



# ARENA VALIDATE

Complete Validation Quickly

## SIMPLIFY FDA SOFTWARE COMPLIANCE

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



**PACKAGED  
SIMPLICITY**



**DOMAIN  
EXPERTISE**



**ONGOING  
SUPPORT**

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 Validate enables you to spend more time on your core competency—and less on validating third-party business applications. With Arena Validate, you can work faster to meet compliance requirements the first time with system implementation. And, you continue to benefit with every future software release, allowing you to re-validate your Arena system with minimal disruption.

DELIVERABLES	KEY BENEFITS
<ul style="list-style-type: none"> <li>✓ 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</li> </ul>	<ul style="list-style-type: none"> <li>• Reduces time and costs associated with developing and executing test cases</li> </ul>
<ul style="list-style-type: none"> <li>✓ Advance Arena release notifications containing risk assessment and impact analysis with respect to validation and updated validation requirements</li> </ul>	<ul style="list-style-type: none"> <li>• Provides customer time to evaluate the scope of upcoming release to assess the impact—no surprises on Arena releases</li> </ul>
<ul style="list-style-type: none"> <li>✓ Validation documentation generated, updated, and shared with each new Arena release</li> </ul>	<ul style="list-style-type: none"> <li>• Continuing benefits of validation documentation for ongoing Arena releases</li> </ul>
<ul style="list-style-type: none"> <li>✓ Senior validation expert assistance with Arena application validation questions and concerns, including best practices and templates</li> </ul>	<ul style="list-style-type: none"> <li>• Ensures ongoing validation support</li> </ul>

## 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 Validate enables you to benefit from continual innovation and software solution enhancements without fearing long, costly, or difficult validation processes.

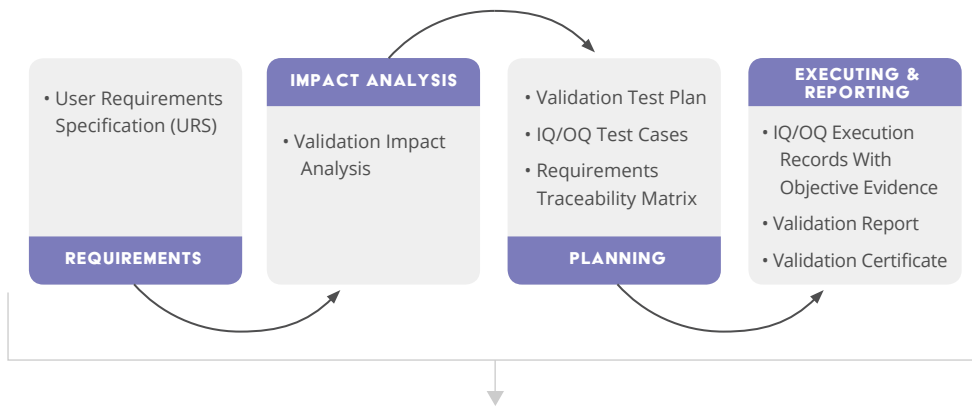
Over 100 medical device customers rely on Arena Validate to quickly complete Arena software validation. Arena has provided successful validation for over a decade.

### Validation Team

Arena Validate 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 Arena Validate, you also avoid all the technical, system-level testing required for traditional on-premises applications.

## ARENA VALIDATE: ALL THE CRITICAL ELEMENTS YOU NEED

Software validation can be challenging when starting from scratch. Arena Validate 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 Validate makes validation easy and eliminates the fear of upgrades. 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](mailto:sales@arenasolutions.com) or call 1.866.937.1438