

# ***The Wrench***

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## **Instrument qualification and alternative aftermarket parts**

The product of an analytical lab is data. It's that data that supports safe, effective products, monitors the environment, and ensures our food supplies. There is a lot of work surrounding your data and a single sample injection. It encompasses everything from initial and continuing run calibrations all the way back to instrument performance qualifications and analyst training. Ultimately, the purpose of all this work is to give confidence in the integrity of your analytical data.

Let's step back and look at one part of the process: instrument qualification. Instrument qualification can be further broken down into four areas: design qualification (DQ), installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). Of these four only two are of concern on a routine ongoing basis – OQ and PQ. It is in these two areas that an aftermarket supplier such as CTS Corp. can be a valuable partner in your all overall maintenance program.

One set of components of operational qualification are instrument functions tests. Functions tests examine the important routines an instrument performs. They should perform according to vendor specifications, but more importantly need to meet your in-house requirements for the instruments intended use. For an HPLC unit testing may include flow rate accuracy, gradient linearity and wavelength accuracy. Testing may be either holistic (entire system) or individual component in nature. At the OQ stage modular testing may be the preferred route as it potentially allows system components to be swapped in and out. Once we reach the next level, performance qualification, a holistic approach is preferable.

OQ tests may or may not need to be performed on a routine basis, but they should be done whenever an instrument has undergone major repairs or changes. At the OQ stage the lab is in control; it is the labs responsibility and their opportunity to set the standards and specifications it needs to meet and then choose a vendor that will work for them. Likewise this is their chance to investigate using an alternative to the instrument manufacturer as an instrument parts supplier. Remember, the key to a successful qualification as well as subsequent regulatory audits is not where a part comes from, but how well the system is performing according to your in-house protocols.

The final and most frequent part of an instrument qualification program is the performance qualification (PQ). Typically this part of the program includes some sort of routine or regular testing, either every time a system is used or on a scheduled basis such as monthly or quarterly. An aftermarket supplier may be helpful here, because one of the benefits they can provide is creating a parts program in sync with your preventive maintenance (PM) protocol or creating similar styles of kits across multiple instrument

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platforms allowing you to simplify your overall lab PM structure.

Aftermarket suppliers can be a great choice. These suppliers are generally familiar with a wide variety of different manufacturer instruments, how they work and the parts that are frequently replaced. They are typically smaller than the OEM's and may be more responsive. Many are owned or operated by ex-lab analysts, or instrument service providers so they are acutely aware of the needs of the bench analyst and lab manager. They understand the importance of quality to your operations, as well as their own reputation. The best aftermarket suppliers often provide parts through a variety of channels. They may source parts from the same component manufacturers as the OEM's, or they may even be a component manufacturer to the OEM's. When they do go the route of manufacturing on their own parts, they make the effort to do their own testing; ensuring the geometry, materials, and performance of their product will match what the OEM's are offering.

CTS Corp. falls into many of the categories listed above. We were founded by an ex service engineer for one of the large HPLC OEM's. We have other ex-service engineers and analytical chemists on staff that have years of experience in the lab and working on instruments. All our parts, whether sourced or manufactured, must pass our QC before they are sold. Finally, we strive to work with our customers when issues do arise, as well as for new products to introduce.

Ultimately, while the design qualification and instrument qualification are largely left in the realm of the instrument vendors, the operational qualification and performance qualifications are the responsibility of the lab. This puts a lot of responsibility on the lab operators, but also gives them opportunities for savings and increased flexibility and potentially simplifying the overall lab PM program. By turning to CTS Corp. or other aftermarket suppliers, labs can get the attentiveness, responsiveness, and performance characteristics they need to meet the operational qualification and performance qualification protocols that they have set in place.

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