

Instron Professional Services



For regulated industries such as medical device and pharmaceutical manufacturing, proper software and system validation is essential. Instron's IQOQ services help you meet **FDA 21 CFR Part 820** and **ISO 13485** requirements while ensuring your testing system is fully verified, audit-ready, and optimized for reliable performance.

WHY INSTRON FOR IQOQ VALIDATION?

- **IQOQ Directly from the Original Equipment Manufacturer:** Instron delivers proven validation backed by an expert team of over 300 factory-trained Field Service Engineers.
- **Reduce Validation Time with Expert Support:** Our team helps significantly reduce your validation workload, with some customers reporting cutting their validation time by up to 50%. This streamlined process gives you confidence that your system is installed correctly and performing exactly as intended.
- **Complete Peace of Mind:** Instron's IQOQ documentation packs are developed by product experts and delivered onsite by a factory-trained Field Service Engineer, saving valuable time and resources while ensuring your system is expertly installed, fully documented, and ready for validated performance.

WHAT SYSTEMS CAN INSTRON PERFORM IQOQ ON?

Instron offers IQOQ services for static, autoinjector, dynamic, and MT torsion (linear and biaxial) testing systems. IQOQ is recommended for all new installations, as well as for system relocations and upgrades.

INSTALLATION QUALIFICATION (IQ)

Installation Qualification (IQ) demonstrates that your Instron testing system and software are installed correctly, with all required components, documentation, and supporting materials in place for proper ongoing operation.

Throughout the process, Instron manuals are supplied and referenced to confirm that installation aligns with manufacturer specifications and that all operational prerequisites are met.

OPERATIONAL QUALIFICATION (OQ)

The Operational Qualification (OQ) process is designed to verify that the testing system operates as intended and is capable of consistently producing accurate, valid results.

A comprehensive OQ includes:

- Validation of system operation
- Functional checks of the software
- Confirmation that all calculations performed by the system are accurate and properly executed
- Verification of the transducer(s)*

SOFTWARE FUNCTIONALITY CHECK

The software functionality check evaluates the major components of the Instron software under validation to ensure all features operate as designed. Documented evidence, such as screenshots and saved software files, is provided for future reference.

This thorough documentation and manufacturer-supported process offers peace of mind during audits, knowing you can rely on Instron's expertise and comprehensive validation support.

CALCULATION VALIDATION

The Instron IQOQ package includes verification of customer-selected calculations to meet your specific testing needs. Sample data files are provided and replayed on your system, with software-generated results compared against independently derived expected values using methods such as Excel and hand calculations. For each calculation, a detailed data sheet is created and attached to the validation results.

With a dedicated team of validation experts performing these checks, you gain added peace of mind knowing your calculations are thoroughly reviewed, accurate, and audit-ready.

TRANSDUCER VERIFICATION

Transducers are verified in accordance with Instron's NVLAP accreditation under lab code 200301-0 to ISO/IEC 17025 standards.

Instron maintains the largest NIST-traceable commercial deadweight stack in North America, with a primary force standard capability of 130,000 lbf. This allows us to provide exceptional accuracy and some of the lowest measurement uncertainties in the calibration market.

***Please Note:** Transducer calibration services are purchased separately from the IQOQ validation package.

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