EDC | eREG

Reduce System Validation Burden with Advarra Technology Validation Support

At Advarra, we're committed to setting up our customers for success in the highly regulated clinical research environment. This includes providing resources and expertise to ensure 21 CFR Part 11 validation at your organization. While validation is ultimately the responsibility of the implementing organization, we aid your path towards validation within our Part 11-compliant systems, Advarra EDC and Advarra eReg. Our approach ensures rapid time to value through implementation, integration set-up, validation, and migration to establish a validated, centralized source for your data and documents.

Benefits Summary		
	Building a Compliant Foundation	
	Experienced Implementation Staff	Validation Specialists
	SOP Evaluation	Validation Documentation Development
	Supporting Your Unique Workflows	
	SOP Development	Configuration Specifications
	User Requirements (URS)	Traceability Matrix
	Reducing Validation Time and Cost	
	Validation Plan	Traceability Matrix & Test Suite Approvals
	Installation Qualification Report, Scripts	Operation Qualification Report, Scripts
	User Acceptance Testing (UAT)	Executed Test Suites
	Validation Summary Report	
	Ensuring Process Understanding	
	Weekly Implementation Meetings	Self-Paced Video Trainings
	Learning Modules	Training Documentation
	Maintaining Your Validated State	
	Change Control Information	Vendor SOPs
	Upgrade eLearning Modules	Updated System Validation Packet
	Risk Analysis	Validation Summary Report
	Release Impact Assessment	Sandbox Environment

Why Validate with Advarra?

Reduce Initial Validation Burden and Costs

Advarra will staff your project with implementation and validation professionals that have experience in guiding research teams of all sizes through validation, training, and successful go-lives'. Key materials like Advarra's core Validation Packet, as well as supporting materials like SOPs and customer templates are also provided to aid and reduce your testing burden.

Maintain Validation and Ensure Audit Confidence

Our validation tools and resources prepare your organization to maintain your validation with each new Advarra eReg and Advarra EDC upgrade. This includes extensive release notes, release highlights, an updated validation packet, and access to updated templates. By supporting diligent documentation updates and training, your organization will feel confident if audited by the FDA.

Validation Process

Implementation

Building a compliant foundation

To achieve a validated system, it is best to understand your organization's current workflows and how your organization plans to use the system. Our team at Advarra will answer all your questions regarding what steps your site needs to take to successfully validate your Advarra system to the CFR Title 21 Part 11 provisions, guidance, and requirements during implementation.

This includes an evaluation of your policies and procedures, collaboration on sustainable workflows, development of validation documentation for your organization, and development of processes to allow you to maintain your Part-11 compliant system in a validated state for each new protocol build and upgrade.

SOPs and Customer-Specific Templates

Supporting your unique workflows

To assist your validation efforts, Advarra provides templates for required processes and procedures which we will update together to specifically serve your organization. Examples of templates provided include standard operating procedures, configuration specifications, user requirements, a traceability matrix, and more.

Validation Templates and Materials

Reducing validation time and cost

The initial validation also includes the Advarra Validation Packet, which supplements your validation documentation and reduces the amount of testing and staff time needed to complete your validation. The Validation Packet includes a validation plan, traceability matrix and test suite approvals, installation qualification report, executed test suites, and a validation summary report.

Validation Process (Cont.)

Training and eLearning

Ensuring process understanding

To validate and maintain a validated state, all users must understand and comply with the outlined SOPs. To ensure understanding of processes and to train consistent and intended usage of the system, Advarra provides extensive training materials and virtual sessions.

ADVARRA University™

During implementation, Advarra's implementation staff will dedicate weekly meetings to walk through key workflows and practice key activities in the system. Available throughout implementation and beyond, your organization will also have access to self-paced video trainings, learning modules, and training documentation in the Advarra eLearning Management System to support new users and ensure sustained compliance.

Continued Vendor Support

Ensuring process understanding

Advarra supports your organization beyond initial implementation and provides you with the tools and confidence to maintain validation moving forward through change control, SOPs, and more. For each release, Advarra provides an upgrade walkthrough via our eLearning modules. In addition, Advarra provides an updated system validation packet, with a risk analysis of new features/functionality, and a validation summary report.

From updated documentation to templates that reduce testing burden and instill confidence in your system, Advarra supports your organization's long-term operations and compliance.

Additional Support and Collaboration

Join Product Collaborations

Provide input on upcoming Advarra technology features and functionality.

Engage on our Onsemble Community Forum

Discuss technology, operational strategy, and more with fellow community members.

If your team has questions at any time, either during the validation process or after the system has been upgraded, we are here to help.

Contact your Advarra Customer Relationships Team representative to learn more.

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