

# **IQ / OQ / PQ**

Laboratory Instrument Validation  
Performed and Documented in GLP Format

**Biomatic Technologies**

**Put your company's laboratory  
ahead of the curve in FDA, EPA requirements**

## **OQ - Operational Qualification**

### **HPLC & 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 & 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 & 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

## **IQ - Installation Qualification**

- Inventory of instruction manuals, components and serial numbers
- Installation verification

## **PQ - Performance Qualification**

- System performance and robustness
- Data analysis verification

Is operational qualification / performance verification of an analytical instrument a necessary step for good laboratory practice or merely a regulatory burden? Laboratory equipment 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 affect on the baseline noise, which could results in false LOQ or LOD values.

IQ/OQ/PQ provides a simple, straight forward, 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 being performed.

### **Biomatic specialties**

- Reconditioned Lab Equipment
  - Service & Maintenance of Lab Equipment
    - Instrument IQ, OQ, PQ Validation
    - Asset Management & Inventory Control
    - Contract R & D and Consulting

**Biomatic Technologies Inc.**  
124 Grove St., Suite 225  
Franklin, MA 02038  
**Phone:** (877) 741-3600  
(Toll Free)  
(508) 541-3600  
**FAX:** (508) 541-2323  
**[www.biomatic.com](http://www.biomatic.com)**