

Operational Qualification using the Chemical Solutions Qualification Kits - Tech Information

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What You Need to Know:

The Chemical Solutions brand HSQ™ or PQ Kits™ are specifically designed to support Performance Qualification (PQ) activities. It provides the tools needed to verify that your instrument consistently performs according to user-defined specifications and is suitable for its intended analytical applications.

Understanding the Qualification Stages

Installation Qualification (IQ)

IQ focuses on verifying that the instrument is:

- Delivered as specified (make, model, serial number, software version, location)
 - Undamaged upon arrival
 - Properly installed in the selected environment
 - Connected to the appropriate network or data storage system
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Note: IQ procedures typically do **not** require the use of the HSQ™ Kit.

Operational Qualification (OQ)

OQ ensures the instrument functions according to its operational specifications. While some aspects of OQ involve fixed parameters (e.g., physical dimensions, voltage inputs) that don't require a kit, the HSQ™ solutions **may be used** for functional tests where applicable.

Users should define their own Standard Operating Procedures (SOPs) for OQ, especially when incorporating HSQ™ solutions into their protocols. Users may repeat OQ periodically or after major maintenance.

While instrument vendors are often responsible for OQ, instrument owners may choose to perform OQ in-house if they have the expertise and validated procedures to save money and time.

Performance Qualification (PQ)

This is where the HSQ™ Kit is most applicable. PQ involves demonstrating that the instrument performs consistently and reliably under actual operating conditions. The HSQ™ Kit provides the necessary solutions and materials to support this process.

- Instrument owners are most commonly responsible for PQ.
- PQ is about demonstrating that the instrument performs consistently under actual working conditions, using real samples and user-defined methods.
- Since PQ reflects the intended use of the instrument in a specific lab environment, it's best carried out by the analytical chemists or lab personnel who will be using the system.

Quality Assurance (QA) or Validation Teams

- In regulated industries (e.g., pharma, biotech), PQ is often overseen or co-executed by QA or metrology validation teams.
- They ensure that the process is documented, compliant with SOPs, and meets regulatory standards (e.g., FDA, EMA, USP <1058>).

Definitions from USP <1058>

- Installation Qualification (IQ): Verifies that the instrument is delivered, installed, and operating in a suitable environment.
- Operational Qualification (OQ): Confirms that the instrument functions according to its specifications.
- Performance Qualification (PQ): Demonstrates consistent instrument performance for its intended use.



Click [HERE](#) for PQ & HSQ Kits ordering information and pictures.

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