Qualification and Validation

Comprehensive IQ, OQ and PQ Validation Services to fit your needs

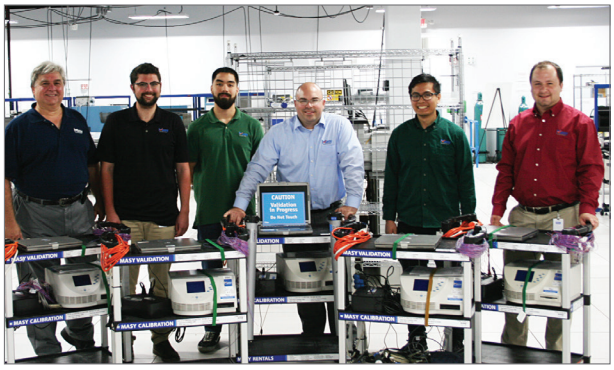
- ✓ Autoclaves & Sterilizers
- ✓ Controlled Temperature Units
- ✓ Steam Quality Testing
- ✓ Steam-in-Place
- ✓ Warehouse Mapping

Masy BioServices

Raising the Bar for Excellence

ISO 9001-2015 CERTIFIED QUALITY MANAGEMENT SYSTEM

Your trusted partner for qualification excellence

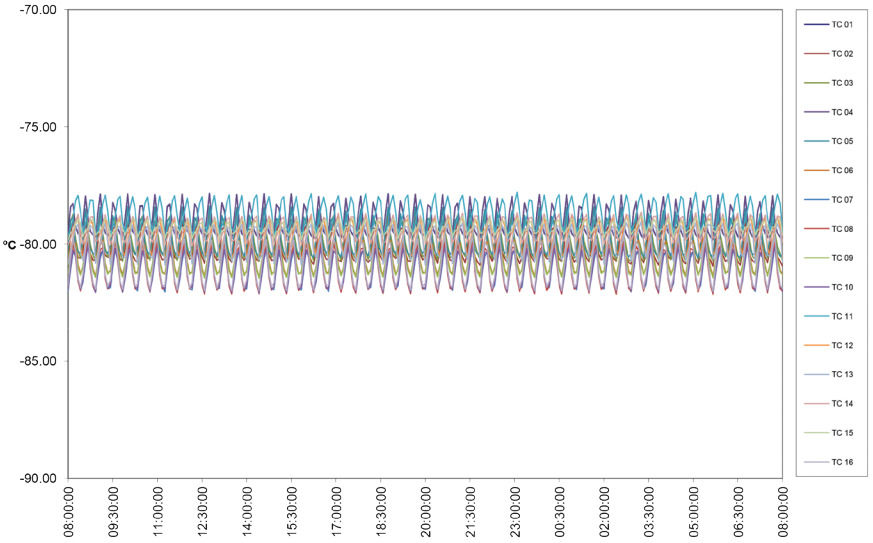


Masy's qualification and validation testing provides documented evidence that equipment is installed correctly, operates accurately, and performs reliably. The Masy validation team executes validation projects throughout the country and abroad which contributes to their diverse experience.

For over 30 years Masy has qualified tens of thousands of environmental chambers and other laboratory equipment of all makes, models, capacities, and conditions. We have the experience to serve your validation needs.

Masy BioServices offers comprehensive qualification and validation services

- ✓ Writing installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) protocols
- ✓ Executing your approved validation protocols
- ✓ A thorough quality review of the final documentation

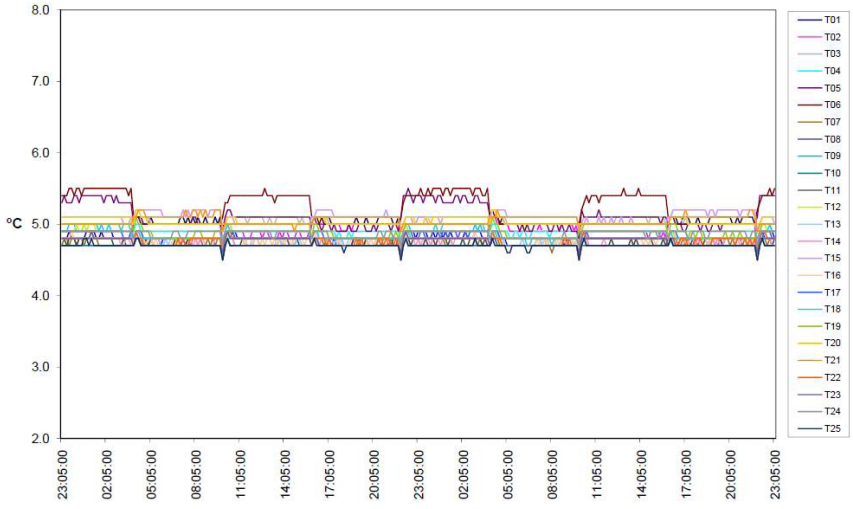


24 hour -80°C freezer study, using 16 sensors

Results you can count on. Reports you can trust.

Masy's validation reports typically include:

- ✓ Executed protocols
- ✓ Real-time, hard copy, and soft copy mapping data
- ✓ Easy-to-read graphical data
- ✓ NIST traceable calibration certificates for all validation equipment used
- ✓ Sensor calibration reports
- ✓ Complete audit trail
- ✓ Validation personnel résumés & training records
- ✓ Summary results
- ✓ Electronic backup files for all studies



48 hour refrigeration study using 25 sensors

The Correct Qualification Protocol for Your Specific Requirements

Masy BioServices performs precise qualification based on your approved standard operating procedures (SOPs). We can follow your Installation, Operational, and Performance Qualification (IQ / OQ / PQ) protocols, or we will work with you to create a custom protocol procedure in accordance with US Food and Drug Administration guidelines and current Good Manufacturing Practices (cGMP).

Masy is also well-versed with the American Society for Testing and Materials (ASTM) E2500, *Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment*, and can develop a risk-based approach to your qualification projects.

Pre-Qualification Services Improve Efficiency and Cost-Effectiveness

As a cost-saving measure we apply our experience with instrumentation and controls, recommending and implementing essential modifications to bring your equipment into compliance. Over time, nearly all equipment will require tuning to maintain optimal performance. Masy BioServices can assess your equipment's performance before validation begins and tune the controls for optimal performance. Through pre-qualification efforts, we can determine if the equipment will likely pass or fail validation – helping you make the best decision before you spend time and money on further testing.

Comprehensive Scope of Qualification & Validation

Steam-in-Place

- ✓ Bioreactors
- ✓ Fermentors
- ✓ Tanks
- ✓ Vessels

Equipment

- ✓ Autoclaves
- ✓ Centrifuges
- ✓ Data Aquisition Systems
- ✓ Depyrogenation Ovens
- ✓ Environmental Monitoring Systems
- ✓ Lyophilizers
- ✓ Process Control Systems
- ✓ Shipper/Transportation Studies
- ✓ Sterilizers
- ✓ Stirrers
- ✓ Steam Quality Testing
- ✓ Vacuum Ovens

Controlled Temperature Units

- ✓ Controlled Rate Freezers
- ✓ Cryogenic Storage Units
- ✓ Environmental Chambers
- ✓ Freezers
- ✓ Incubators
- ✓ LN_2 Chambers
- ✓ Photostability Chambers
- ✓ Ramping Chambers
- ✓ Refrigerators
- ✓ Room Mapping
- ✓ Stability Chambers
- ✓ Warehouses

Post-Qualification Verification of Validation Equipment Confirms Accuracy

All certified validation and calibration equipment used at customer sites is verified upon return to our NVLAP accredited metrology laboratory. This completes the physical execution of the qualification that was performed at your facility. No other validation company provides this level of assurance that their testing equipment is accurate, stable, and repeatable.

Quick Delivery of a Quality-Checked Documentation Package

At the conclusion of your project, Masy will provide a clear, comprehensive validation report, confirming that your equipment is fit for use for your requirements. Our validation reports contain all the necessary data for you to have confidence in your equipment. Each report is independently reviewed by a credentialed quality professional, saving you time and money.

Fast Turnaround Time Keeps Your Operations On-Schedule

Masy understands that any equipment out of service can negatively impact your scheduling and capacity. With our fully-staffed in-house validation team and the largest fleet of validation equipment available, we can confidently meet or exceed your time frame requirements without sacrificing quality or accuracy. Masy's skilled professionals can perform multiple qualifications simultaneously using multiple datalogging systems, keeping your schedule on track.

Masy BioServices

Masy Capabilities

Our integrated suite of metrology, qualification, biorepository storage, continuous and preventive monitoring systems, and equipment rental and sales ensures the accuracy of our primary standards and measurement instrumentation, which verifies the functionality of laboratory equipment and environmental chambers, and provides secure storage of your samples and finished products.

Metrology & Calibration

NVLAP-accredited, NIST-traceable calibration of your primary reference standards and laboratory instruments with minimal measurement uncertainties

Qualification & Validation

Comprehensive IQ/OQ/PQ protocols for controlled temperature units, environmental chambers, warehouse mapping, sterilizers, autoclaves, lyophilizers, and more

cGMP Biorepository Storage

Secure, monitored off-site storage of temperature-sensitive samples and products, at conditions from 70°C to liquid-phase LN_2 (-196°C). Within those conditions, ICH stability storage and custom conditions can also be provided

Continuous Monitoring Systems

Reliable 24/7 environmental monitoring systems with 21 CFR Part 11 compliance meet GMP requirements for critical spaces, featuring excursion alerts and remote viewing and reporting.

Preventive Monitoring Systems

Monitoring the critical parameters of integrated systems to prevent unforeseen equipment failures before chamber or component failure or product loss

Equipment Rental and Sales

Calibration and validation equipment for rental or purchase, including precision weight sets, conductivity standards, validators, dataloggers, thermocouples, sensors, Fluke products, and gaskets and clamps

ISO 17025 Accredited
NVLAP® CALIBRATION
NVLAP LAB CODE 200904-0
ilac-MRA

Masy BioServices is one of a select number of metrology laboratories in North America that meets the rigorous qualifications for National Voluntary Laboratory Accreditation Program (NVLAP) accreditation to ISO 17025. Our current NVLAP scope can be viewed at masy.com/accreditation.

ISO 9001-2015 CERTIFIED QUALITY MANAGEMENT SYSTEM

Masy BioServices is certified to ISO 9001 in recognition of our adherence to a robust quality management system.

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