

Put Your Company's Laboratory Ahead of the Curve in FDA and EPA Requirements

Laboratory Instrument Qualification Performed & Documented in GLP Format

Is operational qualification or performance verification of a laboratory instrument a necessary step for good laboratory practice or merely a regulatory burden?

Laboratory instrument performance deteriorates over time and requires periodic testing to verify the suitability and accuracy of the system for its intended applications. One must consider the individual components of an instrument when assessing the performance of the system. For example, the intensity of a UV lamp deteriorates over time. This has a direct effect on the baseline noise, which could result in false LOQ or LOD values.

IQ OQ PQ provides a simple, straightforward and systematic method to verify the performance of the components, as well as the system. As a result, in a multidisciplinary chemical analysis laboratory, method transfer between instruments will prove to have greater accuracy when IQ OQ PQ is performed.

HPLC and LC Systems

- Temperature accuracy and stability of column heater/cooler
- Holmium oxide wavelength scan (if applicable)
- Detector lamp intensity, and wavelength accuracy
- Detector noise and drift
- Pump flow rate accuracy and repeatability
- High and low pressure shutdown accuracy
- Injector precision (area and retention time)
- Detector linearity and sample-to-sample carryover
- Injection volume linearity
- Gradient composition (step and linear)

GC Systems

- Temperature accuracy, stability and uniformity of column oven
- Detector (FID, NPD, ECD, TCD, FPD) temperature accuracy
- Detector noise and drift
- Gas flow rate accuracy and split flow ration (air, hydrogen, nitrogen, helium, argon/methane)
- Injector precision (area and retention time) and temperature accuracy
- Detector response linearity and sample-to-sample carryover

Capillary Electrophoresis Systems

- Temperature accuracy and stability of capillary compartment
- Holmium oxide wavelength scan (if applicable)
- Detector lamp intensity and wavelength accuracy
- Detector noise and drift
- Injector precision (hydrostatic and electrokinetic)
- Injection time linearity (hydrostatic and electrokinetic)
- Detector linearity
- High voltage accuracy and stability

LC/MS and GC/MS

In addition to the regular HPLC and GC testing:

- Accuracy of Mass scan
- Detector repeatability
- Detector linearity
- Inventory of instruction manuals, components and serial numbers
- Installation verification
- System performance and robustness
- Data analysis verification

For more information about OneSource® multi-vendor IQ OQ PQ services, call (800) 762-4000 or e-mail us at onesource@perkinelmer.com.

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