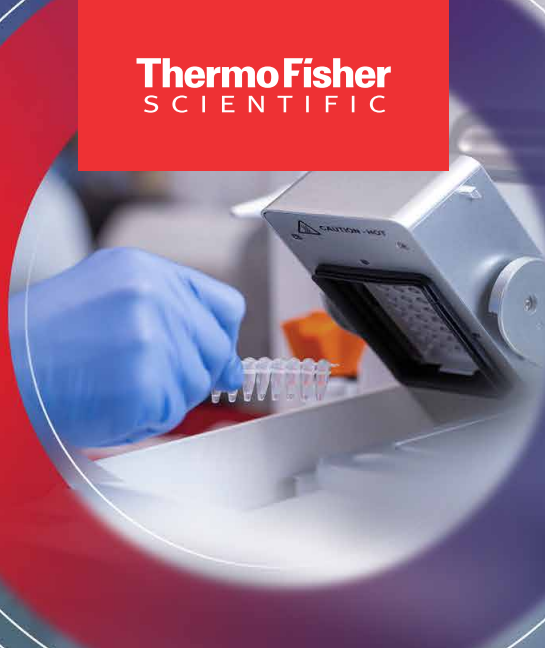
Services and support

Keep conquering disease. We've got your back.

Discover innovative support and instrument expertise to help you make history



You're gaining ground and advancing science with every step. It's a lot of pressure, but you've got the knowledge, and we're here to help you keep going—we believe in you. And it's why we support you with superior services, remote tools, training, and OEM expertise that we've spent over 40 years curating. By getting the most out of your Applied Biosystems™, Invitrogen™, and Ion Torrent™ instruments and applications, you can maintain your focus where it needs to be: **making a positive impact for generations to come**. Our solutions help address your needs, so you can keep conquering disease.

Essential needs for biopharma customers

Essential need 1: **Demonstrating manufacturing compliance**

Current Good Manufacturing Practice (cGMP) refers to the set of regulations enforced by the US Food and Drug Administration (FDA), and it includes establishing strong quality management systems, obtaining appropriate-quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories.

Our cGMP product offering comprises qualification services and a computer system validation consulting service. These help address the FDA's Code of Federal Regulations (CFR) in the following ways.

Qualification services (installation qualification (IQ), operational qualification (OQ), performance qualification (PQ), and instrument performance verification (IPV)) address the following:

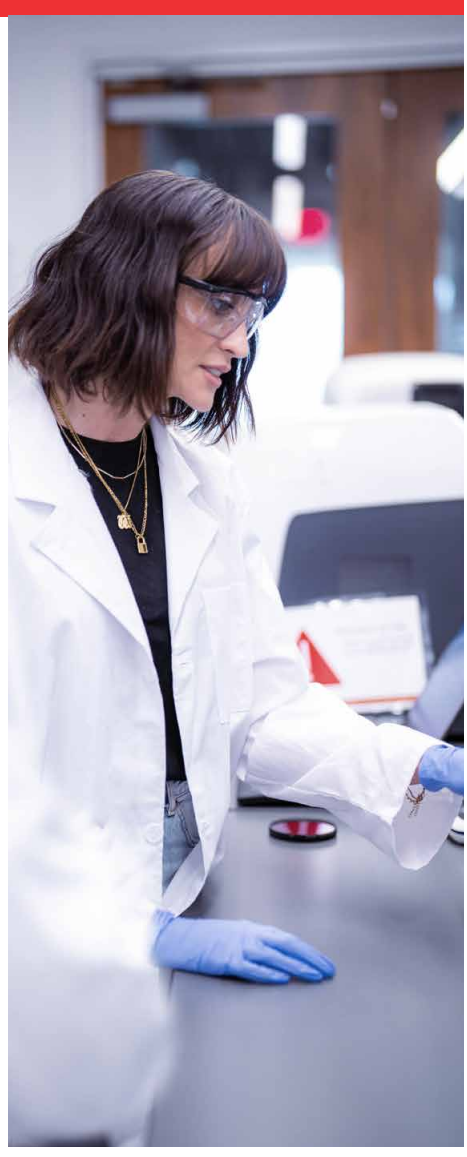
- **21 CFR Part 58**—good laboratory practice (GLP) for nonclinical labs
- **21 CFR Part 210 and 211**—good manufacturing practice (GMP) for human drugs
- **21 CFR Part 312**—good clinical practice (GCP) for investigational new drug applications
- **21 CFR Part 820**—quality system requirements (medical devices)
- **21 CFR Part 11**—electronic records and signatures
- Also applicable to International Organization for Standardization (ISO) standards, including: **ISO 9001, 13485, 14971, 17025, and 15189**

Explore more ›

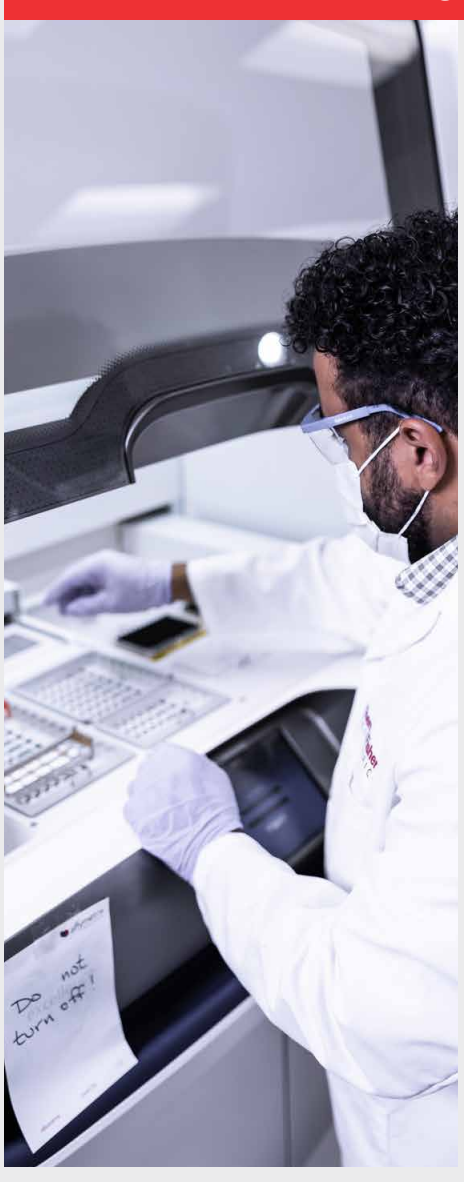
Computer system validation (CSV) addresses the following:

- **21 CFR Part 11**—electronic records and signatures

Explore more ›



Essential need 2: **Ensuring quality control and quality assurance**



Every minute counts when you are conquering disease, and you can't afford to compromise quality on your way to results. Our instrument service plans can help ensure reliability and consistency in your work by providing fast on-site response* and issue resolution.

Your choice of instrument service plans includes the following:

If your repairs need to be done on-site:

AB Assurance Plan—enjoy peace of mind with our most popular instrument service plan. Experience up to 2x faster response times and issue resolution, built-in planned maintenance, and less guesswork when all standard repair costs are included.

Explore more ›

If you are covering a thermal cycler or small benchtop instrument that can go off-site for service:

AB Repair Center Plans—receive your repaired instrument back within 7 to 10 days** and maintain productivity with one of our loaner instruments while you wait for your repair.

Explore more ›

If your instrument is in a validated workflow, or if you need to document that it is performing within manufacturer specifications:

Qualification services (IQ/OQ/PQ or IPV)—meet regulatory and industry standards with our manufacturer-trained and -certified field service engineers. These services are contract service offering enhancements, additions to existing contracts, and part of quality assurance (QA)/quality control (QC) plans.

Explore more ›

* Fast on-site response is subject to regional availability.
** Availability limited in some geographic areas.

Essential need 3: **Ensuring product sterility and purity**

Product sterility and purity are critically important when it comes to the manufacturing phase. The Applied Biosystems™ MicroSEQ™ Microbial Identification System is used for environmental monitoring, contamination investigation, root cause analysis, raw materials testing, and microbial identification in small-molecule and biopharmaceutical manufacturing and service laboratories. Our CSV consulting service helps strengthen the MicroSEQ system.

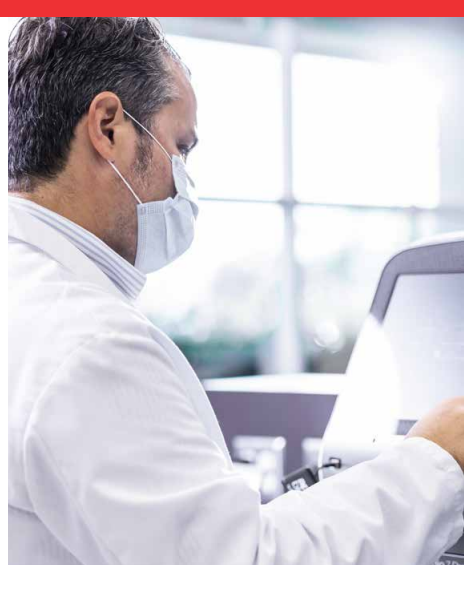
If your computer systems need to meet FDA 21 CFR Part 11.10(a), GAMP 5, or EU Annex 11 data requirements for compliance:

CSV—help save time and control costs when you engage our specialists to guide you through the validation process documenting your data security, auditing, and e-signature software features.

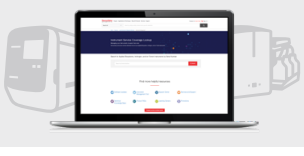
Explore more ›

Download the Good Automated Manufacturing Practice (GAMP™) 5 guide for validation of automated systems in pharmaceutical manufacture.

Download the white paper ›



Our services advantage



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