

# + OVERVIEW

Sequence, Inc. consultants take pride in providing unparalleled Quality and Compliance services to regulated manufacturers.

Sequence, Inc. was formed in 2002 out of a need for **high-caliber consultants** within the life sciences industry. For the majority of its existence, Sequence has been known as a validation service provider specializing in computer, laboratory instrument, equipment, automation, process, and utility validation.

From our roots in validation, we have expanded our **service offerings** and emerged as a leader in comprehensive quality and compliance consulting nationwide and internationally. Our vast experience, effective methodology, risk-based approach, quality products, and reliable staff deliver a level of service that is unsurpassed in the industry. Sequence core competencies include:

- Engineering & Technical Support
- Integration, Automation & Controls
- IT Quality Services
- Software Management
- Laboratory Compliance
- Quality Programs and Compliance
- Remote Monitoring Services



## Our Quality & Compliance Experience

Sequence, Inc. is proud to offer quality and compliance services for software, IT infrastructure, laboratory instruments, analytical methods, equipment, automation, processes, cleaning and utilities, as well as process optimization, laboratory software support, remediation, regulatory compliance services, system/facility startup and much more across the United States, as well as internationally.



We provide turn-key implementation and validation solutions for instrumentation and methods including the **VITEK® 2 Compact**, **VITEK MS®** and **BacT/ALERT® 3D** through our partnership with bioMérieux.



We also have specialized experience integrating process analytics systems such as **Discoverant**, as well as many other software solutions widely used in regulated industries.

Our partnerships, knowledge and experience with the systems, instruments, equipment and processes used throughout regulated industries allows us to offer related support and administration services for comprehensive compliance solutions.

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# + ENGINEERING & TECHNICAL SERVICES

From concept through implementation, Sequence, Inc. has the expertise you need.



At Sequence, we work with our clients to understand the unique requirements of their facility in order to develop a cost effective method to meet functional and quality objectives associated with new facilities, existing facility expansions, shutdowns, and system upgrades.

The vast experience of our personnel provides great perspective and insight into strategies for implementing practical and compliant solutions pertaining to commissioning and integration of control systems, facility start up, processes, and equipment. In addition, we guarantee facility qualification consistent with the evolving harmonized regulatory framework around risk and science-based approaches to regulatory compliance. Our clients across the US, Canada, and beyond benefit from our **industry-leading** approach tailored around planning, management, document generation, and project execution. We are committed to product safety and efficacy through alignment with our client partners to ensure compliance of their regulated facilities.

## Our Services

We offer a wide range of services at Sequence and take pride in our expertise and diverse skill sets. We have the resources and expertise to add value to all of your project needs from start to finish. Sequence is always evolving our service offerings to meet ever changing client needs, and yet maintaining a level of service to our client that is second to none. Sequence can support you in all aspects of the following services:

- Automation Engineering & Validation
- Equipment/Utilities Validation
- Equipment Commissioning
- Building Systems Commissioning
- FAT/SAT Support
- Technical Writing
- Risked Based Verification (ASTM 2500e)
- Manufacturing Support Start-Up
- Functional & Design Specification Development
- Design Reviews
- Tech Transfers
- Decommissioning
- Process Validation
- Manufacturing Process Intelligence

We have quality project resources that have experience in following industries:

- Pharma
- Bio-Pharma
- Medical Device
- Tobacco
- Laboratory
- Hospitals
- K-12 School & University Systems
- Nuclear
- Government Facilities



Sequence stands ready to share our team's expertise in delivering **cost-effective** and **practical** compliance solutions to your organization. We will support the startup, qualification, and validation of your facility and critical systems while meeting aggressive deadlines to ensure quick time to market.



All required engineering performed by associated entity, Sequence Engineering, PLLC (P-1394).

# + INTEGRATION, AUTOMATION, & CONTROLS

The solution may range from a simple user interface to a completely automated line, Sequence can get you where you want to be.

At Sequence we specialize in helping your business reach its potential through the best available combination of hardware quality, software flexibility, and system capability. Our goal is to provide a tailored solution to every job. Our 75 years of combined experience allows us to implement and support our customer's preferred hardware and software solution for many different applications.

## Panel Build Services

- AC/DC Drive and Combination Starter Panels
- Control and Operator Interface (HMI) Panels
- Annunciator and Lighting Panels
- Electrical system design
  - Controls
  - Power distribution
- CAD design
  - Mechanical drawings
  - Electrical drawings
- Pneumatic Control Panels
- Motor Control Centers
- Power Distribution Panels
- On-Site Support
  - Start Up / Troubleshooting
  - Retrofits
- Instrumentation
  - Instrument selection and specifications
  - System design – sizing, integration



## Automation and Control

- Develop and Implement Automated Processes
- Process Design and Simulation
- Network Integration
- Direct Onsite Support and System Maintenance
- Control System Upgrades
- Control System Architectures including PLC, SCADA, and DCS
- Trouble Shooting and Remediation of OEM equipment
- User and Design Specifications
- Equipment Specifications
- System Analysis and Test Plan Development
- Project Management
- Batch Tracking, Alarming, Reporting, and Historian Implementation

Sequence, Inc. is proud to offer integration, automation, and controls solutions to all industries. Solutions range from simple user interfaces to large scale control systems. We deliver superior solutions in a cost effective and timely manner. Our staff has extensive experience in DCS, PLC and SCADA control systems. Furthermore, our staff is capable of providing long term service contracts, hands-on process engineering support, maintenance support, instrumentation support, and 24/7 on-call support.

All required engineering performed by associated entity, Sequence Engineering, PLLC (P-1394)



# + IT QUALITY SERVICES

Our consultants have experience with many of the widely deployed IT solutions in the life sciences industry.

Business solutions such as ERP (*Enterprise Resource Planning*), Content Management, CAPA (*Corrective and Preventative Action*), Change Control, and LIMS (*Laboratory Information Management System*) are essential elements in today's highly regulated environments. Sequence, Inc. consultants are proficient in these and a multitude of other applications. Many of our consultants are also certified in a variety of applications, such as LIMS and Discoverant.

Through our experience, clients see tremendous return on investment in the form of regulatory compliance, early discovery of errors, continuous process improvement, increased employee efficiency, and customer satisfaction. Our approach to validation is to view our clients more as partners than customers. We integrate ourselves within the appropriate business unit in order to understand the objectives, requirements, and compliance strategies around implementing an information system. After gaining a thorough understanding of the project, Sequence, Inc. consultants begin the process of executing a successful validation effort following your SDLC (*System Development Life Cycle*) process from requirements gathering to implementation.

Whether you are implementing a global SAP platform to streamline productivity or designing a custom maintenance management system to support your facility, our consultants have the knowledge, experience, and initiative to effectively lead your validation and compliance efforts.

## Commercial Information Systems Validation Experience

- SAP
- Sharepoint
- Trackwise
- LIMS
- POMS
- Calibration Manager
- Millennium
- NuGenesis
- ATLAS
- Documentum
- LiveLink
- Discoverant
- Oracle
- Maximo
- Empower
- Chemstation
- Donor Management System
- SmartLab

## Custom Information Systems Validation Experience

- Recipe Management Systems
- Maintenance and Calibration Systems
- Batch Production Record Systems
- Document Management Systems
- Electronic Submission Systems
- Barcode Scanning Systems
- Learning Management



# + SOFTWARE MANAGEMENT

Let our team integrate and support a range of software products that achieve compliance for your site.

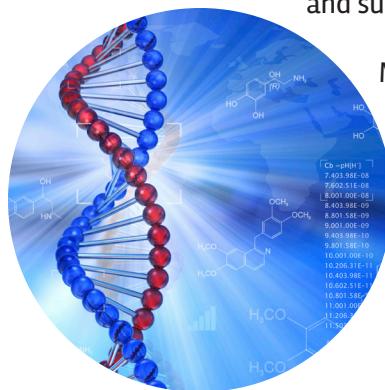
Sequence system implementation and support model services are unsurpassed in the Biotechnology and Pharmaceutical industries. We strive for a hands-on, customer-first approach for software system implementation, validation and support that ensures customer systems are qualified, maintained and supported at the highest standard. Our expertise is utilized in authoring client Standard Operating Procedures and Work Instructions for use, maintenance and administration of computerized systems.

Our Software Management Services team is experience in implementation, validation and support of both small and large-scale manufacturing, laboratory and operational support systems such as:

- Process Analytics / Manufacturing Intelligence
- Enterprise Resource Planning
- Laboratory Sample Management
- Deviation and CAPA
- Maintenance Management
- Learning Management / Training Delivery

## Software Consultants Skilled & Knowledgeable in Discoverant, Noverant™ & More

At Sequence, Inc., we are involved from development to production support for Discoverant manufacturing intelligence platform. This Process Management Informatics (PMI) Software utilizes data from existing system data stores to perform extensive analysis and help improve yield and lower costs. Additionally, we have partnered with Noverant™, and now offer a customized cloud-based training solution that we can implement and support for our clients nationwide.



Many of our software management consultants are certified in the systems we validate and support, including LMS and Discoverant software.

In addition to commercially available software solutions, our software consultants have been involved with the development and implementation of custom client solutions. With our systems validation, implementation, configuration and support services, Sequence, Inc. can be your end-to-end solutions partner.



# + SOFTWARE MANAGEMENT DATA ARCHITECTURE

Let our team organize, integrate and model your data to empower your Analytics and Visualization needs.

Sequence Data Architecture provides guidance for the rollout of a sustainable framework to support your analytics needs. Our Hadoop expertise delivers Data Aggregation and Data Model design to your organization at the appropriate Volume and Velocity for real and near time analytics. Leverage our experience in integrating multi-site and enterprise data sets to Cloud and on-premises Data Lakes to support business understanding through Data Visualization. By utilizing Sequence experience with the delivery of validated and controlled solutions, you will be secure in the answers that were previously just beyond reach.

Our Data Architecture team is experienced in Design, Implementation, Validation and Analytics Support on Cloud Solutions such as Amazon AWS, Microsoft Azure, as well as On-Premises Hadoop and Data Warehousing.

**Services we provide include but are not limited to the following:**

- Data Asset Road Mapping for Use Case Optimization
- Software Selection guidance
- Data Volume and Velocity determination
- Big Data Governance development
- Data Delivery configuration for visualization ingestion
- Statistical model data delivery
- Visualization customizations for Tableau, Pentaho, Spotfire, MiniTab, SAS, JMP, Excel, Sharepoint, and other visualization tools



At Sequence, Inc., we are involved from development to production support for your data architecture and analytical needs. Combine data stores to perform extensive analysis and help improve yield and lower costs without an impact on your production systems while delivering a High Available and Scalable solution. In addition, our consultants have years of experience in Process Manufacturing environments and provide additional understanding to support the needs for product delivery.

Let Sequence leverage the infrastructure you already own to transform your data into an asset that delivers enhanced data visibility to you.

# + LABORATORY COMPLIANCE

We have extensive experience with laboratory instrument qualification, method validation, and tech transfers.



Sequence, Inc. has extensive experience validating analytical equipment, instruments, and methods for the Biopharma and Medical Device industries.

With each quality and compliance effort, our consultants begin with an initial consideration of the technical complexity of the lab system, degree of customization, and intended use by our client. This allows us to implement an **effective, risk-based approach** during each equipment or instrumentation validation effort. Testing performed by Sequence consultants provides documented evidence that the system is installed properly, performs accurately, and produces reliable data.

## Laboratory Equipment Systems Experience

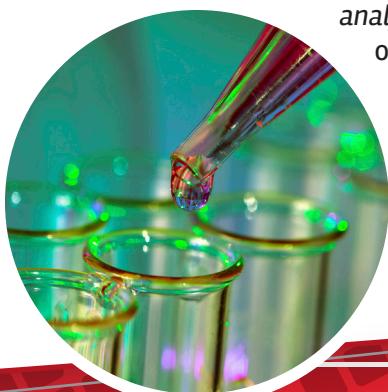
- Centrifuges
- Freezers
- Water Baths
- Isolators
- Stability Chambers
- Vessels
- Cold Rooms
- Refrigerators
- Incubators
- Autoclaves
- Robotic Pipettors
- Ovens
- Tanks



## Laboratory Instrument Systems Experience

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

Past projects include retrospective legacy validation initiatives (*including an initial gap analysis*), prospective/concurrent validation of individual systems, prospective validation of laboratory startups, laboratory relocation, new product/product changeover testing enhancements, laboratory decommissioning, electronic data retention/archival initiatives and much more.



# **+ QUALITY PROGRAMS & COMPLIANCE**

Rely on Sequence, Inc. for remediation, training, quality program development and more.

## **Investigations**

Investigations are central to an efficiently managed regulatory compliance organization. Our consultants have experience in investigations related to corrective and preventive actions (CAPA), complaints, non-conformances, out-of-specification (OOS) incidents, and change controls.

## **Internal/External Auditing**

Auditing ensures your facility is operating at optimal capacity, identifying issues that may cause a disruption in the production process or negatively affect a Quality system.

## **Project Leadership**

1. First, we determine the project goals and define a realistic timeline
2. Next, we transfer this information to a formal project plan, which is used throughout the entirety of the project
3. Finally, we bring the project team together in a cooperative effort so that progress may be leveraged by each member's contribution

## **Remediation**

Sequence, Inc. offers experienced personnel to assist you with all of your remediation needs. We can provide everything from updating existing documentation to reflect an as-built state, to overhauling your complete process, as well as everything in between.

## **Risk & System Assessments**

At Sequence, Inc., we have risk and assessment consultants that are experienced in creating processes for individual system assessments as well as designing new programs to take risk into account when dealing with your systems and processes. We can also execute existing processes for system assessments.

## **Training**

Sequence can provide staff to create and implement corporate training programs, write training material, and deliver that material to all levels of your organization.

## **Quality Program Development**

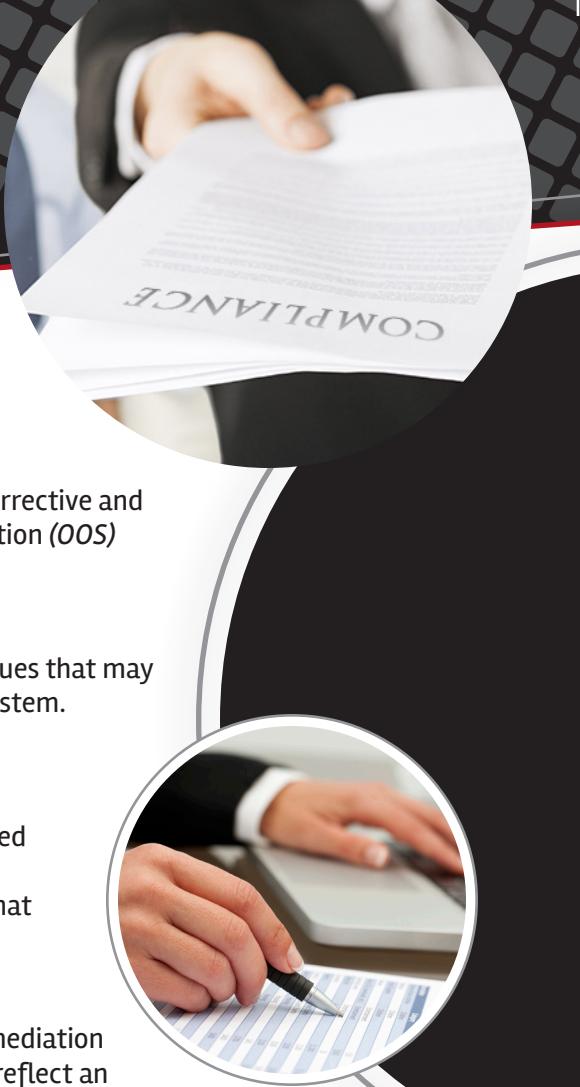
Through Quality Program development, our team can identify the key areas for improvement to maximize efficiency as well as reduce the implementation impact to your business.

## **PAI Readiness**

The seasoned consultants at Sequence, Inc. are prepared to assist clients in assessing the readiness level for a pre-approval inspection (PAI). Performing mock inspections is a key tool in the process of preparation for inspection by various regulatory bodies.

## **QA Review & Support**

Our multi-industry expertise gives our consultants a unique perspective on Quality Assurance and can provide innovative solutions for all of your QA needs.



# + MONITORING SERVICES

A complete solution for all of your monitoring needs.

Sequence, Inc. provides a scalable and customizable monitoring solution for your temperature, humidity, CO<sub>2</sub>, or pressure monitoring needs. Whether you have controlled incubators containing your critical stability samples, low temperature freezers containing valuable cell banks or biologics, or refrigerators used for day-to-day operations, our Sequence Monitoring Center is capable of providing personalized around the clock support to ensure materials are maintained under your specified conditions.

## Monitoring Capabilities:

- Cold Chain
- Environmental
- Food Storage
- Stability Chamber
- Plasma Donor Centers
- Cargo
- Facility
- Blood Banks
- Data Centers

## Our Services:

The Sequence Monitoring Center supports clients across all 50 states and is experienced in the installation, configuration, calibration, validation, quality oversight, and monitoring support of your product, equipment, and/or facility. Through our client dedicated support module, our 24 hour call center, and our ability to provide vendor management, quality oversight and remediation, we are able to provide our clients a complete solution for monitoring support and compliance.

In addition, the Sequence Monitoring Center provides customized data analysis and reporting to help turn raw data into meaningful information. Sequence will work with you to define your reporting and trending needs to ensure you get the information required to meet your project demands.

The data transmitted to our Monitoring Center is constantly assessed for alarms or issues that could adversely impact your product or manufacturing environment. Early detection of an adverse trend can make the difference in avoiding potential product loss, saving you valuable time and money. At the first sign of trouble, a Monitoring Center Specialist notifies you of the situation, immediately initiating the investigation process. It doesn't end there, as Sequence Specialists will work with you throughout the investigation process to determine the scope of the alarm and evaluate the impact to the product or environment. Sequence Quality Assurance is available to review all data to ensure data integrity, results are accurately represented, and to provide guidance through the closure of event remediation.

## Services We Provide:

- Dedicated Support
- Validation Documentation
- Deviation Resolution
- Dedicated Support Module
- Investigations
- Customized Data Analysis
- Adverse Trend Notification
- Calibration
- Trend Reporting
- Quality Oversight
- Alarm Notification
- Vendor Management
- Validation Execution
- Adverse Trend Remediation
- Out of Calibration Reports

