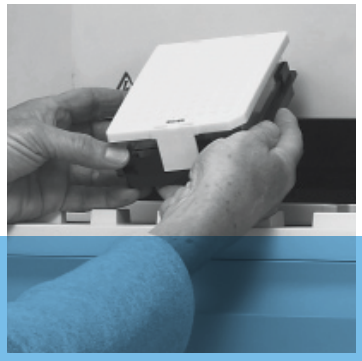
# Qualification Service

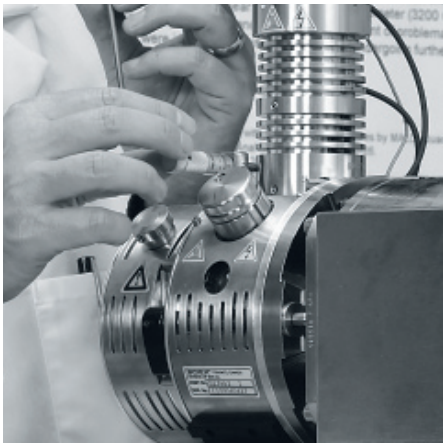
Trust your instrument verification to the company that designs your systems.



# When you face the challenge of regulatory compliance, you need experienced support at your side.

In regulated industries, compliance with government and international standards requires documented verification that your instruments are installed and functioning according to their operational specifications. The process can be complex, time-consuming, and costly.

No one understands your Applied Biosystems instruments better than the people who design, develop, and support them. When you use our Qualification Service, Applied Biosystems trained and certified engineers will help you through your Installation Qualification and Operation Qualification (IQOQ) or your Instrument Performance Verification (IPV) as part of your overall system validation.



# What is the Qualification Service?

IQOQ Service verifies and records that your Applied Biosystems instrument is, at the time of testing, initially installed and operating in accordance with Applied Biosystems specifications. It may also be used to verify operation of a system that has been moved or reinstalled.

IPV Service re-verifies that your previously qualified Applied Biosystems instrument is, at the time of testing, operating according to Applied Biosystems specifications. IPV is performed after an instrument has undergone service, repair, or maintenance that is critical to its performance, or when the instrument has site requirements for a scheduled operational qualification.

Both services will provide you with a comprehensive package that includes Verification Protocol Documentation and all data collected during the execution of the protocol.

## Why Choose Applied Biosystems for Your Qualification Needs?

**Benefits of our Qualification Service include:**

### Experience

Applied Biosystems trained and certified engineers have unmatched experience and knowledge in our instruments and systems. In addition, our certified engineers receive technical support from our factory and field experts.

### Speed

Our experienced, qualified engineers are available and ready to perform verification immediately after installation. Depending on the instrument or system, the service takes only one or two days, reducing laboratory start-up time or downtime after repairs or scheduled maintenance.

### Cost-control

When you use our Qualification Service, we help you reduce your in-house verification time and cost, and reduce your need for in-house technical expertise.

### Peace of mind

Regulatory compliance can be complex, time-consuming, and costly. We can help you through the IQOQ and IPV processes.

# Where Does our Qualification Service fit within a Validation Process?

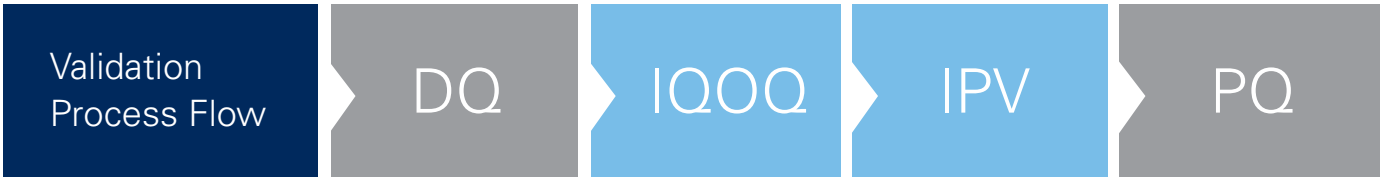
IQOQ and IPV are an integral part of a validation process for compliance with Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), ISO-9000, and other standards.

Installation Qualification (IQ) verifies that, at the time of testing, your system was received as ordered and installed according to Applied Biosystems specifications. It also establishes that your laboratory environment is suitable for operation of the system.

Operational Qualification (OQ) verifies that, at the time of testing, your system functions according to Applied Biosystems operational specifications in your laboratory environment.

IPV Service re-verifies that, at the time of testing, your previously qualified Applied Biosystems instrument is operating according to Applied Biosystems specifications.

Applied Biosystems provides IQOQ and IPV Services




In addition to IQOQ and IPV, validation may require Design Qualification (DQ; verification that your system will meet your user requirements) and Performance Qualification (PQ; verification that your system consistently performs according to its specifications under all anticipated conditions).

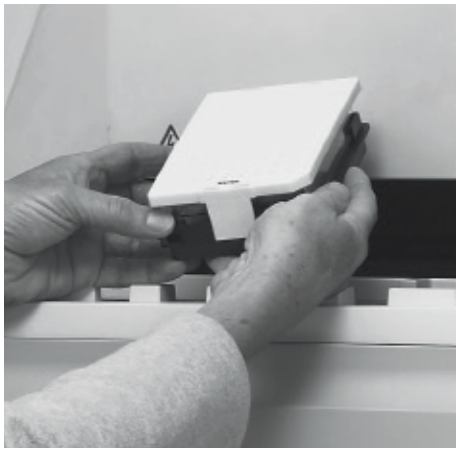
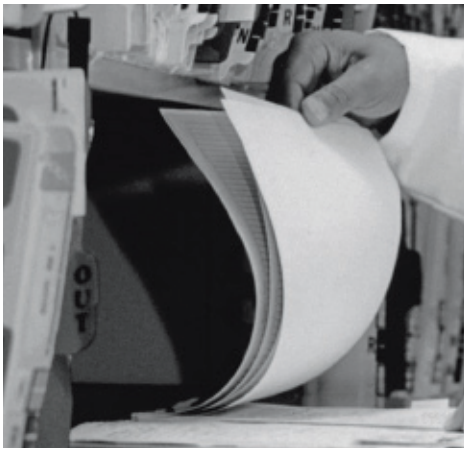
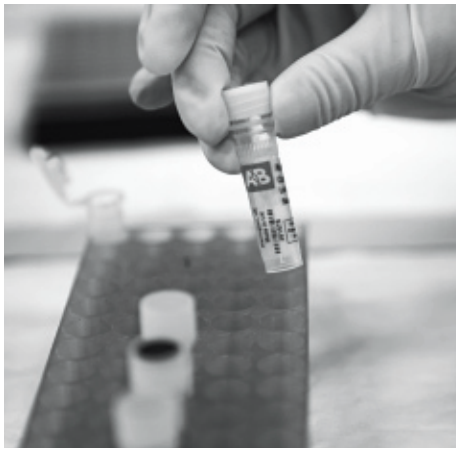
Applied Biosystems offers IQOQ and IPV services only. Supporting documentation assists you within the DQ process. Validation, DQ, PQ, and all other types of use or method testing are not currently offered.

# What does our Qualification Service Provide?

**A Completed IQOQ or IPV Service Package** that is reviewed and approved by both Applied Biosystems and your organization.

**A Qualified Instrument** demonstrated to be operating, at the time of testing, according to Applied Biosystems specifications.

## What Does our Qualification Service Include?

| | | |
|---|---|---|
| Performance of the Verification Protocol | Copies of Procedures Used During Verification | Reagents Needed to Perform the Tests Within the Protocol (for genomic applications only) |
|  |  |  |

# Who Uses our Qualification Service?

At Applied Biosystems, we develop tools that our customers use to make scientific discoveries, create new medicines, and conduct standardized testing. We've worked longest with the life science industry and research community, but today we also serve customers in the fields of human identification, biosecurity, and quality/safety testing.

Customers in all of these dynamic fields can benefit from our Qualification Service, especially those:

- Who develop products for regulated markets
- Who develop products that may eventually enter regulated markets
- Who want the peace of mind that their instruments are operating to Applied Biosystems specifications

| An IQOQ or IPV Report | Supporting Evidence | Approvals |
|---|---|---|
| Relevant Verification Data Sheets that include: Order, System Description and Identification, Utility Description, Customer-supplied Materials, Emissions and Immunity Compliance, Laboratory Environmental Operating Conditions, Operating Procedures, Cleaning Procedures, Training of Users, Software Identification and Documentation, Calibration and Maintenance, Normal Operation, Loss of Power, Program Back-up Archiving and Version Number, Filed Service Report. | Reporting Data, Software Validation Certificates, Engineer Training Certificates, etc. | Pre-execution, Final |

# Who better to trust with your verification needs than the company that designed, developed, and supports your systems?

Because IQOQ and IPV protocols test performance against product specifications, effective verification requires a thorough understanding of your system's detailed design and operation. Our service engineers are intimately familiar with our instruments. They use our proprietary protocols. They have the latest hardware and software updates for each instrument. They have all the specialized tools, reagents, and consumables at hand necessary to perform the verification. And they receive technical support from our factory and field experts. No third-party qualification service can match this combination of training, expertise, and experience.

For more information about our Qualification Service, please contact your local sales representative.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