What is the difference between OQ , PQ and System Suitability - FAQ

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What's the Difference Between OQ and PQ in HPLC Qualification? – A Beginner's Guide

If you're new to working with HPLC systems in a regulated lab, understanding the qualification process is essential. Two important steps in this process are **Operational Qualification (OQ)** and **Performance Qualification (PQ)**. Let's break them down in simple terms:

🔧 Operational Qualification (OQ)

OQ is all about making sure your HPLC system works **as intended by the manufacturer**. It involves a series of tests to confirm that each part of the system performs correctly under controlled conditions.

🕒 When is OQ performed?

- After installation, usually by the instrument installer.

📘 **According to USP <1058>**, OQ can be modular (testing individual components) or holistic (testing the system as a whole). Once OQ is successfully completed, it must be reviewed and approved by your **Quality Unit** and **Management** before the system is used routinely.

📈 Performance Qualification (PQ)

PQ takes things a step further. It checks whether the HPLC system performs **consistently and reliably** under **real-world conditions**—that is, during the kind of work your lab actually does.

🧪 PQ involves:

- Running representative methods with traceable standards
- Verifying that the system meets user-defined specifications
- Documenting that the system is suitable for its intended use

📌 **Important:** PQ is not the same as System Suitability Testing (SST). While both involve performance checks, they serve different purposes.

🔍 PQ vs. System Suitability Testing (SST)

Aspect	Performance Qualification (PQ)	System Suitability Testing (SST)
Purpose	Confirms the system is suitable for routine use	Confirms the system is ready for a specific analytical run

When	After OQ, during qualification process which can be periodically, yearly or after repairs.	Before each batch or run
Scope	Broad: evaluates overall system performance	Narrow: checks method-specific parameters
Regulatory Basis	Part of instrument qualification (USP <1058>)	Part of method validation and routine analysis (USP <621>)

🧰 How Chenmical Solutions kits Can Help

Our HPLC PQ Kits are designed to simplify the PQ process. They include all the tools and materials needed to evaluate your system's performance across critical functions—helping you stay compliant and confident in your results.

🧪 Quick Summary

Step	What It Does	Why It Matters
OQ	Verifies the system works as designed	Ensures the system is ready for use
PQ	Confirms the system works in real-world use	Ensures reliability and suitability
SST	Checks system readiness before each run	Ensures valid results for each analysis

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👉 Want to learn more about our PQ kits? Click ***HERE*** to explore

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