System Validation Services

Validate with Confidence

- Efficient delivery and execution of system validation.
- Cross-functional collaboration with system users, IT department, quality assurance and validation teams.
- Minimize demands on internal resources.

Based on DSI's knowledge and experience from working closely with many of our GLP customers, we have developed a proven, consistent approach to validating DSI systems. We understand the importance of clear communications and disciplined project management to maintain critical timelines. Our team actively collaborates with all stakeholders throughout the validation project to achieve an exceptional validation result.

Project review meetings with business users, IT, QA and team	Validation system and documentation package prepared	On-site execution of IQ/OQ and reports	QA audit resolution	IQ / OQ Validation Summary Report

Efficient Process

System validation properly executed the first time helps to control validation costs and minimizes the challenges associated with developing and maintaining a validated system. We provide the following:

- A clear project plan for the entire process.
- Timely delivery and execution of system validation[1].
- A partnership approach to execute, document, and complete the project on time and on budget[2].

[1] Assumes client resources are available at appropriate times during the validation process.
[2] If project scope changes mid-project, the project timeline and budget will be reassessed.

Timeline

- Test Scripts only often take approximately 1-3 months.
- System Expansion often takes approximately 3-6 months.
- Full-Service Validation often takes approximately 6-12 months.
- Custom Validation timelines will vary based on the deliverables aligned with the customer.

Choose from Several Validation Options

Scripts Only

We provide the test scripts necessary to execute through installation and operational qualifications. This solution is recommended for those experienced with performing validation on complex software systems.

Deliverables
• Installation Qualification (IQ) Test Scripts
• Operational Qualification (IQ) Test Scripts*

Full-Service Validation

We support you with a comprehensive validation solution including project management, detailed validation master plan, all required documentation and on-site support by DSI's experienced team.

Deliverables
• Validation Master Plan (VMP)
• Requirements & Traceability Matrix (RTM)
• Installation and Training
• Installation Qualification (IQ) Test Scripts
• Operational Qualification (OQ) Test Scripts*
• Dedicated on-site support through IQ / OQ execution
• QA Audit resolution of any identified concerns
• Validation Summary Report (VSR) (through IQ / OQ)
• All supporting evidence and supporting documentation
• Final original documentation delivered in binders

The Ponemah Software is considered a COTS (Commercial-Off-the-Shelf) system. The vendor documention can be used to demonstrate the software functions as a specified in the User requirements. Completed OQs are acceptable and compliant within the scope of the specific version or build of a software. OQs that are specific to the system hardware and/or operational location are required to be performed in the client environment with applicable hardware.

Customization

Depending on your unique business, quality assurance or IT needs, DSI can develop a customized approach for your validation needs.

Meets Industry Standards

- Uses Commercial off-the-shelf approach.
- Supports 21 CFR Part 11 compliance.
- Ensures Data Integrity.
- Aids 21 CFR Part 58 compliance.
- Satisfies OECD guidelines.
- Confirmation of calculation results for derived parameters provided.

Email us today at ScientificServices@datasci.com, or visit our website at www.datasci.com/services to schedule a free consultation.

Data Sciences International

119 14th St NW, Suite 100
St. Paul, MN 55112 U.S.A.
Tel: 651-481-7400
Fax: 651-481-7404

Sales: sales@datasci.com

Technical Support:
support@datasci.com

Web: www.datasci.com

European Sales:
sales@datasci.com

Asia Pacific Sales:
sales@datasci.com