COMPLIANCE Validation

Onsite and Remote Support

SL CONTROLS

THINKING AHEAD

COMPLIANCE Validation
Onsite and Remote Support

- Internationally Recognized Solutions in Validation
- Onsite and Remote Staff Support
- Specialists in Medical Device and Pharmaceutical

COMPLIANCE Validation
Onsite and Remote Support

Validation Experts in medical device and pharmacuetical markets

- Specialized Validation Department
- Experienced Validation Engineers
- Solutions from concept and strategy to delivery
- 20 Approx 20 years delivering Validation Solutions
- On site staff support
- Remote staff support
- Full end to end validation solution
- International team, UK, US, Europe, Asia

COMPLIANCE Validation
Onsite and Remote Support

Our **Approach**

> Validation is the requirement to provide documented evidence that a system performs as per specification
>
> *Dermot McMorrow*
> *Compliance Director*

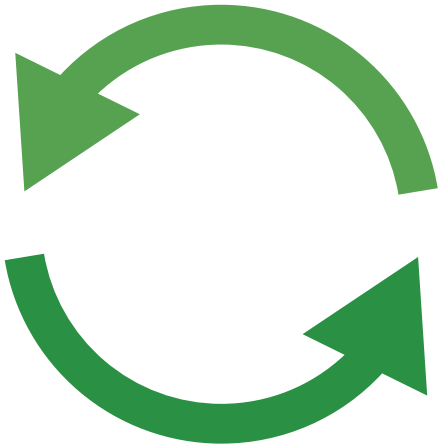
At SL Controls we assess the existing validation process or implement a new validation solution to meet your specific requirements - from inital concept to project delivery and ongoing support SL Controls are the industry experts in Validation.

- Initial concept
- Ensure compliance with user requirement specification
- Generate master validation plan
- Deliver risk assessment
- Categorise software
- Deliver computer system validation
- Deliver process validation
- Deliver product validation
- Test method validation
- Audit readiness preparation

COMPLIANCE Validation
Onsite and Remote Support

Validation
Software Services

- Design and implement validation plan
- Support software coders or process engineers
- Deliver on design specifications
- Review and approve
- Risk assessment / functional / software
- Commence build of coding and production line
- Parallel testing of protocols from risk assessment outputs
- Sign off on protocols
- Test execution - close off deviations
- Validation report



COMPLIANCE Validation
Onsite and Remote Support

Specialist Validation Consultancy

01

Software Validation

An independent reviewer assess code in conjunction with the developer. We have performed source code reviews on multiple platforms catering for the specific needs of customers globally.

Includes planning, verification, testing, traceability, and configuration management.
We provide you with documented evidence that your software is validated. We take a quality risk management approach to all validation projects.

02

Process Validation

We provide expertise in the requirements, design and qualification phases of a project, through to continued support and re-validation.
We ensure you meet all regulatory requirements for your industry.

03

Equipment Validation

We assist you in completing your equipment qualification from initial design stage through to the execution of test protocols and the generation of reports. Experienced vendor neutral Equipment Validation Engineers to qualify your equipment.

04

Test Method Validation

Our team will establish the performance characteristics and limitations of any existing pre proposed method and identify any influences which may change these characteristics.

COMPLIANCE Validation
Onsite and Remote Support

CLIENTS WE WORK WITH

COMPLIANCE Validation
Onsite and Remote Support

VALIDATION EXPERIENCE

MITSUBISHI ELECTRIC
Factory Automation

BIOVIA
Discoverant®

Wonderware
Ireland

SIEMENS

Rockwell Automation

OSIsoft.

EMERSON

Partner
Intelligent Platforms

COGNEX
vision

ZEISS

solutionspt
Industrial IT Solutions

VIDEO

COMPLIANCE Validation
Onsite and Remote Support

CASE STUDIES

COMPLIANCE Validation
Onsite and Remote Support

CASE STUDY 1

Company: Customer 1
Service: Regulatory Compliance Systems & Systems Support
Sector: Medical Device; 500+ employees
Customer Duration: 5 Years

Project Overview: This project consisted of the upgrade and qualification of the FactoryTalk Applications (FactoryTalk AssetCentre, FactoryTalk View, FactoryTalk Transaction Manager and FactoryTalk VantagePoint) along with the installation and qualification of the upgraded production hardware (Allen Bradley PLC's and HMI PC's) and upgraded server infrastructure.

Strategic Targets:
Complete a Gap Analysis to determine scope of engineering and validation effort required.
Generate validation strategy to de-risk the systems upgrades.
Creation of a Pilot Lab environment for testing of applications and hardware offline.
Upgrade and qualification of all effected IT Servers to Windows Server 2012.
Installation and qualification of FactoryTalk Infrastructure Software including FactoryTalk AssetCentre, FactoryTalk Transaction Manager, FactoryTalk View, FactoryTalk VantagePoint and FactoryTalk Services.
Installation and qualification of SQL Server.
Managed the migration of the production databases and AssetCentre database to new infrastructure,
ensuring no loss of critical data.
Upgrade and qualification of production hardware (Allen Bradley PLC's and HMI PC's).
Integration of all applications and hardware to site services.
Update of customer procedures to ensure compliance with current standards.

Outcomes Achieved:
The systems within the customer's facility consist of multiple servers and machines which manufacture the medical device product.
'The systems installed and qualified by SL Controls ensure that the customers systems and procedures are future proofed, scalable and in compliance.'

Full Validation Packages provided for each of the FactoryTalk applications focusing on mitigation of risks, data integrity of systems and compliance with current regulations, e.g. 21 CFR Part 11.

FactoryTalk Server Infrastructure upgraded and qualified.
SCADA PCs, HMIs and PLCs replaced with new hardware and up to date software.

Security of all systems upgraded to ensure data integrity, including the introduction of group based security levels.
Procedures and forms updated to reflect process updates and compliance updates.

SL Controls provided both Validation and Engineering expertise to deliver and validate a major upgrade to production servers and equipment

COMPLIANCE Validation
Onsite and Remote Support

CASE STUDY 2

Company: Large Multinational
Service: Implementation and closeout of Quality Critical CAPA
Sector: Medical Device; 2500 employees
Customer Duration: 8 years
Project Overview: Update to quality critical system to ensure device calibration after a power fail and ensure system cannot operate without verification of correct process parameters.
Implement rollout across 38 production lines.

Strategic Targets:
The high level targets of the project were (after unplanned power outage of system):
Log user out of system.
Generate fault/alarm condition to alert user to the fact that system calibration values are not verified.
Prevent system from running until process values are verified.
Prompt user to use specific client procedures to correct system process values.
Develop solution based on above core elements for 7 different generations of production line.
Roll solution out across plant.

Outcomes Achieved:

Eradicated known potential of incorrect parameters running on quality-critical system.

Ensured that Client closed out CAPA on time, which improved this client site's international metric for implementing CAPA's.

SL Controls solution is to force the user to verify correct calibration values of system before starting production after a power fail by improving PLC/HMI/Archestra logic.

After a System Power Fail, Our system;

Logs the users out of the HMI
Uses PLC to generate a fault condition with an alarm on the System HMI stating 'calibration values not verified'
Puts invalid values into the calibration Device Values in the PLC, preventing the system from running
Ensures that system cannot be started unless values are verified by trained personnel

SL Controls provided a comprehensive solution within a limited timeframe.


SL CONTROLS
THINKING AHEAD