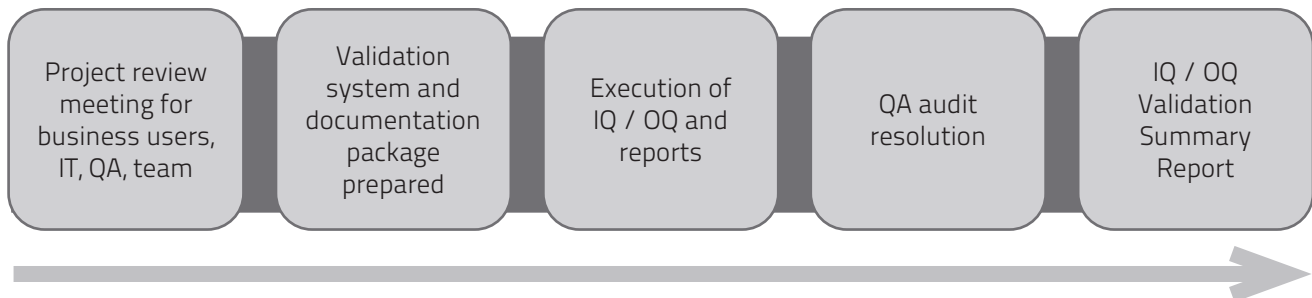


# System Validation Services

Validate with Confidence

- Efficient delivery and execution of system validation
- 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.



## 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<sup>1</sup>
- A partnership approach to execute, document, and complete the project on time and on budget<sup>2</sup>

<sup>1</sup> Assumes client resources are available at appropriate times during the validation process.

<sup>2</sup> If project scope changes mid-project, the project timeline and budget will be re-assessed.

## Choose from Several Validation Options

### Scripts Only

We provide the documentation templates and 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 (OQ) Test Scripts
▪ Master Document Template (Validation Master Plan, User Requirements & Traceability Matrix, System Design/Configuration Specifications, Validation Support Report)

### Validation Service

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 (URTM)
▪ System Design and Configuration Specification (SDCS)
▪ Installation and Training
▪ Installation Qualification (IQ) Test Scripts & Release Memo
▪ Operational Qualification (OQ) Test Scripts & Release Memo
▪ 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 leather binders
▪ Back-up electronic file storage at DSI on secure server

### 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
- Aids 21 CFR Part 58 compliance

Contact us today for more information. [ScientificServices@datasci.com](mailto:ScientificServices@datasci.com) or go to <https://go.oncehub.com/jdoyle> to schedule an appointment.