Simplify Compliance and Maintain Arena Validation

Spend less time validating Arena with our complete package of requirements, impact analysis, protocols, execution records, reports, and validation knowledge base experts.

We understand how disruptive change can be in your compliance environment. However, software applications must be upgraded to meet your expanding business requirements, new technology, and industry demands. Arena VMS enables you to spend more time on your core competency—and less on validating third party business applications. With VMS, you can work faster to meet compliance requirements the first time with system implementation. And, you continue to benefit from validation service with every future software release, allowing you to re-validate your Arena system with minimal disruption.

Who Benefits
Quality Assurance and Regulatory Managers
Partner with Arena’s validation experts and leverage our comprehensive validation methodology. Whenever Arena introduces a new software release, you will receive an updated documentation package to complete the latest Arena system validation. Faster system validation gives you greater peace of mind while reducing costs.

Executive Management
Be confident that your team has the necessary documentation to validate your Arena system. With Arena, you receive a modern, quality management solution that is easy to validate. Arena VMS enables you to benefit from continual innovation and software solution enhancements without fearing long, costly, or difficult validation processes.

Over 100 medical device customers rely on Arena VMS to quickly complete Arena software validation. Arena has provided successful validation for over a decade.

Validation Team
Arena VMS reduces the validation burden placed on your team. Our team validates the Arena application against predefined requirements (intended uses as defined by Arena), allowing your team to review our validation scope and supplement your validation with additional unique intended uses. With VMS, you also avoid all the technical, system-level testing required for traditional on-premises applications.

Deliverables
- A comprehensive set of validation documentation including requirements, impact analysis, test plan, protocols, execution records, traceability, and reports for use as objective evidence of software validation
- Advance Arena release notifications containing risk assessment and impact analysis with respect to validation and updated validation requirements
- Validation documentation generated, updated, and shared with each new Arena release
- Senior validation expert assistance with Arena application validation questions and concerns, including best practices and templates

Key Benefits
- Reduces time and costs associated with developing and executing test cases
- Provides customer time to evaluate the scope of upcoming release to assess the impact—no surprises on Arena releases
- Continuing benefits of validation documentation for on-going Arena releases
- Ensures ongoing validation support

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A Closer Look at our Validation Package

Software validation can be challenging when starting from scratch. Arena VMS is a proven, detailed validation package where we do most of the work, leaving you to review Arena validation scope, determine your unique intended uses, and supplement the validation package with such unique use cases.

VALIDATION DOCUMENTATION PACKAGE
- User Requirements Specification (URS)
- User Requirements Traceability Matrix
- Software Modification Validation Impact Analysis
- Installation Qualification (IQ) Validation Protocols
- Operation Qualification (OQ) Validation Protocols
- Validation Test Plan
- Installation Qualification (IQ) Protocol Execution Records
- Operation Qualification (OQ) Protocol Execution Records
- Validation Report
- Serious Incident Report
- Validation Certificate

21 CFR Part 11 Part 820 Regulations

Arena helps medical device companies meet 21 CFR Part 11 and Part 820 regulations. We enable compliance by offering an application designed to contain the required technical elements of a compliant system. Arena includes the critical elements of change and document management, design control process (DHF/DMR), electronic records, electronic signatures, and quality management.

Improve Company Performance Today

Arena VMS makes validation a snap. So, start using Arena today and let us lighten the burden of validation.

To find out how you can join our community of innovative customers, contact sales@arenasolutions.com or call 1.866.937.1438