



Medical Device Regulatory Compliance

Design Group is a leading supplier of quality and compliance consulting services for the medical device industry. Our clients benefit from our expertise in Quality Management Systems, Risk-Based C&Q, Auditing, Packaging and UDI, and our support of more substantial concerns including Adverse Events, Recalls, Inspections, and Remediation.

Industry experienced professionals provide engineering and compliance solutions that are built into the project lifecycle by using elements of Quality by Design in project/product master planning, specification development, risk assessment, design control, equipment commissioning and qualification, process validation, and Design V&V activities.

Our proven approach employs science and risk-based methodologies to deliver flexible and diverse solutions to meet each client's unique needs. Our professionals understand both the quality culture and documentation requirements needed to mitigate potential findings and remediate observations.

Design Group's recognized industry experience and partnerships with many world-class organizations, provides the unique perspective and knowledge to simplify and streamline your compliance strategy.

Our Services

- Equipment/Facility Commissioning & Qualification
- Sterilization, Cleaning & Process Validation
- Design V&V & Design Transfer
- Auditing
- Quality Management Support
- Regulatory Consulting
- Final Product Packaging & Unique Device Identifiers

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Regulatory Compliance

- MDD/MDR & IVDD/IVDR Migration
- MDSAP Certification Support
- 510K/PMA Filing Support
- Organizational Change Management
- Change Notifications
- CE Marking

Equipment/ Facility Commissioning & Qualification

Design Group professionals provide efficient and effective GxP solutions that align with the latest science and risk-based approaches used in industry, including ASTM E2500, GHTF, GAMP 5, and ISPE. Professional services include validation planning, risk assessments, development and execution of technical studies, configuration management, and equipment troubleshooting for facility, utility, and process systems.

Sterilization, Cleaning and Process Validation

We deliver Validation services with a technical understanding of processes, compatibility, cross contamination, risk mitigation, sampling requirements, techniques, and method development. We use multivariate analytical (MVA) tools and apply statistical process control practices and/or process analytical technology (PAT) to design and implement the most compliant and complete solution.

Design V & V and Design Transfer

Our professionals support the development of project plans, ensuring the client's requirements are properly defined and managed throughout the Design to Manufacturing Transfer process. We help develop technically sound design requirements and ensure the requirements are properly assessed and implemented for regulatory notifications, Design History Files, Device Master Records, Device History Files, production procedures and quality records to allow for successful testing of the process outputs.

Auditing

Design Group's auditing services support a wide range of regulations, standards and industries including FDA, ISO, EU, and corporate standards across for medical device establishments. Our ASQ certified auditors and national presence are key to our ability to provide multi-site and vendor auditing services in a growing global economy. These coupled with our process and product understanding allow for the implementation of effective vendor control and internal auditing programs.

Quality Management System Support

Design Group delivers consulting services for quality management systems review, implementation and harmonization projects, offering insight to current regulatory environments, recent trends, and techniques for continuous improvement to ensure continuous compliance. Our teams support management and development of quality programs including electronic quality management systems, deviations, CAPAs, and integrated change control programs.

Regulatory Consulting

We offer regulatory compliance services supporting product compliant handling, recall management, risk mitigation plan development, regulatory notifications, annual product reviews and other regulatory service needs.

Final Product Packaging & Unique Device Identifiers

Design Group offers a unique and extensive packaging integration heritage and first in class design, integration and implementation packaging, labeling, and UDI solutions. Our industry seasoned professionals leverage their knowledge and experience in program/project management, supplier relationships, automation and controls, procurement, installation management and validation to provide turn-key management of final product packaging and UDI solutions.

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.