

Molecular Spectroscopy Compliance



Complete compliance portfolio for molecular spectroscopy

Whether your measurements are subject to government regulation or your work requires regular verification of instrument performance, Thermo Fisher Scientific can provide a solution that's right for your company. Our portfolio approach allows you to select exactly what you need to achieve compliance for your Thermo Scientific spectrometer. This reduces your time and resource investment to commission it and keep it running properly.

ISO Certified Quality System

Product development and manufacturing sites are fully ISO 9001:2000 certified to give you confidence in the design and construction of the spectrometer and software package.

Complete System Qualification

Each package is tailored for specific techniques, instruments and accessories to shorten the qualification cycle and provide reliable checks for system performance.

Certified Installation

Factory trained and certified technicians and factory-supplied test data ensure fast, accurate and fully documented installation and qualification.

Custom Validation

Turn-key plans and documented procedures, executed by experts, reduces the hassle factor and time commitment of system validation.

Operator Training

On-site training and a full complement of supplemental courses offered at factory training centers ensure operators understand and execute proper system operation procedures.

21 CFR Part 11

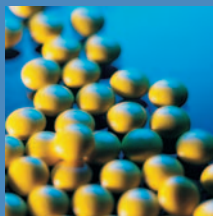
Software tools and the expertise to configure systems for complete compliance with FDA requirements for data security and traceability.

For the latest information on the Thermo Scientific compliance portfolio for Molecular Spectroscopy instruments, please visit <http://www.thermo.com/comply>.

Qualify Your Instrument in Hours and Commission it in Days

When you purchase a new spectroscopy instrument from Thermo Fisher Scientific, you collaborate with trained experts who will efficiently qualify it for operation and help you confidently validate the entire system – allowing you to commission it faster and get results sooner.

Thermo Fisher Scientific is the only company that offers a full-system approach to qualification for FT-IR, Near-IR, UV-Vis, and Raman spectroscopy equipment, and sampling accessories.



PHARMACEUTICAL

With the sheer number and scope of regulatory requirements faced by producers of drug products and devices, the extra burden of commissioning new systems and keeping them in compliance can put a strain on internal resources. Our knowledge of the regulations and complete offering of compliance products and services help provide cost-effective implementation, and confidence that the spectrometer is working as expected. This allows you to focus on the business of producing high quality, safe, and effective products.

Your Complete Compliance Portfolio fo

ISO Certified Quality System

Key to compliance in any industry is partnership with a trusted, quality conscious instrument supplier who has well-documented procedures and a proven quality system. At Thermo Fisher, we intensely focus on producing quality products and have achieved ISO 9001:2000 certification. You can be assured that your system will provide accurate and consistent results throughout its lifetime.



Complete System Qualification

Each system's qualification package provides all the tools needed to provide fully documented evidence that the system will produce reliable and accurate results. Our unique approach to qualification covers the instrument, software and accessories as a complete unit. What's more, many common procedures are used across instrument types and models which reduces the effort required to develop qualification processes and validation plans for sites with multiple Thermo Scientific instruments.

Certified Installation

Save valuable time by taking advantage of our factory trained and certified field service engineers to fully execute the specified qualification protocols at system installation. Within hours, you can have a fully qualified instrument with detailed and signed documentation demonstrating operational conformance to factory specifications. Our field service program also includes maintenance plans and event-based system re-qualification after instrument service or relocation.



CONSUMER PRODUCTS

The quality of end-user products is of key importance to the success of companies that market directly to consumers. In our highly competitive world, lack of compliance with a company's quality system can lead to poor product acceptance, which in turn can cause price erosion and lower profitability. The use of our system qualification packages, certification services and operator training provide the confidence that your results are accurate and help you comply with your internal quality system.



In today's world, assuring the safety and quality of food products makes regulatory compliance more than just an issue of meeting the requirements, it makes good business sense. At a minimum, food quality issues may lead to poor customer acceptance, or worse, legal actions and product recalls, all of which can be devastating to your business. Our ISO 9001 certified quality system ensures our spectrometers are of the highest quality. And our system qualification packages, certification services, and operator training courses provide the documentation and training to give you confidence in the results you obtain and help ensure compliance with quality standards.

Thermo Scientific Molecular Spectroscopy Applications



Custom Validation

Validation is a fact of life in highly regulated industries; regardless of what part of FDA 21 CFR your lab or business falls under. Whether it is Part 58 (cGLPs), Parts 210 and 211 (cGMPs), Part 820 (QSRs) or Part 11 (electronic records), our Spectroscopy Validation program can provide complete validation – from the overall plan and requirements traceability, to protocol design and execution. To reduce the “hassle factor” and minimize the time to get a new system validated, services are quoted as part of instrument purchase, and delivery is timed to coincide with instrument installation.

Operator Training

Training is an important requirement for system qualification and validation. Operators must know how to use the system's key functions to ensure they get the most out of their day-to-day work. On most systems, basic operation training is provided with the installation. We also offer a variety of supplemental training courses either onsite or at our factory training centers.



21 CFR Part 11 Compliance

With the appropriate software options, all of our molecular spectroscopy products can be configured to fully comply with the FDA 21 CFR Part 11 regulations for “closed systems.” What's more, all products use a common administration tool that allows managing user and instrument compliance policies from a single point of control, regardless of how many Thermo Scientific instruments are used in the organization. Additional features provide complete data file security and traceability, even when the instrument's application software is not running.



As a supplier to other businesses, you know your customers expect the highest quality materials or components. Regardless of the quality standards or regulations with which you must comply, the cost of poor quality can be high in terms of rejected lots, loss of purchasing contracts or worse, legal action. Our ISO 9001 certified quality system, system qualification packages and services, and operator training to help you comply with internal or external quality standards and give you confidence in the results from your spectrometer.

Molecular Spectroscopy Compliance Products at a Glance



	FT-IR	Raman	NIR	UV-Vis
Certified Quality System	ISO 9001:2000	ISO 9001:2000	ISO 9001:2000	ISO 9001:2000
System Qualification Packages	ValPro	ValPro	ValPro	UV Validator
System Qualification Services	Install Certification and Annual Recertification	Install Certification and Annual Recertification	Install Certification and Annual Recertification	Install Certification and Annual Recertification
Validation Consulting Services*	Spectroscopy Validation Program	Spectroscopy Validation Program	Spectroscopy Validation Program	Spectroscopy Validation Program
Operator Training Courses	Onsite & Thermo Scientific Training Institute	Onsite & Thermo Scientific Training Institute	Onsite & Thermo Scientific Training Institute	Onsite & Thermo Scientific Training Institute
21 CFR 11 Compliance Operator Software	OMNIC™ with OMNIC DS	OMNIC with OMNIC DS	RESULT™	VISION ^{security} ™
21 CFR 11 Compliance Administrator Software	Thermo Scientific Security Administrator	Thermo Scientific Security Administrator	Thermo Scientific Security Administrator	Thermo Scientific Security Administrator

* Validation Consulting Services are not available on all instruments and all geographical locations. Please contact your local Thermo Scientific representative for availability information.

Certified Quality System

- Thermo Fisher Scientific's Madison, WI (USA) and Cambridge (UK) facilities are fully ISO 9001:2000 certified.
- Sites are recertified by independent ISO auditing firms on a regular basis.

System Qualification Packages

- Documentation binder (DQ/IQ/OQ/PQ) with step-by-step IQ/OQ procedures, checklists, and signoff documents
- Procedures follow industry-standard methodologies such as ASTM, ISO, as well as US, European, and Japanese Pharmacopoeia
- Traceable reference materials, available in formats for either manual or automated testing procedures
- Factory-certified performance test data (on selected instruments)
- Software for performing and tracking OQ, PQ or performance verification test results (on selected instruments)

System Qualification Services

- System installation certification performed by factory trained and certified field service engineers
- Signed procedures, and/or qualification certificates assembled into the system qualification binder
- System recertification also available as part of annual maintenance plan and for one-time events such as system relocation

Validation Consulting Services

- Validation Plan (VP), User Requirements Specification (URS) and Functional Requirements Specification (FRS) documentation
- Requirements Traceability Matrix (RTM), Design Specification (Configuration & Infrastructure Requirements) and Risk Assessment / Gap Analysis
- Development and execution of Validation Protocols & Scripts
- Validation Summary Report

Operator Training Courses

- Basic operation onsite training during installation
- Supplemental training courses available onsite or at a factory training center

21 CFR 11 Compliance

Operator Software

- Application user names and passwords use Windows®-based network technology to maximize security and minimize set up and maintenance.
- File system protection and audit trail continuously active; even when instrument software is not running

Administrator Software

- Administration server tool provides single point of control to configure user and software policies for all instruments
- Full administrator control over file and folder protections, audit trails, user access policies, electronic signature meanings and events

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Australia +61 2 8844 9500
Austria +43 1 333 50340
Belgium +32 2 482 30 30
Canada +1 800 532 4752
China +86 10 5850 3588
Denmark +45 70 23 62 60

France +33 1 60 92 48 00
Germany +49 6103 408 1014
India +91 22 6742 9434
Italy +39 02 950 591
Japan +81 45 453 9100
Latin America +1 608 276 5659

Netherlands +31 76 587 98 88
South Africa +27 11 570 1840
Spain +34 91 657 4930
Sweden/Norway/Finland +46 8 556 468 00
Switzerland +41 61 48784 00

UK +44 1442 233555
USA +1 800 532 4752

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Calibration No. 0521
 Accreditation applies to wavelength and Absorbance filters used in the CVC.

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