Computer System Validation

Providing Peace of Mind

The CSols Validation services portfolio leverages our industry experts' experience. We provide a science and risk-based methodology using ever-evolving best practices. This strategy delivers peace of mind for our clients, regardless of whether their validation needs involve a LIMS or other lab informatics systems, an MES, a QMS, an LMS, or specific instruments.

Why CSols

Validation is a significant part of one-time implementation projects. It doesn't make financial sense for your organization to dedicate internal resources to this infrequent effort. In situations like the following, an external validation expert is a reasonable option:

- ✓ Validation work has been delegated to or assumed by the IT staff who don't know the complete requirements or don't understand the affected system. They could require extensive support from on-site personnel to define the project scope.
- ✓ On-site personnel are responsible for validation, but they have limited availability. They are already fully engaged with scientific endeavors and lack the bandwidth to devote themselves to the validation project
- ✓ In the worst-case scenario, the validation project has stalled or failed because no one in your organization has the required expertise or the necessary time, and your system rollout is in jeopardy—not to mention your regulatory compliance status.

There are many reasons that organizations seek input from experts to assist them with their validation needs. CSols has earned the reputation of delivering on time and within budget for more than 20 years. However, CSols isn't just any validation company; we possess the three key elements that guarantee a successful validation project:

1. Hands-on experience with informatics systems, QMS, LMS, and MES (and more)
2. Complete knowledge of regulatory rules and requirements
3. Best practices and proven software assurance validation and project management methodologies

CSols will ensure your validation execution is *A*ttributable, *L*egible, *C*ontemporaneous, *O*riginal, *A*ccurate, *C*omplete, *C*onsistent, *E*nduring, and *A*vailable (ALCOA+) and is fully auditable.

Benefits You Receive

Our clients benefit from our knowledge of informatics systems and the ways that laboratories engage with them. We take a risk-based approach to test the relevant and critical aspects of your system. Hundreds of clients have used our validation services to ensure that their systems meet regulatory guidelines, on time and within budget.

Additionally, our expertise includes real-life validation experience, and we know the common failure points targeted by auditors, such as incomplete record keeping or testing. Therefore, we can develop and execute your validation plan in the most efficient manner while ensuring minimal and acceptable risk.

Non-Compliance Repercussions

- Warning letters - 483
- Consent decree(s)
- Lawsuits/Fines
- Plant shutdown
- Indictments
- Economic instability
- Staff downsizing
- Bankruptcy
- Product recalls

System Expertise

- CDS
- ELN
- LES
- LIMS
- LMS
- MES
- QMS

Regulatory Knowledge

- FDA
- USDA
- MHRA
- EMA
- GAMP5
- PICS
- Annex 11
- ISO 9000

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Working with CSols, you get:

Our People

- Highly skilled and experienced (avg 15 yrs) scientists, information technologists, and regulatory experts
- Real-world regulatory expertise
- Experts in life science laboratory informatics systems, so your internal resources' involvement is minimized when we are creating or executing test cases
- We understand your lab processes/workflows, scientific data, and the underlying science, so we are better able to develop realistic test cases and perform risk assessments

Our Process

- Risk-based CSA approach to CSV
- Expert in prospective and retrospective CSV and remediation
- Fully developed suite of validation processes including specifications, code review, etc., if customer requires them
- Quality oversight from the strategic validation master plan, to developing and executing test scripts and everything in between

Our Services and Deliverables

Validation Planning:

- Validation master plan (VMP) development
- Validation summary report creation
- Change control process design

Validation Lifecycle

- Risk Assessment (RA)
- Vendor Audit
- User Requirement Specification (URS)
- Functional Requirement Specification (FRS)
- Configuration/Design Specification
- Traceability Matrix
- SOPs
- Data Migration and System Retirement Plans

Validation Testing/Verification

- Installation Configuration (IQ)
- Functional Testing (OQ)
- Requirements Testing (PQ)
- Execution and Deviation Support
- Test Reports

For all three testing stages:

- Development
- Execution support
- Deviation resolution
- Final report

Testimonials:

"I just wanted to thank you very much for your contributions on the validation of our LIMS. We were thoroughly impressed by your knowledge and skill level of the industry regulations and felt confident with our project in your hands. The fear of an audit is gone."

Healthcare
Compliance Services

"Your leadership made the difference on this project; your guidance and services from the Validation Plan development and Risk Assessment through the execution of the Test Scripts were superb."

Specialty Pharma Company
(QA / R&D)
Project Management & Validation

Remember, lacking validation knowledge, not thoroughly testing your system, or not correctly documenting your efforts can lead to observations during your next inspection or preapproval inspection (PAI). Engage with CSols and be assured that your informatics system is fully compliant, fully documented, and defendable against an audit.

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