Equipment Validation Documentation

Helmer Scientific offers several packages to help meet validation requirements.

Equipment Validation Guides

Installation Qualification (IQ)

- » Demonstrates that the instrument is properly installed to manufacturer's spectifications
- » Documentation provided in checklist format
- » Assists with the validation process

Operational Qualification (OQ)

- » Demonstrates that the installed equipment operates as intended
- » Documentation provided in checklist format
- » Assists with the validation process

Performance Qualification (PQ)

» Each guide provides an outline of suggested topics for Performance Qualification.

IQ/OQ Documentation CDs are Available for:

Freezers

Refrigerators

Platelet Agitators

Platelet Incubators

Plasma Thawing Systems

Ultra-Low Freezers

Equipment Validation Services also avaialbel from Helmer Scientific

Note: It is the responsibility of the end-user facility or their designee to complete the equipment validation.

Temperature Validation Package

The temperature validation package certifies the temperature performance of a unit. A multiple point temperature recorder maps the temperature inside the chamber.

- » Documentation of the chamber temperature
- » Temperature Validation Certificate
- » Certificate of Calibration for the test instrument

Temperature Validation Packages are Available for:

Freezers

Refrigerators

Platelet Incubators

Ultra-Low Freezers

Note: Temperature mapping is performed at the factory and must be ordered at the time the unit is purchased.

Certificate of Calibration

The Calibration Certificate validates that the monitoring system was calibrated to a National Institute of Standards and Technology (NIST) traceable thermometer prior to shipment from Helmer.

- » Certificate for monitoring system
- » Certificate for measuring device used to calibrate monitoring system

Certificate of Calibration is Available for:

Freezers

Refrigerators

Platelet Incubators

Ultra-Low Freezers



