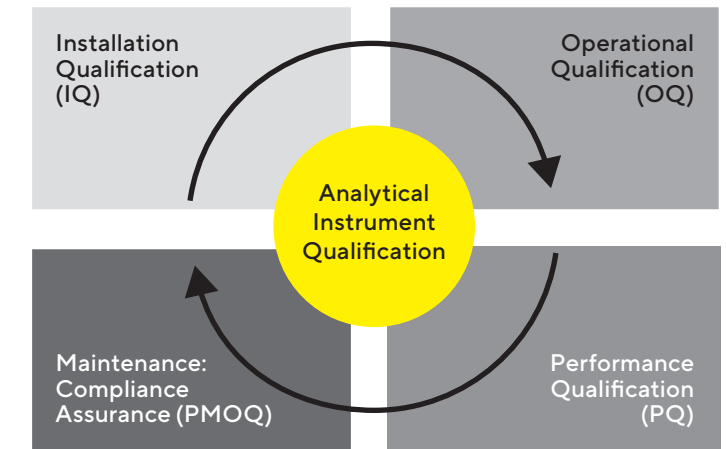


Octet[®] System Qualification Products and Services

Regulations and global standards, including US FDA 21 CFR Part 11, EU GMP Annex 15 and USP <1058>, require documented verification that your instruments are delivered, installed and routinely calibrated and functioning according to their operational specifications. Sartorius offers a full line of qualification products and services to help you meet your initial and ongoing system qualification requirements.

Our Installation and Operational Qualification (IQOQ) and Performance Qualification (PQ) services verify and record the instrument's ability to meet specified criteria after installation, move, software upgrade or major service events. These services include comprehensive testing using established conditions and known sample characteristics.

Our comprehensive Compliance Assurance (PMOQ) service, which includes all tests performed during OQ along with additional light source changes, should be scheduled at 6-month intervals to ensure the system is maintained in a



calibrated state and to reduce the risk of using out-of-compliance systems. We recommend to have instruments checked and formally tested regularly to confirm they are working according to manufacturer's specifications and to identify possible impacts due to normal wear.

IQOQ Kits and Services

Our comprehensive IQOQ Kit and service includes the following tests performed by certified Sartorius Service Scientists and Engineers:

- Order and System Verification to ensure that the instrument and computer ordered was received and fully documented
- Documentation Verification to ensure that user guides and other documentation are recorded
- Installation Verification to ensure that the installation meets specifications

- Software Identification Verification to record current versions and verify compatibility
- Verify that instrument is installed in a suitable environment for operation
- Instrument communication and initialization check
- Instrument XYZ stage alignment check
- Instrument optical system check
- Light source power check
- Plate temperature accuracy check
- Shaker speed accuracy check
- Signal (nm shift) accuracy and reproducibility verification
- Baseline drift and RMS noise verification

PQ Kits and Tests

Sartorius PQ Kits* provide a rapid and convenient method to verify the performance of Octet® Systems. Instrument performance qualification can be performed using one or both of two tightly controlled assays, depending on the intended use of the instrument. Both assays make use of a well-characterized antibody-antigen binding pair.

The PQ-Kinetics Assay Kit (PQ-K) verifies signal levels, signal precision, kinetic (k_a , k_d) and affinity (K_D) constants are within specification for an antibody-antigen binding interaction.

The PQ-Quantitation Assay Kit (PQ-Q) verifies signal levels, sample recovery, and precision are within specification in a two-step binding assay for quantitation.

* PQ products are currently only available for the Octet® RH16, R8 and RED96e Systems.

Recommended Frequency

IQOQ

To help ensure optimal performance and to support instrument compliance, we recommend IQOQ service to be performed at the following times:

- At instrument installation
- After major repair or replacement of critical components
- After relocation
- After functionality is added to the system, such as software upgrades

PMOQ

For instrument calibration purposes, we recommend PMOQ to be performed on a semi-annual basis. One annual PMOQ service is included in the Compliance Assurance Service Contract for all systems. Additional or stand-alone PMOQ service can also be purchased separately.

PQ

PQ Kits can be purchased and run by end user at any specified interval – weekly or monthly – based on the quality requirements of your laboratory. Sartorius certified personnel will run an initial PQ following instrument installation, after relocation, and after software upgrades. A partial PQ will be run following a major repair to the instrument.

Comprehensive Service Contracts

Sartorius Comprehensive Service Contract(s) ensure your instrument is performing optimally with minimal downtime. Routine maintenance and qualification after software upgrades and major repair events is included with every GxP comprehensive service contract.

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