

# Kinetiq Data Protection and Compliance Service—Part 11

## Is your organization prepared for a Part 11 audit?

**Did you know that certain clinical trials management systems, mHealth mobile applications, IRB administration systems, and electronic regulatory binders are subject to 21 CFR Part 11?**

With the growing prevalence of technology in research, compliance with Part 11 is increasingly critical, but many organizations aren't aware that they're required to be Part 11-compliant.

**Kinetiq experts can walk your organization through the steps needed to build a risk-based Part 11 program**, bring your operations into compliance, and maintain compliance going forward.

## Non-Compliance is Costly—Where Does Your Organization Stand?

Organizations that are non-compliant risk FDA citation or may even be forced to halt operations.

Take advantage of Kinetiq expertise to ensure your organization can continue to adopt technological solutions to clinical trials management challenges.

### Common Approach to Part 11 and HITECH



Education



Assessment



Remediation

## Training and Education

**Did you know that Part 11 training is required by 21 CFR 11.10(i)?**

Kinetiq has developed an industry-specific training curriculum that will prepare your organization for the rigors of Part 11 compliance. The training covers all aspects of Part 11 preparation and compliance, as well as sample assessment documents.

## Part 11 Mock Inspection

Kinetiq will take your organization through a rigorous mock inspection to reveal any gaps in compliance before an inspector does. This includes utilizing a proprietary framework to review and evaluate security policies, procedures, and controls. The key deliverable is a detailed report outlining your level of compliance with the Part 11 framework, and recommendations for remediation, as applicable.

## Remediation

Based on the outcome of the Part 11 Mock Inspection report, Kinetiq will recommend a strategic partner from our independent consultant network who works with your organization's specific needs.

**Your Kinetiq consultant will provide a road map to filling any compliance gaps**, including development of robust processes and staff training.

## Move at the Speed of Kinetiq

Connect with us today to find out how we can move your organization forward.

Contact us at [info@KinetiqIdeas.com](mailto:info@KinetiqIdeas.com) for more information.