

# 21 CFR Part 11 Compliance Regulatory Compliance Services

## Electronic Records; Electronic Signatures

### Meeting regulatory compliance requirements through strategic initiative programs

Regulatory compliance services and solutions address your 21 CFR Part 11 concerns as well as business issues impacted by this regulation. Our expertise helps to lower your project risk and provides the essential information needed for implementing compliance programs.

### Here's how our Compliance Services can work with you...

- Design and execute 21 CFR Part 11 compliance programs
- Review/write corporate policies and guidelines
- Provide on-site training for compliance
- Institute procedural control systems
- Provide system assessment and gap analysis
- Generate and manage remediation programs
- Execute and manage remediation projects
- Provide ongoing life cycle services to maintain the compliance status
- Manage Global Programs

### A Risk-based 21 CFR Part 11 Compliance Program

In order to ensure compliance with regulatory requirements, a formal company wide 21 CFR Part 11 Compliance Program is required. This program should include a stepwise methodology for the assessment and remediation of all applicable computerized systems. This program should describe the company's roadmap to compliance.

- Ensure corporate policies address all compliance issues
- Develop and execute company wide Part 11 training program
- Build a 21 CFR Part 11 compliance team
- Establish a company specific 21 CFR Part 11 interpretation
- Develop a company compliance program and plan with a reasonable schedule
- Execute the compliance program in accordance with the plan. For example, the plan should comprehend for each site of the company at least the following tasks:
  - Update SOPs system addressing part 11 specific requirements
  - Write SOPs that clarify which records are replacing paper records
  - Identify systems by site
  - Define the company's risk based assessment and validation status
  - Develop system remediation plans
  - Implement system remediation plans (technical and procedural)

## What is FDA's current thinking regarding 21 CFR Part 11?

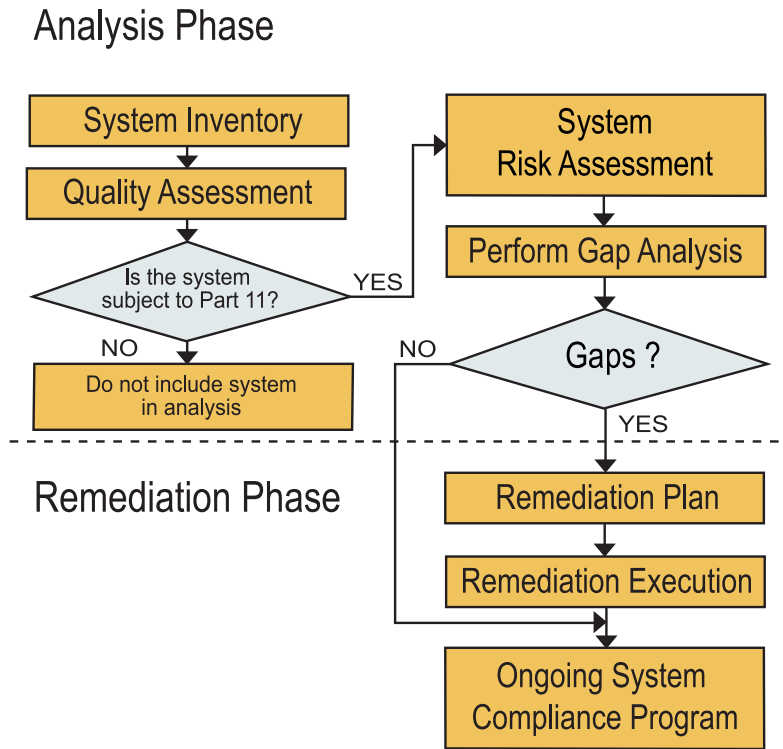
FDA is embarking on a re-examination of Part 11; while re-examination is under way, FDA will...

- Narrowly interpret the scope of Part 11
- Enforce predicate rule requirements for records subject to Part 11
- Continue to enforce certain provisions of Part 11
- Exercise enforcement discretion with respect to Part 11
- Not normally take regulatory action to enforce compliance of legacy systems with respect to specific Part 11 requirements

Excerpts from FDA Guidance for Industry, Part 11, Electronic Records; Electronic signatures – Scope and Application

# Recommendations for Achieving Compliance

## 21 CFR Part 11 System Compliance Strategy



## Deliverables

Typical deliverables for 21 CFR Part 11 compliance services include:

- Risk assessment strategy
- Compliance policies and guidelines
- System inventory lists and gap assessments
- System specific recommendations plans
- Overall remediation project plans
- Quality- and project plans
- Final project reports
- Supplier audit reports
- Company specific training documents
- Document templates
- SOP for company specific Part 11 interpretation
- SOP for record retention and producing electronic copies
- SOP for purchasing and development of new systems
- SOP for classification of company specific GxP records

[www.propack-data.com](http://www.propack-data.com)

[www.rockwellautomation.com](http://www.rockwellautomation.com)

### Corporate Headquarters:

Rockwell Automation, 777 East Wisconsin Avenue, Suite 1400, Milwaukee, WI, 53202-5302 USA, Tel. (1) 414 212 5200, Fax (1) 414 212 5201

### Headquarters for Allen-Bradley Products, Rockwell Software Products and Global Manufacturing Solutions

Americas: Rockwell Automation, 1201 South Second Street, Milwaukee, WI 53204-2496 USA, Tel. (1) 414 382 2000, Fax (1) 414 382 4444

### Headquarters for Dodge and Reliance Electric Products

Americas: Rockwell Automation, 6040 Ponders Court, Greenville, SC 29615-4617 USA, Tel. (1) 864 297 4800, Fax (1) 864 281 2433

### Headquarters Worldwide for Propack Data, A Rockwell Automation Business

Propack Data GmbH, Vincenz-Priessnitz-Str. 1, 76131 Karlsruhe, Germany, Tel. (49) 721 9650-6, Fax (49) 721 9650-888, [propack-data@ra.rockwell.com](mailto:propack-data@ra.rockwell.com)

Headquarters for Americas, 2000 Regency Parkway, Suite 675, Cary, NC 27511 USA, Tel. (1) 919 465 1741, Fax (1) 919 465 1742

Headquarters for Asia Pacific, Rockwell Automation, 55 Newton Road, #11/02 Revenue House, Singapore 307987, Tel. (65) 6356 9077, Fax (65) 6356 9011