

**VALIDATION  
QUALIFICATION**

# What Makes Masy Validation Services Different

Masy Systems reputation is for performing validations accurately, quickly, efficiently and under a firm contract basis. Our focus includes environmental chamber validation services for the pharmaceutical and biotech industries. Masy's NVLAP accredited calibration lab provides calibration certificates noting NIST traceability for all instrumentation used to execute validations at your facility.

## Experience

Masy has nearly 25 years of validation history serving the Biotech and Pharmaceutical industry.

## Performance

We tune your chambers within optimal specifications BEFORE validating to ensure optimal results.

## Efficiency

Masy executes validations within tight deadlines without sacrificing quality or accuracy.



## Masy Performs Validations of:

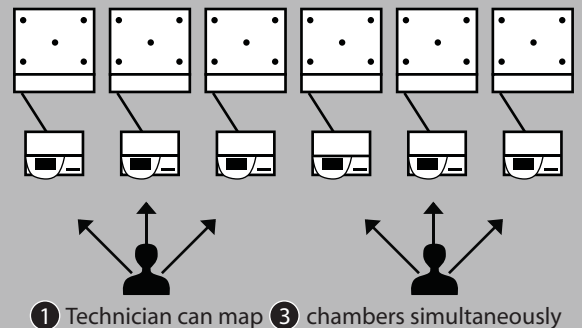
Autoclaves	Vessels
Sterilizers	Tanks
Refrigerators	Lyophilizers
Cold Rooms	Centrifuges
Storage Rooms	Fermentors
Warehouses	Incubators
Steam in Place (SIP)	Freezers
Ovens	Cryo Storage Freezers
Vacuum Ovens	Incubator Shakers
Process Ovens	Shipper Containers
Depyrogenation Ovens	Stability Chambers
Bioreactors	Stability Rooms

## Masy's unbeatable validation process

Masy Systems minimizes time spent at your facility by providing highly trained technicians who can perform multiple qualifications simultaneously. We allocate sufficient equipment for our staff to meet or beat your target timeframe.

Other companies offer a 1-to-1 approach which takes 4x more man hours when compared to our efficient approach...

**Saving you precious time and money.**



## Environmental Chamber Mapping

Based on your standard operating procedures (SOPs), Masy Systems performs precise thermal and humidity mapping, empty chamber thermal distribution and load penetration studies with in-depth analysis. We also calibrate your process controls traceable to NIST, and will create and execute your protocols. As a cost-saving measure we apply our experience with instrumentation and controls, recommending and implementing essential modifications to bring your equipment into compliance.



## Masy is now using the next evolution in validation systems

*DATATRACE<sup>®</sup> RF*



**Masy Owns the  
Largest Fleet of  
Validation Equipment  
in North America**

### Pre-Qualification

Masy will adjust the controls before we perform a validation. It's a little known fact that 60% of chambers need adjustments to reach optimal levels. By adjusting the controls first we can determine whether the chamber will pass or fail.

### IQ / OQ / PQ

Masy Systems creates protocol procedures or follows your Installation, Operational or Performance Qualification (IQ, OQ, PQ) protocols in accordance with FDA, GLP and cGMP guidelines.

- **IQ** - Establishes that the equipment is properly and safely installed
- **OQ** - Verifies that the chamber consistently meets operational specifications such as alarms and controls and empty chamber requirements
- **PQ** - Validates that the chamber consistently meets performance specifications under loaded conditions
- **"As Loaded"** - Verify that the chamber consistently meets operational specifications on an "in-use" chamber

### Report Completion & Quality Assurance Report Review

Masy will create a report which typically includes:

- Executed protocol
- Real time, hard copy and soft copy mapping data
- Calibration certificates for all mapping equipment used, noting NIST traceability
- Sensor Calibration reports
- Validation personnel training records
- Summary results

All Validation Qualification reports undergo a full in-depth quality assurance review. We follow documented work instructions to review the final report prior to release to our customers.

A **Validation Report Checklist** will be completed to provide evidence of the quality review. Masy will also retain a full digital copy of the filed document to assist you remotely with audit questions.

### Post Verification of Equipment

All certified validation and calibration equipment used at our customer's site is verified upon return to our NVLAP accredited calibration lab. This completes the physical execution of the qualifications that took place at your facility. No other validation company provides this level of confidence that their equipment is accurate, stable and repeatable.



CALIBRATION BIOPHARMA STORAGE EQUIPMENT RENTALS AND SALES  
VALIDATION

**MASY  
DOES  
MORE**