Design Group

Control System Integration: Life Sciences

Design Group is a multi-discipline engineering firm serving the Life Sciences industry and is one of the largest System Integrators in the United States. Our expertise spans a broad range of Life Sciences market sectors including cell & gene therapy, biotech, medical device, and pharmaceutical. Our SMEs have a thorough understanding of 21 CFR Part 11, EudraLex Vol. 4, Annex 11, and ISPE GAMP 5 guidelines. Design Group's internal Quality Assurance program ensures a robust and quality delivery of the system. A disciplined design and execution approach allows Design Group to deliver quality solutions with consistency.

Our Approach

Project Definition	Electrical & Control System Engineering					System Turnover
PFD	Electrical Definition	System Engineering & Design Specifications	Vendor/ Contractor Assessments & Bid Package Development	Procurement Services	Construction Management	Installation Check Out/System Prep
P&ID						
Equipment Layout	Software Development Lifecycle					Commissioning & Qualification
Sequence of Operation	Software Functional Design	Software Detailed Design	Software Development & In-Process Verification	Software Factory Acceptance Test		
User Requirements Document						Project Close-Out

GMP Applications

- Process Control Systems
- Environmental Monitoring Systems
- Equipment Integration & Data Collection
- Data Historians & Reporting
- Manufacturing Execution Systems
- Electronic Batch Record Systems
- HMI Mobility Solutions

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Project Definition & Management

Design Group works with clients to define project boundaries, capture requirements, set the automation vision and strategy, and perform the necessary assessments to develop detailed implementation and validation plans. Our team starts with evaluating data integrity and compliance strategies, then deploys technical controls implemented with automation and procedural controls where needed, to ensure there are no gaps in compliance.

Electrical and Control (E&C) System Engineering

Engineering professionals ensure that all electrical and control system aspects of the project are detailed and documented to meet the specific needs of each client. Our team will develop hardware design specifications (HDS), instrumentation specifications, and panel designs. Design Group self-performs all control panel fabrication and will provide factory acceptance test (FAT) services based on application-specific protocols.

Infrastructure & Network Design

Design Group deploys on-premises network hardware and infrastructure, industrial data centers, and/or cloud-hosted IaaS/SaaS computing assets to build a robust and secure OT/IT network adhering to ISA standards.

Software Development Lifecycle

Design Group builds high-quality software solutions in the least possible time by following a disciplined software development life cycle. Using a hybrid V-Model and Agile approach to define requirements, design, develop, test, deploy and maintain the software systems.

Computer System Validation

Design Group engages end-users to develop requirements and identify CQAs and CPPs to build a comprehensive and defendable validation strategy. Following the ISPE GAMP5 Risk-Based Approach, Design Group generates all documents and executes all tests that demonstrate traceability of user-requirements through design, test, validation and summary reporting.

Post Go-Live (Operations Assistance)

The development of operational and administrative SOPs in accordance with GAMP 5 is essential for manufacturing operations and maintaining compliance. Design Group's scope of supply includes these key deliverables to ensure a complete turnover of the system to operations.

Control Platform Expertise

- Emerson DeltaV
- GE Industrial
- Ignition
- OSI Soft
- Rockwell Automation Plant PAx
- Siemens Industrial
- Wonderware

Project Definition

- System Level Impact Assessments
- Data Integrity & ERES Assessments
- CQA/CPP Definition
- URS/FRS/DDS Development
- Process/Data Flow Diagrams
- Vendor Selection & Audits
- Equipment General Arrangement

E&C System Engineering

- Hardware Design Specification
- Instrument/Device Specification
- Communication Protocols
- Control Panel Hardware Selection
- Wiring & Interconnections
- Panel Design & Fabrication
- UL508A Certified

Infrastructure & Network Design

- Computing Platform Specification
- Hardware/Software Compatibility
- Network Hardware Specification
- Network Design

Software Development Lifecycle

- Design Specs (CS, FS, SDS)
- Agile In-Process Verification
- Software Acceptance Testing

Post Go-Live Support

- Business Continuity Planning
- SOP Development
- Training of Operators/Staff

Design Group operates from 45+ offices in the US and India providing engineering, consulting, and technical services to the world's leading companies in the Life Sciences, Food & Beverage, Advanced Technology, Industrial, and other market sectors. Our nearly 1,500 technical and engineering experts have direct industry experience in industrial automation, control system integration, facility and process engineering, architecture, construction management, regulatory compliance, enterprise technology, and other consulting services.