



Life Sciences
Solutions™

Validation and Compliance Services

Meeting the need for cost-effective 21 CFR Part 11 solutions

Overview

The FDA's 21 CFR Part 11 regulation mandates the use of electronic records and signatures by all companies using computer systems to produce or distribute FDA-regulated products. Today, in view of the FDA's intention to limit enforcement using a risk-based approach, many regulated companies are evaluating the conduct of their own projects to meet compliance objectives.

Surveys report that a substantial percentage of life science firms continue to identify GxP critical systems requiring remediation and validation. And in most cases, the internal resources needed to assess systems, develop remediation plans, and deliver solutions are in short supply.

A life sciences company must invest millions of dollars in achieving regulatory compliance while simultaneously continuing to develop new products and maintain profitability. At the same time, those regulatory requirements—including 21 CFR Part 11—have introduced complex technologies and procedures into every facet of the business. With your company resources at a premium, CTG's cost-effective and timely approach to identifying critical systems using our risk assessment methodology and delivering validation services and solutions enables your business to attain compliance while continuing its progress toward corporate goals. We've implemented validated computer systems for North American and European life sciences clients for over eight years, and a growing number of life science

companies are turning to us for support of their 21 CFR Part 11 efforts.

CTG's 21 CFR Part 11 implementation specialists have international expertise in life-cycle software development, GxP validation, and the management of validation documents. They provide a full range of compliance services for:

- Research and development
- Clinical trials
- Manufacturing
- Marketing and sales

CTG Uses Your Approach

CTG understands that your company's interpretation of the 21 CFR Part 11 regulations defines your approach to achieving compliance. We transition our team to work in your environment alongside your own professionals. We follow your internal procedures, methodologies, and business processes, and we use your templates. Our delivery experts work with you to develop a services plan and training program that ensure that we start the job—and complete it—while adhering fully to your approach.

Need help developing an approach? Our specialists have the wide experience and flexibility needed to create the necessary processes, templates, procedures, and training programs. In fact, we can deliver a full-service, turn-key compliance solution.



CTG Manages the Resources

CTG can provide resources on a staffing basis to support your projects or manage our team onsite to guarantee the quickest possible response to any requirements that may arise for additional validation experts, technical writers, software developers, and testers. Our 38 years of experience in mobilizing, training, and managing highly-skilled IT staff ensures not only the optimal approach, but a wide range of cost efficiencies for your validation and remediation project. Conformance to your requirements is additionally assured through our Service Quality Assessment, which is administered at the end of every project.

CTG Delivers the Solutions

CTG offers a variety of options to support your compliance initiatives, including:

- System risk assessment
- System and Instrumentation validation
- Supplier audits and technology selection
- Inventory and prioritization of GxP critical systems
- Assessment of GxP systems for 21 CFR Part 11 compliance
- Development of replacement/remediation plans
- Delivery and validation of replacement/remediated systems
- Complete lifecycle management of individual projects
- Program management
- Application support of non-compliant systems while compliant replacement systems are developed

CTG's Commitment to Quality

CTG ensures the consistent delivery of the highest-quality services through proprietary best practices formally defined in our global quality system. CTG is among the first in our field to have designed and implemented a comprehensive Total Quality Management (TQM) program. Our program, called Innovations in Quality (IQ), guides our employees worldwide in qualifying opportunities, delivering projects on time, hiring the right professionals, and ensuring that client requirements are fully satisfied. IQ has been certified or assessed to meet international quality standards, including:

- **ISO 9001:2000:** Part of a series of quality management and quality assurance standards published by the International Organization for Standardization. Our quality system is registered to ISO 9001 worldwide, and its implementation is formally assessed every year by an independent auditor, the Bureau Veritas Quality International (BVQI).
- **Software Engineering Institute's Capability Maturity Model (CMM):** A method for evaluating the maturity of a software development organization. On a scale of 1 to 5, CTG's software development practices have been independently assessed to level 3, an accomplishment that is achieved by only 17% of companies applying for a formal assessment.

Backed by 38 years' experience, CTG provides IT staffing, application management outsourcing, consulting, and software development and integration solutions to help Global 2000 clients focus on their core businesses and use IT as a competitive advantage to excel in their markets. CTG combines in-depth understanding of our clients' businesses with a full range of integrated services and proprietary ISO 9001:2000-certified service methodologies. Our 2,700 IT professionals based in an international network of offices in North America and Europe have a proven track record of delivering solutions that work.

More information about CTG is available on the Web at www.ctg.com.



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Two NorthShore Center, Ste. 110
Pittsburgh, PA 15212-5838
Phone: 412/323-8600
Fax: 412/323-8088
www.ctg.com