Regulatory Compliance

GxP Compliance

Reliability Matters

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 all of the compliance gaps and weaknesses, as well as a roadmap to address or close the 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 the validation of your spreadsheets. We analyze, remediate, and validate your spreadsheets in no time.

IT Infrastructure in a Controlled Environment helps you to realize a secure and easily maintainable IT infrastructure that supports and sustains 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.

We also offer GDPR Compliance services:

The General Data Protection Regulation (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.

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.

Contact Us

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Published by Computer Task Group, Inc.

Backed by more than 50 years of experience, CTG (NASDAQ: CTG) has a proven track record of reliably delivering high-value, industry-specific staffing services and solutions to its clients, including IT staffing, application management outsourcing, consulting, and software development and integration solutions. CTG combines in-depth understanding of our clients' businesses with a full range of integrated services and proprietary ISO 9001:2000-certified service methodologies. CTG has operations in North America, Western Europe, and India. The company regularly posts news and other important information online at www.ctg.com.

 Rev. 05/19