

TECHNOLOGY COMPLIANCE.

Increased regulatory pressures and internal governance requirements demand a new path for technical and enterprise compliance. The old ways just don't work any more.

THE CHALLENGE.

Staying current with regulatory changes, internal security and information governance protocols and requirements for technology validation and compliance is hard work.

It's estimated that regulatory costs will go up by 200% in the next several years, creating unanticipated expense for businesses.

Old compliance models and tools are ill-equipped to meet an ever-changing compliance requirement.

THE REQUIREMENT.

Whereas in the past compliance was largely seen as a periodic "one and done" exercise, today's compliance needs are ongoing and real-time.

Compounding the issue is the adoption of new technologies, creating opportunities for business risk due to poor compliance data quality and a lack of standardization. Today's compliance requires:

- Risk Assessment: Discovery of GxP critical and business critical compliance risk areas
- <u>Test Strategy</u>: Identifying the tasks, leadership, objectives and metrics scope
- <u>Validation Planning</u>: 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
- <u>Record Retention</u>: Documenting strategies, tested platforms, technologies and processes, resultant actions and validation outcomes and a compliance scorecard for future audit needs

KEEPING YOU COMPLIANT.

PCG offers a cost-effective way to ensure technology compliance and keep you out of trouble.

- · 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 &

DOCUMENTATION & REPORTING

ASSESSMENT

- Testing Approach Strategy
- Validation Methodology
- Testing Activity Lists and Ownership
- Test Script Development
- Process & Data MigrationInstallation Qualification
 - Operational Qualification
 - Performance Qualification
- · Constraints Testing
- Incident Logging
- Outcomes Documentation
- 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

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