Consulting™

Data Protection & Compliance Services

Ensure your organization is prepared for a Part 11 audit

Did you know that certain clinical trial 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.

Training and Education

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

Advarra 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

Advarra will take your organization through a rigorous 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.

Non-Compliance Is Costly—Where Does Your Organization Stand?

Organizations that are noncompliant risk FDA citation or may even be forced to halt operations. Take advantage of Advarra® expertise to ensure your organization can continue to adopt technological solutions to clinical trials management challenges.

Remediation

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

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

Is your organization prepared for a Part 11 audit?
Contact Consulting@advarra.com to get started.

ADVARRA™

advarra.com