What is the difference between Verifications Validation and Qualification - PRIMER

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If you're new to working in a lab or regulated environment, you've probably heard the terms ***verification*** , ***validation*** , and ***qualification*** —and they can sound pretty similar! But each one has a specific meaning and purpose, especially when it comes to ensuring reliable results and meeting regulatory standards.

Let's break them down in simple terms:

Validation
Validation is about proving that a method or process works for its *intended use*. It's like saying, "We developed this method ourselves, and we've tested it thoroughly to show that it does what it's supposed to do."

This is required when you're using a **non-compendial method**—meaning a method that's not already published in an official source like the USP (United States Pharmacopeia).

Verification
Verification is used when you're applying a method that's already been validated by someone else—like a compendial method from the USP. You're not re-validating it from scratch; instead, you're confirming that it works *as expected* in your specific lab, with your equipment and conditions.
Think of it as a quick check to make sure everything is working properly in your setup.

Qualification
Qualification is all about the **instruments** and equipment. Before you can trust your results, you need to make sure your HPLC, UV-Vis, or other lab instruments are installed correctly, working properly, and performing consistently.

This includes steps like Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).

Quick Summary for Beginners:

- **Validation** = Proving a new method works for its purpose.
- **Verification** = Confirming an existing method works in your lab.
- **Qualification** = Making sure your instruments are working correctly.

These terms are often used in regulated industries like pharmaceuticals, where accuracy and compliance are critical. Understanding the differences helps ensure your lab stays audit-ready and produces reliable data.

***NOTE**: If you're interested in the original reference, this explanation is based on an article by Drs. Ira Krull and Michael Swartz in LCGC North America, Volume 23, Number 10 (October 2005), page 1100.*

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