

Validation Services



SEAMLESS INTEGRATION OF VALIDATION & TECHNICAL SUPPORT

ULTRA LOW FREEZERS
CRYOGENIC FREEZERS
PHARMACEUTICAL REFRIGERATORS
INCUBATORS
AUTOCLAVES



COMPLETE VALIDATION & QUALIFICATION SERVICES
(TURN KEY SOLUTIONS)

Validation & Qualification Solutions for laboratory equipment

SANYO is a vertical component manufacturer that can provide turn-key solutions for validation and qualification in accordance with all current GMPs, GLPs, GCPs, 21 CFR Part 11, PAT, ISO and specific customer requirements and applications. Because many of our key component parts are designed and built by SANYO, we offer the most precise and in-depth validation resources specific to SANYO laboratory products. Whatever your validation needs are, SANYO provides comprehensive expertise in laboratory equipment to meet your exact compliance needs. SANYO validation systems employ advanced technology coupled with the latest trends to insure compliance with accurate and time efficient completion.

- IQ / OQ / PQ
- Factory acceptance testing
- Qualification of critical utilities
- NIST traceable calibration
- Customized validation protocols
- Onsite protocol execution
- Commissioning of equipment
- Sanyo warranty service coverage

innovation
performance
reliability
support

validation

VALIDATION

As a leader in commercial, refrigeration, energy and environmental products, SANYO offers a robust source of proven technologies and technical services deployed throughout a range of biomedical and medical research products.

Pioneering developments in consumer and industrial products are applied to all SANYO products through the development model of Vertical Component Integration™. Because many of our key component parts are designed and built by SANYO, we offer only the most precise and in-depth validation resources specific to SANYO laboratory products.

Detailed Validation Support Package

Sanyo also offers detailed protocols including all required specifications manuals and support documents. This package will assist your validation team in the qualification process, greatly reducing the time required to complete the entire validation.

Sanyo validation systems are calibrated and maintained to the highest quality standards, while providing and retaining detailed records for all tested equipment.

As the manufacturer we are the most knowledgeable on our equipment. We offer validation services for Sanyo equipment and a total solution in fulfilling other regulatory requirement.

VALIDATION SOLUTIONS

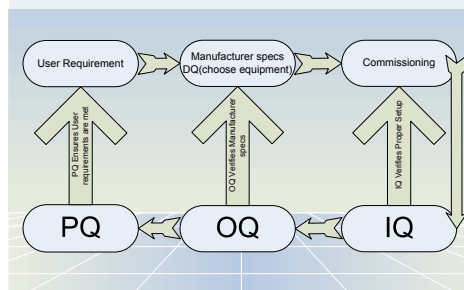
Turn Key Solutions available for:

- Ultra low freezers
- Cryogenic freezers
- Pharmaceutical refrigerators
- Incubators
- Autoclaves

Sanyo can assist throughout the entire process from helping you to choose your equipment through the extended warranty and service contract options to keep your equipment running. We help you match the appropriate equipment to your requirements (DQ) as well as arranging inside delivery and setup (commissioning) of the equipment.

IQ / OQ / PQ

In addition, Sanyo can perform the onsite qualification of your equipment (IQ/OQ/PQ); IQ documents the proper installation of the equipment, PQ documents proper operation of the equipment as specified by Sanyo or other manufacturers, and PQ documents proper performance of the equipment as you will use it.



FACTORY ACCEPTANCE

We offer in depth factory acceptance testing covering alarms as well as temperature/CO2 stability and recovery. This service can also be customized to your SOPs.

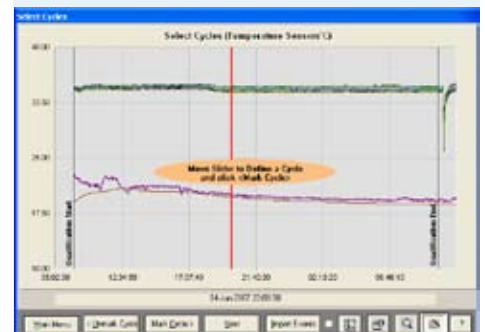
THERMAL VALIDATION

Sanyo provides a thermal validation solution specifically designed to conform with new FDA data protection guidelines (21 CFR Part 11) and meet international and European cGMP requirements for inspection of pharmaceutical, biotechnology and medical device (EN285, EN554) manufacturing. Sanyo simplifies the entire validation process by reducing setup time and minimizing sensor handling, automating sensor calibration, systematically organizing study data and generating required regulatory reports.

Sanyo implements a wired process validation system designed around the measurement and reporting requirements of the most intensely regulated industries. Our system meets the standards for cGMP regulated industries for thermal validation and has broad regulatory compliance.

We offer a complete package of thermal management including simulations and measurement:

- Measurement of temperature profiles
- Data analysis
- System design





v a l i d a t i o n

SANYO VALIDATION SOLUTIONS

	In-House	Third party	Manufacturer
Equipment experience	Broad based	Broad based	Most Sanyo specific experience
Up to date technical info	General knowledge	General knowledge	Direct updates
Unexpected service issues	Must be certified	Must be certified	Immediate solutions
Time consuming	More prep. time	More prep. time	Most experience
Knowledge of Industry standards	Insufficient resources	Broad based	Best applicable knowledge

EQUIPMENT SETUP

In order to trace and keep intact accuracy and performances of your laboratory equipment a regular schedule of calibration and preventive maintenance is needed.

Our objective is to provide confidence that the tested equipment meets the performance and compliance requirements of our customers. The acceptance phase may also act as the final quality gateway, where any quality defects not previously detected may be uncovered.

Commissioning your equipment involves the following tasks:

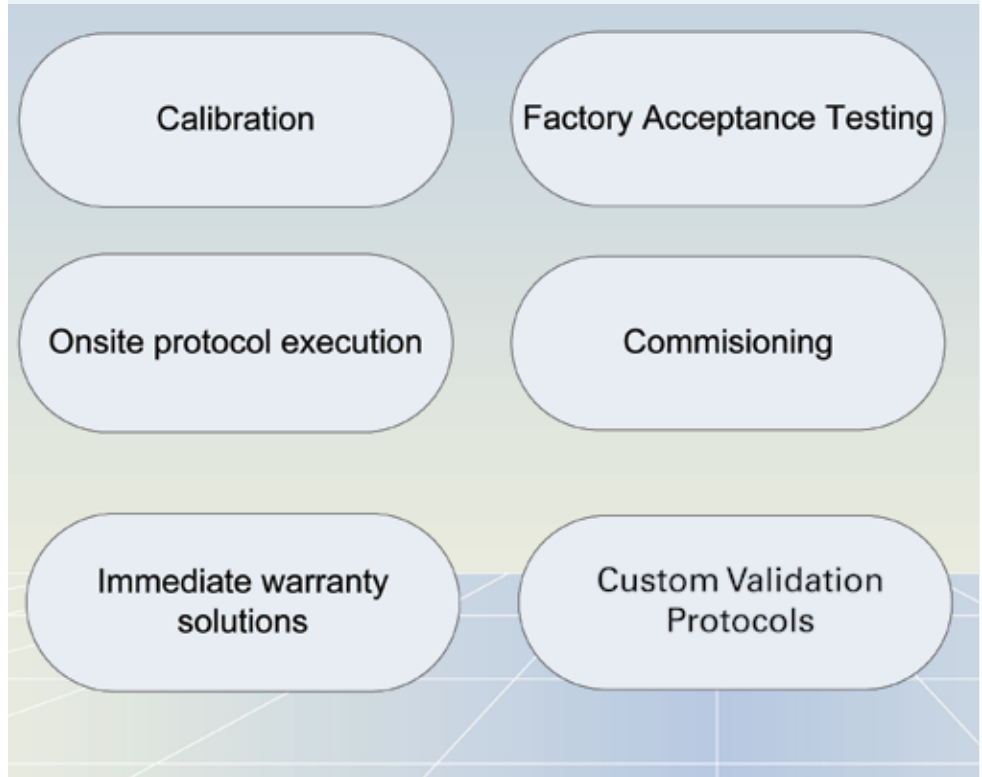
- Ensure unit meets all user requirements
- Setting up the equipment
- Installation of all necessary accessories
- Calibration
- Test operation of equipment

EQUIPMENT OPERATION & INSTALLMENT

In this area, we also offer support that is exactly tailored to your requirements:

- General handling of the unit
- Functions of the unit and its components
- Safety instructions for operation of the unit
- Aspects of starting, operation, applications and maintenance

SANYO EQUIPMENT SETUP



SANYO VALIDATION SERVICES BY MODEL

	Temp.	CO ₂	O ₂
Validation by Model	x		
MDF-150°C Freezers	x		
MDF-86°C Freezers	x		
MDF-30°C Freezers	x		
MBR Blood Bank Refrigerators	x		
MPR Pharmaceutical Refrigerators	x		
SR-L Undercounter Series	x		
MIR Incubator Series	x	x	
MCO O ₂ /CO ₂ Incubators	x	x	x
MLS Top Loading Autoclaves	x		
MAC Benchtop Autoclaves	x		

Service

SERVICE SOLUTIONS

Seamless integration of technical and validation services. Any service issues discovered during the validation process can be quickly resolved. Our detailed protocols are prepared before final customer visit reducing on-site time and cost. We can help our customers develop all aspects of a validation master plan.

Sanyo's highly qualified engineers can help with detailed preparation and set up for customers to avoid delivery of equipment not meeting customers' exact needs.

EQUIPMENT SERVICE

Comprehensive Equipment Service

Sanyo's customer-driven biomedical service program that guarantees local attention from qualified Sanyo service representatives, whenever and wherever support is needed.

- New Unit Installation and Training
- Preventative Maintenance
- Warranty and Non-Warranty Repairs
- Calibration/Validation Services
- Refurbishment and Reconditioning
- Customized Service and Warranty Programs
- Loaner Units
- In-Stock Parts for Immediate Delivery

Prices and conditions may vary by market.

EXTENDED WARRANTY

Your Sanyo laboratory equipment is a major investment that you will want to protect for years to come. You store your life's work in your preservation equipment such as ultra low freezers and medical refrigerators, and chances are that you will own your unit past the initial warranty period. By extending your warranty you can avoid repair costs that are unexpected and unbudgeted.

The **Sanyo Connect Extended Warranty Program** takes the worry out of repairs. Eliminate out of pocket expenses.

- Determine the time period you want to extend your current warranty.
- Order at the time you place your purchase order for your Sanyo laboratory equipment.

Extended warranty includes:

- All mechanical, electrical & compressor components
- All labor charges

Sanyo laboratory equipment offers long lasting performance with state of the art innovative features, and now a long lasting extended warranty that covers against unexpected expenses for up to the first 5 years of ownership

Cost Effective • Avoid multiple service visits and extend the longevity of your purchase.

Comprehensive Coverage • Ensure years of dependable performance and reliability with a complete repair program for all defects from workmanship.

Exceptional Service • Our service specialists are factory-trained with several years of experience and committed to Sanyo's standard of excellence.

Peace of Mind • We offer a wide selection of extended warranty options to protect your valuable investment.

Valued Relationship • Our commitment to offering complete and long lasting solutions for your unique needs.

Satisfaction Guaranteed • At Sanyo we continue to meet the diverse requirements of our customers, and support programs that assure reliability & extend the life of your equipment.



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