



Quality and Compliance Practice

Validant understands that compliance with the FDA's Quality Systems and GxP regulations are of the utmost importance. We help companies comply with these vast and ever-changing quality and regulatory standards.



Key Focus Areas

Validant's quality compliance professionals assist our clients with Quality Management Systems in a variety of areas. Our consultants serve as subject matter experts and team leaders as well as providing hands-on tactical support.

Leadership

Validant has participated in various large scale quality systems projects for Fortune 500 companies. Validant provided leadership including project managers and subject matter experts in the areas of CAPA management, clinical compliance, and quality audits. We have experience with a variety of audit types including FDA, third party EU audits, corporate internal audit programs, as well as Supplier audit and Clinical Trial Site audits. Validant professionals help clients to achieve full regulatory compliance. They know the regulatory requirements of CFR parts 11, 210, 211 and 820, ISO 13485 and ISO 14971.

Expertise

Our consultants have led the successful remediation of multiple CAPA initiatives – driving a backlog of CAPA's to completion through rigorous investigation and timely completion of the CAPA report. Our auditors helped our clients to develop and deploy robust internal audit programs that help assure successful regulatory audits. They are adept at creating and implementing audit programs, from the audit policy, to the master audit schedule, and on to execution of audits and resolution of audit findings.

Partnership

Whether your organization is in need of occasional support from an experienced industry professional or is looking to ramp up for key projects, Validant is ready to deliver the expert talent you need. We invite you to learn more about our solutions and how we can become your trusted resource provider.

Key Areas of Focus:

- Clinical Operations
- FDA 483 and Warning Letter Action Plans and Remediation
- Corrective and Preventative Action (CAPA) Systems
- Auditing and Gap Analysis (QSIT, GXP, ISO)
- Methods and Process Validation
- Supplier Assessment, Management and Improvement

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