Design Group

Regulatory Compliance

Design Group is a leading supplier of validation, quality engineering, and regulatory consulting services to the biotech, pharmaceutical, and medical device industries. Experienced engineers and scientists possessing current industry insight use proven tools to employ science and risk-based methodologies to deliver flexible and customized solutions.

Our broad compliance solutions integrate into the project lifecycle through the generation of master planning activities, specification development, risk assessments, equipment commissioning and qualification, and cleaning and process validation. Partnerships with world-class organizations provide a simplified perspective, streamlining validation strategies that deliver robust and efficient solutions.

Experienced in regulatory enforcement actions, Design Group helps to mitigate potential findings or remediate recent observations by being a single point of accountability. This uniquely positions Design Group to provide independent quality assessments, audits, and remediate findings for client and third party contract manufacturers.

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Regulatory Compliance

Commissioning & Qualification

Design Group delivers Commissioning and Qualification (C&Q) solutions and services for client facility, utility, process, and packaging systems in alignment with the latest science and risk-based standards used in the industry including ASTM E2500, ISPE Baseline Guide 5, and ICH Q8, Q9, & Q10.

Computer System Validation

Design Group's multi-disciplined services allow for a partnership between the Regulatory Compliance, Control System Integration, and Enterprise Technology Consulting Practices to build a robust computer and software validation program for systems at all levels of the ISA 95 pyramid. Support can range from program development to the development of clear and robust specifications, to the integration of key elements for data integrity and ERES compliance, to the application of GAMP 5-based risk management tools, and the generation and execution of custom validation protocols.

Process & Cleaning Validation

Design Group provides process validation strategies demonstrating technical understanding of process development and manufacturing methods. These strategies effectively deliver process validation programs that incorporate scientific rationale and justification to align with regulatory guidance and industry standards.

Quality & Regulatory Compliance

Design Group delivers consulting services for the review of quality management systems, offering insight about the regulatory environment, recent trends, and techniques to ensure compliance with current regulatory requirements. Other services offered include Quality Engineering services for development of standard operating procedures, quality program documentation, annual product reviews, regulatory filings, root cause analysis, change management system documentation, and other regulatory and compliance management documentation.

Auditing

Audit services support a wide range of regulations, standards, and industries including FDA Regulations (cGMP and GLP), ISO standards, ICH guidelines, European commission, and internal company standards for the biotech, pharmaceutical, and medical device industries employing Quality Engineers and ASQ certified auditors.

Process Development

Design Group professionals apply statistical and process management tools and process analytical technology (PAT) to design and implement complete solutions in process development. Our process development services support the formalization of critical process parameters and critical quality attributes as a key input to Process Validation.

Commissioning & Qualification

- Validation Planning
- Specification Development
- Risk Assessments
- Project Management
- Technical Studies
- Equipment Troubleshooting

Computer System Validation

- Program Development
- Specification Generation
- Data Integrity & ERES Planning
- Risk Management & Mitigation
- Protocol Development & Execution

Quality & Regulatory Compliance

- Quality System & SOP Development
- CAPA & Root Cause Analysis
- Internal & External Audit Support
- Remediation Planning
- Regulatory Filings

Process Development

- Product Development
- Manufacturing Technical Support
- Validation
- Technology Transfer
- Multivariate Analytical (MVA) Techniques/Tools

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 Food & Beverage, Life Sciences, Advanced Technology, Industrial, and other market sectors. Our nearly 1500 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.