CTG

REGULATORY COMPLIANCE

GxP Compliance

The main objective of GxP regulations is to ensure patient safety when performing clinical studies or when using pharmaceutical products and/or medical devices. Validation plays a critical role in achieving this objective. Whether you are a start-up company in need of professional expertise to set up and implement a business model for Quality, Validation, and Compliance, or a big life sciences company in need of resources to execute and manage validation and compliance projects, CTG Regulatory Compliance (RC) is fully equipped to get the job done and satisfy your expectations.

OUR SERVICES

Our services are based on lean, scalable, risk-based, and agile concepts, all following the latest standards in the market.

Regulatory Compliance Consultants

Our consultants are the cornerstone of our organization. We invest in the personal training and competence development of our professionals since they are critical to our business, and therefore to your business.

GxP Compliance Services

To accommodate your organization to meet GxP compliance, we offer a variety of GxP Compliance Services:

Compliance Assessment and Remediation will give you a full, detailed picture of compliance gaps and weaknesses, and a roadmap to address shortcomings.

Vendor Audits will allow you to obtain a full compliance picture of your business partner by identifying the risks that can impact your business.

Agile Computer System Validation, being our core service, will ensure the validated state of your entire system landscape. The basic principles and concepts described in this service are also applied to the following validation services:

- **ERP/SAP Validation** leverages ERP/SAP knowledge and documentation to enhance validation.
- **Outsourced Spreadsheet Validation** takes full ownership of your spreadsheet validation. We quickly analyze, remediate, and validate your spreadsheet.

IT Infrastructure in a Controlled Environment helps you realize a secure/easily maintainable IT infrastructure that supports the high level of data integrity, availability, and confidentiality required by regulated environments.

Equipment Qualification enables us to qualify a wide range of your laboratory and manufacturing equipment according to the latest standards.

Agile Methods in software development, such as Scrum, increasingly dominate the classic waterfall and V-model approaches, to which Computerized System Validation has been oriented. CTG can provide Scrum development team members, fully trained on Compliance and Validation, who can operate in a regulated environment.

Training based on your specific needs and requirements will help your organization get a better understanding of compliance topics. Training programs feature workshops, business cases, and simple tests to facilitate the learning objectives.

Coaching provides you with a lasting quality experience through coordination, management, and control of your validation and quality projects to ensure compliance within the expected level of quality, time, and budget.

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ISO 27001

GxP compliance also implies safeguarding the confidentiality, integrity, and availability of your data. The implementation of an Information Security Management System (ISMS) based on the ISO 27001 framework will provide a solid basis for your organization's data integrity and security program. This also prepares your company to achieve globally recognized certification to boost the market's trust in you.

Commitments

We Commit

- Successful FDA and EU inspections
- Significant reduction of validation time, effort, and cost

We Care

Our commitment to long-lasting compliance through our free hyper-care program:

- No-cost remediation of major issues after inspection, within the scope of our work
- On-call assistance during inspections
- We promise you one day of free-of-charge aftercare, within the first year after services were completed, to assess the validated state of the system and provide recommendations.

GDPR Compliance Services

We also offer General Data Protection Regulation (GDPR) Compliance services. GDPR became effective on 24 May 2016. Its major purpose is to protect personal data of individuals in the EU and provide them with the necessary means to exercise their rights to manage their personal data. If you are interested in our service offerings concerning GDPR Compliance, please request a GDPR Compliance flyer, which will provide you with an overview of our services.

Contact Us

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About CTG CTG (NASDAQ: CTG) is a leading provider of digital transformation solutions and services that accelerate clients' project momentum and achievement of their desired IT and business outcomes. We have earned a reputation as a reliable, results-driven partner focused on improved data-driven decision making, meaningful business performance improvements, new and enhanced customer experiences, and continuous innovation. CTG has operations in North America, South America, Western Europe, and India. The Company regularly posts news and other important information online at www.ctg.com.

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