



Equipment, Utility, & Process Validation

Sequence, Inc. is capable of meeting your companies ever changing equipment, utilities, and process validation needs. Whether you are adding a new CIP skid or constructing a new facility, Sequence consultants are available to lead your validation effort. Our employees' wealth of knowledge provides an invaluable resource when time to market is such a critical factor.

Our clients benefit from our industry leading approach tailored around planning, management, document generation, and project execution. Sequence consultants remain current on the latest regulations, standards, and guidance documents in order to ensure we provide up-to-date validation services to our clients. Our team supports each client's engineering and quality organizations by developing a partnership-like approach on each validation initiative.

DELIVERABLES INCLUDE BUT ARE NOT LIMITED TO:

- User Requirements Specification
- Factory Acceptance Testing
- Site Acceptance Testing
- Commissioning Plans & Protocols
- Validation Master Plan
- Functional Requirements Specification
- Design Specification
- Risk Assessment
- Component Impact Assessments
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Traceability Matrix
- Final Reports
- Validation Summary
- Change Control
- Auditing
- Compliance Remediation
- General Validation Consulting

PROJECT EXAMPLES:

- Prospective/Concurrent Validation of an Individual System
- Production Expansions
- Plant Shutdown Activities
- New Facilities
- Production Equipment Relocation
- New Product/Product Changeover Enhancements
- Equipment Decommissioning Initiative

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www.sequencevalidation.com



EQUIPMENT, UTILITY, & PROCESS VALIDATION EXPERIENCE:

- HVAC
- Environmental Qualification
- Steam Sterilizers
- Lyophilizers
- Centrifuges
- Temperature Controlled Units
- Pasteurizers
- Tablet Coating
- Fill Lines
- Glasswashers
- Depyrogenation Tunnels
- Vessels
- Chromatography Skids
- Incubators
- Fermentors
- Fluid Bed Dryers
- Net-Weight Fillers
- Packaging Lines
- Thermal Validation
- Filtration Systems
- Granulating Encapsulation
- Clean-In-Place (CIP)
- Steam-In-Place (SIP)
- Facility Qualification
- Compressed Air and Gases
- Water Systems including WFI, RO, DI, Purified Water, Clean Steam, etc.

Sequence, Inc. differentiates the quality and value of our services by staying current with today's best practices and international regulatory expectations for commissioning, qualification, and validation. The vast experience of our personnel provides great perspective and insight into strategies for implementing practical and compliant solutions pertaining to equipment, utility, and process validation. We ensure our services are consistent with the evolving harmonized regulatory framework around risk-based and science-based approaches to regulatory compliance.

Sequence, Inc. stands ready to share our team's expertise in delivering cost-effective and practical compliance solutions to your organization. We will support the initiatives of your equipment, utility, and process validation projects while meeting aggressive deadlines to ensure quick time to market.

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