

SUSTAINABILITY COMPLIANCE.

21 CFR PART 11

FDA



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COMPLIANCE. DONE RIGHT.

Peace of mind for medical device, pharmaceutical and biotech companies through 21 CFR Part 11, Part 211 and Part 820 regulatory assessment, testing and validation.

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.

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

ENSURING 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

TESTING & VALIDATION

- Process & Data Migration
- Development
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Constraints Testing
- Incident Logging
- Outcomes Documentation

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

DESIGNED FOR BUSINESSES THAT RELY ON TECHNOLOGY, SAAS OR "PAY AS YOU GO" PLATFORMS AND STANDARDIZED GXP PROCESSES WHO REQUIRE RIGOROUS AND ACCOUNTABLE REGULATORY COMPLIANCE.

GO FROM ZERO TO COMPLIANCE IN ABOUT 12-16 WEEKS

COMPLIANCE | CONFIDENCE | PEACE OF MIND

