

Analytical Instrument & Laboratory Equipment Validation

Sequence, Inc. has extensive experience validating analytical instruments and laboratory equipment. Whether you are constructing a new laboratory, relocating an existing one, or simply purchasing a system to enhance your capabilities, Sequence is here to provide your validation consulting needs. Sequence has consultants with varying educational backgrounds including bioanalytical, chemistry, and engineering. With each validation effort, our consultants begin with an initial consideration of the technical complexity of the system, degree of customization, and intended use by our client. This allows us to implement an effective risk-based approach during the validation effort. Testing performed by Sequence consultants provides documented evidence that the system is installed properly, performs accurately, and produces reliable data.

With the explosion of technological advances in the life sciences industry, new analytical instruments seem to pop up every day. From automated microbial identification to Ultra Performance Liquid Chromatography, Sequence consultants have experience successfully executing validation efforts for most systems utilized in industry. Sequence has developed an effective approach to analytical instrument validation by combining current industry standards with our client's procedures to deliver validation projects that are completed on time, within budget, and with quality that stands up to any regulatory audit.

Laboratory equipment has also evolved with the advancement of modern day technology. The days of monitoring chamber parameters with chart recorders have been replaced with complex, real-time computer systems capable of trending, alarming, and data analysis. Sequence consultants have a proven track record of effectively validating the spectrum of temperature controlled units as well as other laboratory equipment such as robotic pipettors and air samplers. Sequence consultants are trained on the use of numerous test instruments and equipment utilized during validation testing such as Kaye Validator 2000 and Veriteq data loggers. Sequence also offers qualification templates and thermal mapping procedures to improve the effectiveness and efficiency of our client's laboratory equipment validation activities.

DELIVERABLES INCLUDE BUT ARE NOT LIMITED TO:

- Supplier Assessment
- Validation Plan
- Requirements and Functional Specification
- Risk Assessment
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Final Reports
- Traceability Matrix
- Validation Summary
- Change Control
- Periodic Review
- Auditing
- Decommissioning Protocol

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www.sequencevalidation.com



ANALYTICAL INSTRUMENT SYSTEMS VALIDATION EXPERIENCE:

- DNA Characterization Systems
- Microbial Detection & Identification Systems
- Microplate Readers
- Viable Cell Counters
- Microscope Camera Systems
- Real-Time PCR Systems
- Particle Counters
- Spectrophotometers
- SEC-MALLS
- TOC Analyzers
- Titrators
- Densitometers
- Atomic Absorption Systems
- HPLC
- UPLC
- GC
- LCMS
- Capillary Electrophoresis Systems
- FT-IR
- Fluorometers
- Nephelometers
- Cyanide Analyzers
- Gel Chip Analyzers
- Nephelometers
- Polarimeters
- Gel Chip Analyzers

LABORATORY EQUIPMENT SYSTEMS VALIDATION EXPERIENCE:

- Centrifuges
- Refrigerators
- Freezers
- Incubators
- Water Baths
- Autoclaves
- Isolators
- Robotic Pipettors
- Stability Chambers
- Ovens
- Vessels
- Tanks
- Cold Rooms

PROJECT EXAMPLES OF SEQUENCE, INC.:

- Retrospective Legacy Validation Initiative (including an initial gap analysis)
- Prospective / Concurrent Validation of an Individual System
- Prospective Validation of Laboratory Start-up
- Laboratory Relocation
- New Product / Product Changeover Testing Enhancements
- Laboratory Decommissioning
- Electronic Data Retention/Archival Initiative

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