

accroma
accuracy is key

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Qualification of accroma® sample preparation systems



accroma delivers Compliance for your Sample Preparation

- Professional and certified qualification services
- Compliance with regulatory requirements
- Complete Documentation and Traceability
- Support whenever you need it



- ✓ **Modular Documentation Structure**
- ✓ **Individual Component Testing**
- ✓ **Comprehensive System Tests**
- ✓ **Certified Qualification Engineers**
- ✓ **Certified Reference Samples**
- ✓ **Certified Analytical Instruments**



Play it safe with professional and certified IQ/OQ from accroma labtec

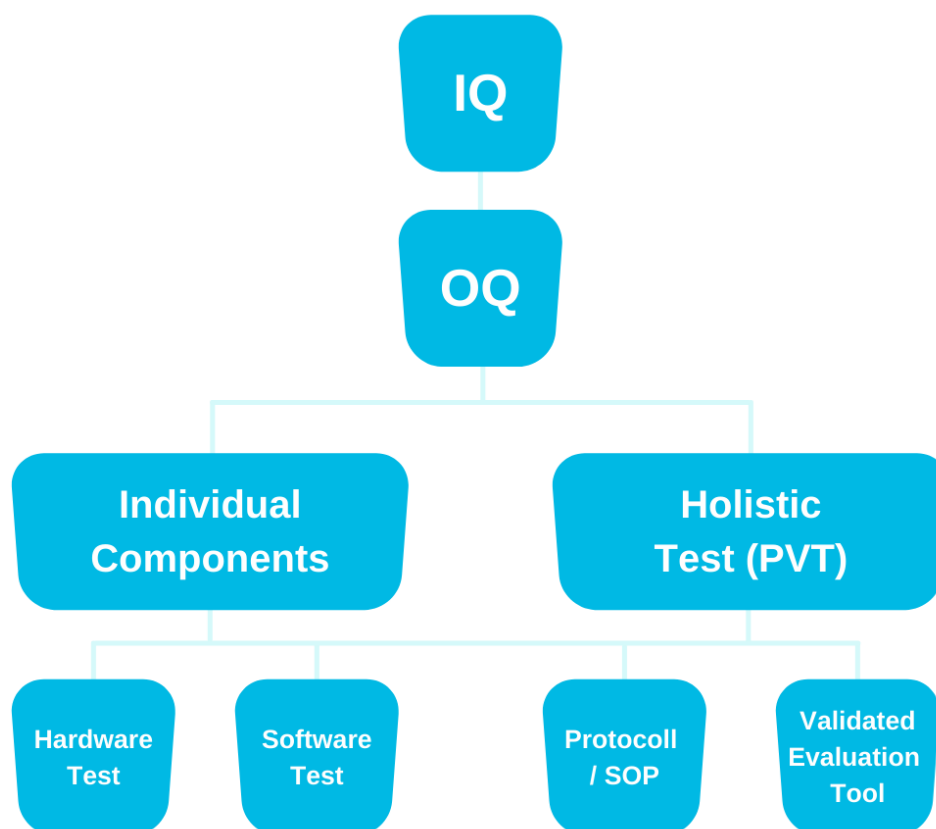
As a QA manager in a regulated environment, you must ensure that new analytical instruments are commissioned and used in accordance with the applicable regulations. However, the systematic fulfillment of these applicable regulations according to USP, FDA, GAMP, PIC/S and other authorities is associated with a high level of effort.

accroma labtec has developed a service offering that takes this work for you. In this way, we not only ensure that each individual hardware and software component of your sample preparation system are functioning properly, but also that the system as a whole does its job according to regulations. Your advantages are obvious: You save valuable time and money.

We qualify your system(s) cleanly documented according to regulations and your requirements

IQ & OQ performed in a systematic way

- Identification and legitimacy of the person who is carrying out the qualification or re-qualification
- Identification of all devices, software and documents that are the subject of the qualification.
- Performance tests of the whole system, which prove the accuracy and correctness of the results.
- The correct operation of the device including user training, if this is requested.





Installation Qualification (IQ) - get it right from the start.

First and foremost, the IQ ensures that the environment is suitable for the safe operation of your system. Furthermore, the IQ describes in detail how the accroma and third-party components have been installed. All hardware components and the connections between the individual components are neatly documented. The same applies to the software: The IQ documents exactly how the PC and the software are configured. This provides you with a valuable record of how your system was set up on day one of operation.

Operation Qualification (OQ) - Hardware Test

In the OQ, each hardware component is individually subjected to a functional test to check safety, function, and reliability. The tests performed in accordance with the manufacturer's specifications thus provide the documented proof that your hardware components work reliably, accurately, and safely.

Operation Qualification (OQ) - Software Test

Analogous to the verification of the correct functioning of the hardware, software tests ensure that all features of the respective software are working properly on the computer on which it has been installed.

Performance Verification Test (PVT) - A holistic test to ensure overall system performance

After each individual component has been checked with a function test, the next step is to check the system as a whole. The so-called Performance Verification Test (PVT) consists of a series of tests, which are carried out with certified samples (USP Prednisone tablets). It proves that your system including all components, is working properly and the samples are prepared:

- accurately with corresponding recoveries
- precisely with specified repeatability
- reliably without carry-over

The tests are performed using standard operating procedures (SOP). The qualification engineers are highly trained and certified with regard to the performance of these tests according to the specifications of the SOPs. The results of these tests are documented, evaluated in a statistically meaningful way and checked in a tool, validated for this purpose.

accroma - Your partner regarding regulatory compliance

IQ / OQ

The documented qualification of your equipment according to valid regulations provides you with security and protection for the worst case scenario.

PQ Support

If desired, our specialists will support you in the qualification of your methods.

PVT / Re-Qualification

Periodical and documented review of system performance

Support Contracts

Preventive maintenance ensures the proper functioning of your system(s) and minimizes Downtime

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