computerised systems related to product manufacturing. Good Automated Manufacturing Practice (GAMP) serves as a globally recognised Qualifikation guide.

Target setting DQ, IQ, OQ and PQ measures

The main target should be to guarantee a perfectly reproducible production in a defined quality and this with technically faultless facilities, equipment, utilities and processes and according to reproducible procedures.

An overview of qualifications of DQ, IQ, OQ and PQ



- The **DQ** is the documented proof that the planned design of the device is suitable for the intended use.
- The **IQ** confirms the complete specified delivery and installation in accordance with regulations. Devices and their parts are identified, device configuration is proven and manufacturer specifications are documented for trouble-free operation.
- The **OQ** verifies that the device is working according to plan and in accordance with regulations. Users receive, among other aspects, useful information for the SOP (Standard Operating Procedure) and user training.
- The final **PQ** is the performance check of the devices according to a defined procedure. It provides proof that the DQ process requirements are fulfilled under real conditions. The aim is to approve the device for laboratory use and to ensure that it meets the requirements of regulatory authorities, standards, guidelines, audits and internal quality assurance.

Modern device qualification

The entire process has raised many issues since its launch and is frequently subject to strong criticism, as the initially unspecific requirements for the individual qualifications led to an unprecedented variety of approaches. This often manifests itself in mountains of paper, immense effort, time delays in projects and huge additional costs. Even today, expensive qualified lab technicians are often and for long periods of time involved in the Qualification of equipment instead of focusing on their field of expertise.

It is precisely during the support of the customer where the holistic A.KRÜSS qualification concept comes in. One of the primary objectives is the simplification of processes and the reduction of effort to a justifiable level. At A.KRÜSS, we do not Qualification because we are obliged to do so, we do it to increase product quality and higher plant availability for the customer. We know that quality control in the laboratory must be executed in an effective and reliable manner. Trust in the quality and validity of analysis results is the basis for professional work in both normal and highly regulated areas.

The future of device qualification

In the early days of device qualification there was a regulatory change every three to four years. Since the turn of the millennium new guidelines and requirements for quality assurance are published almost every year. This is a development which will certainly proceed more rapidly, also with regard to digital transformation in the laboratory, where analysis and measuring equipment, sensors, processes and data will be linked in the future. Processes and structures are already being constantly reassessed. Institutions such as the Fraunhofer IPA are involved in the SiLA initiative (Standardisation in Lab Automation) on new communication interfaces, software solutions and standards. At A.KRÜSS we are observing these developments with excitement and interest and evaluating them for our process modifications. We always focus on the fact that our qualifications are a quality feature and can help to proactively implement future regulatory requirements..

The qualification models of A.KRÜSS

In addition to standard qualification, we offer an advanced solution: The PharmaKit was developed specifically for device implementation in highly regulated laboratories. This advanced solution includes the examination, commenting and conformity assessment of fixed written DQ requirements in the customer specifications. Furthermore, it includes the required upgraded qualification and documentary attestation of conformity with GAMP5, GMP, USP1058 and 21 CFR Part 11.
All solutions of A.KRÜSS qualifications correspond with the "risk-based" approach which was introduced at the turn of the millennium. The equipment is checked and installed by our specialists with traceable test equipment. They have years of experience in the qualification of measuring instruments and know how the controls for the basic conditions of a routine operation must be defined. This ensures that the technology is suitable and works flawlessly.

Our qualifications also include maintenance and calibration. Our specialists are equipped with the necessary special tools and measuring equipment and possess proven specialist expertise in test equipment management. The qualification also includes SOP (Standard Operating Procedure) consultation and employee training sessions carried out on the device of the respective employee.
The qualification documents we use the latest specifications and standards. They can be examined by the customer before qualification on request. They comply with the requirements for effective comprehension, with clear structures and a standardised, modular document structure. As a result, processes can be carried out quickly and the documents are extremely precise. Of course, our qualification documents already meet the requirements for future GMP-compliant qualification with computer-assisted software solution.

Please feel free to call us for details.
Dr. Cornelia Göbel will be pleased to inform you
Phone 040 – 514 317-0, A.KRÜSS Contactform

Commissioning packages & services at a glance

Each work environment requires different specifications for the installation of the measurement devices. The three Krüss commissioning service packages meet different requirements:

Commissioning

Our service specialists will be happy to commission your new KRÜSS measuring instrument on your own premises.
After successful installation and functional testing, your service staff will benefit from comprehensive instruction and user training. We will be pleased to answer all your open questions and give helpful expert tips during setup. For example, you will receive recommendations on the proper cleaning or on the calibration of your new measurement instrument. The entire commissioning is documented with a training protocol.

This commissioning package is suitable for all customers who work in compliance with GMP/GLP or ISO9000.

Overview of the services:

- Installation and set-up of the device functions
- Commissioning and simple function test on site
- Testing of the environment and application
- Adaption of the device settings (methods) to the environment and application; plus detailed SOP advice
- Instruction and user training
- Documentation of commissioning with a personalised training protocol

Commissioning including IQ/OQ/PQ qualification

This commissioning is enhanced by a documented qualification of the new measurement instrument and extensive on-site inspections. The IQ/OQ/PQ service ensures that necessary quality demands on the measurement instrument and regulatory requirements are reliably fulfilled.

The entire service is documented by a commissioning report and includes the following qualifications:

- **Installation Qualification (IQ):**
Documented proof that your new device has been installed in accordance with GMP-critical requirements. Measurement and control technology, materials used, surfaces and add-on parts are tested.

- **Operational qualification (OQ):**
Documented proof that the system specifications are fully achieved in the entire measurement range.

- **Performance qualification (PQ):**
Documented proof that all relevant plant components and systems meet the defined specifications and requirements in the operating state.

With this installation package, we support customers who are subject to regulatory requirements for commissioning of their new measurement instrument, these include, for example, specification criteria of the European Union or the US Food and Drug Administration (FDA).

Overview of the services:

- Sample qualification documents for internal approvals
- Comprehensive equipment qualification with detailed procedure description (flow chart)
- Pre-configuration of methods for necessary measurement tasks
- Set-up of routine tests and checks for the user
- On-site calibration of all important parameters according to traceable norms and standards
- Extensive training and briefing of operators and device supervisors

Commissioning in the pharmaceutical industry

The GMP-compliant production of medicinal products and active pharmaceuticals is a condition for successful market licensing. In this context, quality assurance plays a central role, because quality deviations may directly affect the health of consumers.

In order to conform to the strict guidelines of the European Union or the US Food and Drug Administration (FDA), applied measurement devices have to be qualified. The qualification is structured in four phases:

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

For commissioning in the high-regulated pharmaceutical sector, our experts have developed a special service package. With our premium commissioning, we ensure that the necessary quality requirements for the measurement instrument and the regulatory requirements are reliably fulfilled and documented. As a result, a part of the necessary laboratory process validation has been done.

This commissioning (on-site service) for highly regulated laboratory analysis complies with the specifications of the following guidelines:

GAMP5;GMP; USP1058 as well as.

21 CFR Part 11.

Overview of the services:

- DQ support by processing customer's own specifications.
- Includes all necessary IQ/OQ/PQ services in the clients' working environment
- Preparation of all necessary test protocols, documents and certificates with traceability records
- Includes all the required certified test equipment as well as required measurements as well as control and specialized equipment that is necessary for the qualification process
- Includes SOP (Standard Operating Procedures) based on security aspects of audit trail, user management and data integrity
- Includes extensive application-based training for users