SUSTAINABILITY COMPLIANCE.

21 CFR PART 11

PCGSERVICES.COM
**THE CHALLENGE**

Staying current with best practices is good business. When working with the FDA, good practices are the law.

For companies that rely on technology for product, services and systems.

Compliance with FDA regulations takes rigorous understanding, testing and validation to ensure lowered business risk and cost. This is especially true in companies driven by technology.

**FDA 21 CFR PART 11 OVERVIEW**

The Food and Drug Administration (FDA) has established specific regulations for drug makers, medical device manufacturers, biologic developers and contract research organizations (CROs) that requires implementation controls, documentation and audit traceability for software and systems involved in processing electronic information.

Implemented in 2003, Part 11 specifically defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable and the equivalent to paper records.

Current information architectures and technology integration increasingly makes Part 11 (Electronic Records; Electronic Signatures) an extremely high priority for companies that must meet regulatory compliance requirements.

**THE REQUIREMENT**

To put it plainly, companies must be compliant with regulations or risk breaking the law—which leads to fines, increased business cost and reputational damage.

To ensure compliance, companies must undertake and complete the following:

- **Risk Assessment**: Discovery of GxP critical and business critical compliance risk areas
- **Test Strategy**: Identifying the tasks, leadership, objectives and metrics scope
- **Validation Planning**: Determining the business processes, platforms and technology to be tested
- **Compliance Testing**: Auditing and testing practices and processes, platforms and technology for regulatory requirement compliance
- **Record Retention**: Documenting strategies, tested platforms, technologies and processes, resultant actions and validation outcomes and a compliance scorecard for future audit needs

**THE TARGETS**

- Medical Device Manufacturers
- Life Sciences Companies
- Biotechnology Companies
- Pharmaceutical Companies
PCG has recognized the need to ensure 12 CFR Part 11 compliance for its customer clients’ businesses. As a result, PCG has created a SUSTAINABILITY\textsuperscript{FDA} solution offering that covers four key areas that lead to FDA 21 CFR Part 11 compliance:

- **RISK ASSESSMENT**
  - Initial Risk Assessment
  - Technical Risk Assessment
  - Detailed GxP Risk Assessment
  - Determination of Risk Likelihood
  - Conducting the Risk Assessment
  - Documenting Risk Assessment
  - A Risk Mitigation Plan

- **STRATEGY & PLANNING**
  - Testing Approach Strategy
  - Validation Methodology
  - Testing Activity Lists and Ownership
  - Test Script Development
  - Process & Data Migration
  - Development
  - Installation Qualification
  - Operational Qualification
  - Performance Qualification
  - Constraints Testing
  - Incident Logging
  - Outcomes Documentation

- **TESTING & VALIDATION**
  - Assessment, Strategy, Planning, Testing and Acceptance Criteria
  - Control and Operational Procedures
  - GxP Compliance
  - Design Compliance
  - Technical Compliance
  - Installation Compliance
  - Operational Compliance
  - Performance Compliance
  - Change Management & Version Control Compliance
  - Traceability Matrices
  - Compliance Certifications
  - Quality Management Training

- **DOCUMENTATION & REPORTING**
  - Assessment, Strategy, Planning, Testing and Acceptance Criteria
  - Control and Operational Procedures
  - GxP Compliance
  - Design Compliance
  - Technical Compliance
  - Installation Compliance
  - Operational Compliance
  - Performance Compliance
  - Change Management & Version Control Compliance
  - Traceability Matrices
  - Compliance Certifications
  - Quality Management Training

The solution is designed to take into account the unique attributes found in SaaS, “pay-as-you-go” and cloud-based technology platform environments by covering these specific topics:

PCG’s SUSTAINABILITY\textsuperscript{FDA} solution adds value to the sales process, accelerating deal closure.

**ADDITIONAL OPPORTUNITY**

PCG’s SUSTAINABILITY\textsuperscript{FDA} solution is applicable to these expanded sales opportunities:

- 21 CFR Part 58 (Good Laboratory Practice)
- 21 CFR Part 110 (Food Good Manufacturing Practice)
- 21 CFR Part 210/211 (Drug Good Manufacturing Practice)
- 21 CFR Part 312 (Investigational New Drug Application)
- 21 CFR Part 314 (New Drug Approval)
- 21 CFR Part 600/601/610 (Biologic Industry)
- 21 CFR Part 606 (Blood Industry)
- 21 CFR Part 700/701 (Cosmetic Industry)
- 21 CFR Part 820 (Medical Device Industry)

Confidently sell and solve prospect and customer compliance challenges by adding PCG to your NetSuite sales and implementation team.

**GO FROM ZERO TO COMPLIANCE IN ABOUT 12-16 WEEKS**