Confidence in compliance with Thermo Fisher services

FAQ guide for biopharma customers

Thermo Fisher Scientific provides a comprehensive suite of qualification and consulting services to help biopharma laboratories maintain Current Good Manufacturing Practice (CGMP) compliance, strengthen data integrity, and enable reliable instrument and system performance. These frequently asked questions (FAQs) highlight how our services support your workflows and regulatory needs, helping you quickly understand the value and benefits we offer.

Q: What is a computer system validation (CSV)?

A: CSVs are an industry process that enables **data accuracy, reliability, consistent intended performance, and the ability to detect invalid or altered records.** This is a critical requirement of electronic record compliance.

Q: What is the purpose of Thermo Fisher Scientific CSV consulting services?

A: CSV consulting services help enable pharmaceutical laboratories with preparing standardized validation documentation for Thermo Fisher instruments and software used in regulated environments. The service supports compliant installation, configuration, testing, and use of the computerized system while utilizing proven manufacturer templates.

Q: What are SAE features?

A: Applied Biosystems™ SAE Administrator Console Software enables connecting client software to enforce user security policies, role-based access control, auditing, and e-signatures. These features regulate permissions within Thermo Fisher software applications.

- **User security policies**—authenticate user access based on password policies required by the system administrator; a default system administrator user account is provided with the ability to manage additional user accounts
- **Role-based access control**—controls user functional access to the client software based on an admin-defined role
- **Auditing**—tracks auditable events performed by users in the client software and changes to the SAE settings; the software supports silent or prompt audit modes and generates system audit reports
- **E-signatures**—prompts and capture e-signatures as an indicator of specified meaning-selective functions in the client software; system administrators can configure e-signature policies for selective functions
  - i.e., there are four types of e-signatures:
    1. Typewritten signature
    2. Scanned image signature
    3. Click-wrap signature “I Agee” or “Accept” button (Thermo Fisher SAE software features use this type of e-signature)
    4. Digitized signature by digital capture device

These SAE software feature functions help laboratories maintain appropriate control and integrity of electronic data within the Thermo Fisher software.

Q: What is the scope of Thermo Fisher CSV consulting services?

A: The CSV service is a **consulting solution** that guides customers through the development and execution of **12 validation documents** focused on the use of **security, audit, and e-signature (SAE) software features** to control instrument workflows.

The service is **limited to the validation of SAE functionality** and does **not** include validation of the entire computerized system, such as IT infrastructure, operating systems, network, backup/restore, or disaster recovery.

Q: How does Thermo Fisher approach risk analysis?

A: All CSV engagements follow a **risk-based methodology aligned with the GAMP 5 Guide for Validation of Computerized Systems**. This approach helps define appropriate scope, documentation, and testing activities based on system complexity and intended operation.

Complete service process and timeline

Q: What is the CSV service process and typical timeline?

A: CSV consulting services follow the standard process outlined at kickoff:

1. Project kickoff and service overview
2. Gathering of required system information through CSV questionnaires
3. Draft documentation generation and preparation
4. Delivery of standardized manufacturer CSV templates
5. Customer review and approval cycles of the CSV draft documents
6. Final document delivery and approval of the final documents
7. CSV protocol execution (on-site or remote)
8. Customer post approval and acceptance of the CSV executed documents and objective evidence
9. Project closure

Completed draft documents are prepared by Thermo Fisher specialists and then provided to customers for formal review within this same structure.

The typical model timeline for a full documentation cycle, including all customer internal processes for review, approval, and execution, is approximately 10 to 12 weeks. Actual customer project timelines may vary depending on customer skills, availability, review cycle requirements, and more.

What is a qualification?

Q: What is an instrument hardware qualification?

A: Installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) or instrument performance verification (IPV) services verify and document your instrument's ability to meet manufacturer specifications for performance. This is performed by a field service engineer (FSE).

- **IQ**—provides documented evidence and verification that the instrument has been delivered and installed according to manufacturer's specifications
- **OQ**—provides documented verification that the instrument subsystems are operating as designed; verifies that the functionality of an instrument meets the manufacturer's operational specifications
- **PQ or IPV**—provides documented verification that the instrument system can perform effectively and reproducibly within performance specifications; helps enable confidence in results by verifying that the accuracy and precision of an instrument is maintained
- **Requalifications (OQ, OQ/PQ, or OQ/IPV)**—provide documented verification that the instrument continues to operate as specified by the manufacturer; typically performed annually after an initial IQ, OQ, or PQ/IPV has been completed, or according to user's standard operating procedure (SOP) requirements

The IQ, OQ, PQ/IPV terminology is industry standard use and can be used in many circumstances. For Thermo Fisher, it is applied in both the instrument hardware and CSV services, but the scope is very different.

Q: What is a CSV IQ-OQ and PQ?

A: This is a completely different service compared to an instrument hardware qualification. This is performed by one of our highly skilled CSV specialists on-site or remote, depending on the customer.

- **IQ**—verifies the system's physical installation, including hardware, software, and environmental setup, against manufacturer specs and design documents
- **OQ**—tests the software's functionality under controlled conditions, helping ensure it meets operational requirements and performs accurately, reliably, and securely
- **PQ**—demonstrates the system consistently performs as intended in real-world, day-to-day scenarios, meeting user requirements in production environments

When does the CSV activity start?

Q: When can the CSV activities start after the purchase?

A: After customers purchase, FSEs install and qualify the hardware. Subsequently, it's highly recommended that field application scientists (FASs) coordinate training, helping ensure customers understand software features before initiating the CSV. The CSV technical project manager engages post-training to guide document development, approvals, and test execution phases of the validation.

Systems supported

Q: Which systems are supported by Thermo Fisher CSV services?

A: CSV consulting services are available for most Thermo Fisher–supplied instruments and their associated software platforms used in regulated environments. Supported systems include:

- Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System Software
- Applied Biosystems™ QuantStudio™ 6 Flex Real-Time PCR System Software
- Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR System Software
- Applied Biosystems™ QuantStudio™ 7 Pro Real-Time PCR System Software
- Applied Biosystems™ QuantStudio™ 12K Flex Real-Time PCR System Software
- Applied Biosystems™ QuantStudio™ Absolute Q™ Digital PCR System Software
- Applied Biosystems™ 7500 and 7500 Fast Instrument Software
- Applied Biosystems™ AccuSEQ™ Real-Time PCR Detection Software
- Applied Biosystems™ 3500 Genetic Analyzer Series Software
- Applied Biosystems™ SeqStudio™ Genetic Analyzer Series Software
- Applied Biosystems™ SeqStudio™ Flex Genetic Analyzer Series Software
- Applied Biosystems™ MicroSEQ™ ID Microbial Identification Software
- Invitrogen™ iBright™ System Software
- Invitrogen™ Attune™ NxT and CytPix Flow Cytometer Software

Additional systems may be available. For more information or to ask questions, please contact our CSV team by emailing csv-support@thermofisher.com.

Computer environment and IT responsibilities

Q: Are CSV engagements performed on networked systems?

A: Thermo Fisher CSV engagements are performed on standalone, isolated instrument computers to maintain stable and repeatable validation conditions. Do not apply IT, domain, networking, or security policies to computers prior to:

- Software installation
- Hardware qualification
- CSV
- Disaster recovery/backup imaging per customer SOP

Keeping the system in its manufacturer-supported configuration helps ensure that validation testing and documentation can be completed successfully.

After CSV activities are completed and the customer has taken a full system image of the validated state according to internal SOPs, customers may choose to network the system. The full true system image provides the validated point of recovery for future updates.

Customer-supplied computer environment and IT requirements

Q: Can Thermo Fisher perform a CSV on a customer-supplied computer and/or image?

A: Unfortunately, Thermo Fisher cannot support a CSV engagement to be performed on customer-supplied computers and/or images even if they meet our minimum software requirements. A customer CSV service as provided by Thermo Fisher is based on internal software, IT specifications, and conditions and is validated to internal software quality standards. Thermo Fisher cannot guarantee any software feature or software functional performance if there is a deviation from the internally validated specifications by using a customer-supplied computer environment.

Ownership and responsibilities

Q: Who owns the CSV documentation?

A: All CSV documentation produced through the engagement is **customer owned**. Thermo Fisher facilitates the validation process with standardized templates, and our specialists help pharmaceutical laboratories complete their internal computerized system validation records.

Q: Who approves the final validation documentation?

A: Customers determine how the documents are reviewed and approved according to their own internal procedures. Thermo Fisher provides completed documentation for customer evaluation and acceptance.

Q: Does a CSV include validation of laboratory methods?

A: No. Thermo Fisher CSV consulting validates the SAE software feature configuration and operation of the **instrument software and computerized instrument system**. Validation of laboratory methods, scientific processes, and internal IT procedures remain within the customer's responsibilities.

Q: How are discrepancies handled during a CSV project?

A: Any unexpected results found during documentation or qualification activities are formally documented, reviewed, corrected as appropriate, and rechecked using good documentation practices to help ensure a clear and organized validation package. Most discrepancies can be corrected and documented by a comment or note within the document and section. For larger issues, there is an exception process that can be used to support the formal quality management system (QMS) needs.

Q: Is CSV documentation provided in local languages?

A: All CSV documentation is provided in English. Translation into local languages remains within the customer's responsibilities.

Q: Who provides project coordination?

A: All engagements are coordinated by the Thermo Fisher CSV technical project manager, who help facilitate:

- Stakeholder communications
- Document exchanges
- Reviews and revisions
- Validation logistics
- Summary reporting
- The formal project closure

Q: How do I begin a CSV engagement?

A: Contact your Thermo Fisher sales representative to confirm system eligibility and initiate quoting for the appropriate CSV consulting service tier.

Ready to begin your CSV with confidence?

Thermo Fisher CSV consulting services help enable pharmaceutical laboratories by providing standardized manufacturer templates, certified specialists, and coordinated project management. This allows customers to efficiently demonstrate compliant configuration, testing, and operation of Thermo Fisher instruments and software within their own QMSs.

Learn more at **thermofisher.com/csv**