

Peace of Mind

Facility, Process
& Instrument Compliance

When was the last time you checked the accuracy of your detector's wavelength? Does your GC, UV-Vis and FTIR spectrometer, or other lab equipment, conform to manufacturer's specifications?

Assessment

Development

Implementation

GMP/GLP
Compliance

Have you checked the accuracy of your incubator's temperature, CO₂, or humidity?

The Food and Drug Administration, United States Environmental Protection Agency, and other regulatory agencies require that analytical instrumentation used in laboratories for routine and day-to-day operations

comply with appropriate codes and approved design intentions, and that manufacturer's recommendations be considered.

Biomatic's IQ, OQ, PQ -- Installation Qualification, Operation Qualification and Performance Qualification -- verifies your system's performance for regulatory agencies and your clients. Biomatic provides regulatory compliance programs tailored to fit our clients' needs. We have a solid understanding of FDA/EPA regulations, including 21 CFR Part 11 and CROMERRR implementation, and our validations are thorough and well documented. Our protocols, rather than being generic, are customized based on our clients' needs, whether applied to a GMP/GLP regulated facility or a standard laboratory environment.

Being a multi-vendor service provider, we can validate all the equipment in your labs. In addition, we employ a universal template to simplify auditing, and use fully traceable NIST and vendor standards and equipment.

*Biomatic Technologies ... your
one-stop resource for IQ, OQ, PQ
validation and compliance.*



Technologies Inc.

'a total solutions company'

Boston, MA ■ Raleigh, NC ■ West Haven, CT

- IQ, OQ, PQ Validation & Regulatory Compliance
- Lab Equipment Service, Maintenance & Calibration
- Asset Management & Inventory Control Programs
- Contract Research & Method Development

Biomatic

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IQ OQ PQ

Facility, Process & Instrument Validation

21 CFR Part 11 & CROMERRR Compliance



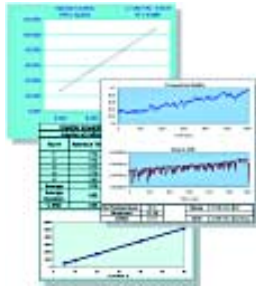
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Total Compliance Solutions

On-site IQ, OQ, PQ services are offered for a wide range of laboratory instruments, including: clean rooms, incubators, environmental chambers, freezers, HPLC, LC, FPLC, GC, GC-MS, UV-Vis/FTIR Spectrophotometers, CE, and various other equipment.



Biomatic Technologies has extensive hands-on experience in the design and operation of modern analytical laboratory equipment and offers fast turnaround and competitive prices. In addition, we provide 21 CFR Part 11 and CROMERRR compliance.

All tools and devices used for our validation program are NIST or vendor traceable. Thermocouples, data loggers, CO₂ and humidity sensors, tachometers, flow meters, light sensors and other tools are calibrated frequently and a certificate of calibration for each measuring device accompanies validation documentation.

For more information about our comprehensive IQ, OQ, PQ Validation & Regulatory Compliance services or our other programs, such as service and maintenance of laboratory equipment or asset management and inventory control programs, please contact Biomatic at (781) 341-1444 or visit our website at www.biomatic.com.

Providing IQ OQ PQ Validation For:

Clean Rooms

Environmental Chambers

HPLC & LC-MS

GC & GC-MS

CE & CEC

UV-Vis Spectrophotometer

FTIR Spectrophotometer

Standard Lab Equipment

Incubators

Freezers & Refrigerators

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Validation Benefits

- ▶ Complete maintenance, system history and inventory of components and documentation. Universal IQ, OQ, PQ template format.
- ▶ Verification of components' installation, including electrical, plumbing, and communication connections.
- ▶ Verification of components' functionality, operation, and conformity to manufacturer's specifications.
- ▶ Performance verification of facilities and laboratory equipment for routine R&D, QA/QC, EPA, FDA, and client-compliance operation.
- ▶ Pre-scheduled and annual verification program matched to your company's needs and budget.
- ▶ Cost effective and fast turnaround for your laboratory equipment IQ, OQ, PQ.
- ▶ Only NIST and factory traceable materials and equipment used.

Test Protocols

Operational Qualification

Clean Rooms

- Airborne particle count
- Microbial test culture
- Air flow velocity measurements
- Pressure differential monitoring
- Voltage leak test
- Light intensity measurements
- Temperature and humidity mapping

Incubator, Freezers, Refrigerators & Stability Chambers

- Includes temperature, CO₂ and humidity calibration
- Recovery mapping
- Load testing
- Short-term and long-term monitoring
- Light intensity measurements

HPLC & LC-MS

Systems
(HP/Agilent, Waters, PE, Varian, Shimadzu, Gilson, other brands)

- Temperature accuracy and stability of column heater/cooler
- Detector lamp intensity, wavelength accuracy, noise, and drift
- Pump flow rate accuracy and repeatability
- Injector precision
- Detector linearity and sample-to-sample carryover
- Injector linearity
- Gradient composition
- Mass accuracy and sensitivity

GC & GC-MS

Systems
(HP/Agilent, Varian, other brands)

- Temperature accuracy, stability, and uniformity of column oven
- Detector (FID, NPD, ECD, TCD, MS) temperature accuracy, noise, and drift
- Gas flow rate accuracy and split flow ratio (air, hydrogen, nitrogen, helium, argon/methane)

Installation Qualification

- Inventory of instruction manuals and components
- Installation verification

Performance Qualification

- Data analysis verification
- Only NIST and factory traceable materials and equipment used
- System performance and robustness