



On-site computer system validation service

Trust your computerized system validation to the company that designs and supports your system

If your laboratory is required to validate your computerized system, an instrument qualification (IQ/OQ) is only the starting point. Global standards (e.g., ISO 17025 and ISO 15189) and country-specific requirements necessitate validation of electronic record-keeping systems to help ensure accuracy, reliability, consistent performance, and record retention. Our on-site validation services can help you meet these requirements and reduce your compliance risk. They also help identify each operator accessing the system as well as helping to ensure each system's ability to identify altered or invalid records.

Experienced support for compliance

Whether you have limited in-house expertise or you simply want a fixed-price plan to help you meet your requirements, our professionals—working closely with your staff—can assist you in getting into production faster while helping to control validation costs and manage your compliance risk.

Confirmation of conformity to user needs is obtained by comparing actual system performance to predetermined requirements. This is accomplished by executing test procedures and collecting objective evidence (computer-screen captures, printed reports, data files, etc.). The point is not to produce a mountain of documentation, but to demonstrate that validation activities were properly planned and that the tests were executed according to the plan.

- **Knowledge and experience**—No one knows Applied Biosystems™ instruments or software better than the company that designs, builds, and supports them. We have a long history of testing and validating our systems in complex laboratory environments.
- **Cost control**—Our on-site services offer the support you need to help meet your validation requirements at a predictable price. Once you choose your level of service, you will know the validation service cost. There are no hidden fees or variable costs.
- **Help reduce validation time**—Our expertise and best practices will help you validate your system quickly and efficiently while reducing laboratory start-up and downtime.

- **Project management**—Our project management team methodology helps manage risk, control costs, and efficiently validate your instrument systems.

What do you receive with our computer system validation service?

Working closely with your lab director (or designee), an assigned certified project manager (PM) will devise a plan for addressing your specific laboratory system requirements. Following the GAMP™ 5 methodology, the PM will first draft a validation plan (VP) and user requirement specification documents tailored to your specific needs and intended system uses. The PM will publish a system configuration specification to help ensure that the system is also configured to meet your requirements and intended use. A test plan and documents for software installation and operational qualification (IQ/OQ) and instrument performance verification (IPV) are generated to challenge your system's performance and help ensure that the system requirements are met. Our on-site execution of the IQ/OQ/IPV is conducted to provide documented evidence that the system is functioning according to your requirements. The results are summarized in a validation summary report and delivered in a comprehensive package.

On-site standard validation provides you documented evidence that validation was performed by our certified representatives. Whether this is required due to system changes or the initial validation of a preexisting system, validating your system is essential in order to capture system requirements and verify that those requirements are met. Testing and validation include:

- Comprehensive computer system validation—user requirements and associated test cases to help ensure that electronic records are generated, maintained, and archived in an accurate, reliable, and secure manner
- Expedited delivery of documentation

Supported software

Computer system validation is available for the following Applied Biosystems instrument software packages:

- SDS Enterprise Edition 2.x Software for 7900HT Fast Real-Time PCR Systems
- SDS v1.4 21 CFR Part 11 Module Software for 7500 and 7500 Fast Real-Time PCR Systems
- SDS v1.5 21 CFR Part 11 Module Software for 7500 Fast Real-Time Systems
- ViiA™ 7 Real-Time PCR System v1.x Software
- MDC v3.x Software for 3500xL Genetic Analyzers
- 21 CFR Part 11 Software Module for QuantStudio™ systems
- Customized software packages available upon request

Features

- Multiday, full-service delivery by experienced and trained professionals
- Library of traceable documents, test cases, support evidence, and a final report to document your computer system validation
- Helps support global compliance requirements (e.g., ISO 17025 and ISO 15189)
- Specifications defined to test high-risk system functions according to GAMP 5

Deliverables

- Validation plan
- Risk assessment for the system
- User requirements specification (URS)
- System configuration specification
- Test plan
- Installation qualification (IQ) testing and results
- Operational qualification (OQ) testing and results
- Instrument Performance Verification (IPV) testing and results
- (Optional) assessment for compliance with electronic records and signatures
- Validation traceability matrix
- Quality assurance review
- Validation summary report
- Review of standard operating procedures (SOPs)
- Technical support

Prerequisites

- Recently qualified or requalified instrument (hardware IQ/OQ or OQ/IPV)
- SOPs as related to the lab system

Our validation approach

Flexible data acquisition, fast data processing, and record retention

If you are printing, approving, and storing paper documents and maintaining your electronic records, some requirements include validation of the integrity of your electronic records.

We offer software that can help you demonstrate compliance with requirements such as ISO 15189 and ISO 17025. In order to validate your computerized laboratory system in accordance with requirements, it is necessary to place controls in the system. Controls can be of two types: procedural and technical. Procedural controls are processes that are documented, approved, and enforced typically through SOPs. Technical controls are enforced through hardware and software. They help reduce human effort through automation, thereby reducing the incidence of human error. We offer dedicated software packages to help you control security and access, and to implement use of electronic signatures.

Not all software packages are created equal. Contact your sales representative if you are unsure about your software package.

The right choice for your validation services

Whether you choose on-site validation or another option within our portfolio of compliance services, Thermo Fisher Scientific is the right choice to help reduce your validation time, control your validation cost, and help reduce your compliance risk.

Flexible pricing plans

To help you control validation costs, we offer cost savings on multisystem engagements for on-site validation.

If you require further customization for your validation process or a broader scope of validation services, please contact us for more information.

Ordering information

Description	Cat. No.
7900HT Real-Time PCR System, Enterprise Computer System Validation Service	CON00035
ViiA 7 Real-Time PCR System, Computer System Validation Service	CON00045
7500 and 7500 Fast Real-Time PCR Systems, Computer System Validation Service	CON00046
3500 series genetic analyzers, Computer System Validation Service	CON00036
7500 and 7500 Fast Computer System Validation Service QST	CON00046QST
QuantStudio real-time PCR systems, Computer System Validation Service	CON00048

For more information on our computer system validation service, contact your sales or service representative or email complianceservices@thermofisher.com

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