

Information Systems Validation

Sequence, Inc. consultants have worked with numerous clients in the Pharmaceutical, Biotech, and Medical Device industries to validate a variety of Information Systems. 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.

Business solutions such as ERP (Enterprise Resource Planning), document management, CAPA (Corrective And Preventative Action), and LIMS (Laboratory Information Management System) are essential elements in today's highly regulated environment. Sequence consultants have extensive experience in these and many other types of applications. Many of our consultants are also certified in a variety of applications. 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 perceive 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 consultants begin the process of executing a successful validation effort following the SDLC (System Development Life Cycle) from requirements gathering to implementation. Often times, clients request that our consultants remain available for future enhancements to systems due to their satisfaction of our services during the initial validation effort. Sequence also has extensive experience decommissioning Information Systems while ensuring data is successfully archived or migrated to a replacement system.

In addition to commercially available software solutions, Sequence consultants have been involved with the development of custom client solutions through all phases of the SDLC. Our experience with custom applications includes solutions for maintenance management, laboratory data acquisition and storage, manufacturing data acquisition and storage, process management, regulatory submissions, document storage and management, and many others.

DELIVERABLES INCLUDE BUT ARE NOT LIMITED TO:

- User Requirement Specification
- Validation Master Plan
- Functional Requirement Specification
- Design Specification
- Risk Assessment
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Traceability Matrix
- Final Reports
- Validation Summary
- Change Control
- Auditing
- Compliance Remediation
- General Validation Consulting

For all of your Information Systems validation and compliance efforts, consider making Sequence, Inc. your implementation partner. We have consultants available for long and short term projects who will give you the commitment and expertise necessary to meet your timeline, budget, and compliance requirements.

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www.sequencevalidation.com

KNOWLEDGE BASE:

- C++
- XML
- HTML
- ASP (Active Server Pages)
- SQL
- Java
- Perl
- Visual Basic.net
- Citrix
- PHP
- COBOL
- FORTRAN
- Windows Platforms
- Oracle Databases
- UNIX
- Novell
- Excel Spreadsheets
- MS Access Databases
- Toad
- Crystal Reports
- PowerBuilder
- Filemaker Pro
- Test Director
- WinRunner
- Rational Robot
- Linux

COMMERCIAL INFORMATION SYSTEMS VALIDATION EXPERIENCE:

- SAP
- Documentum
- Sharepoint
- LiveLink
- Trackwise
- LabWare
- SQL *LIMS
- SampleManager
- POMS
- Maximo
- Calibration Manager
- Empower
- Millennium
- Chemstation
- NuGenesis
- Donor Management System
- ATLAS
- Statlia

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
- LIMS

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