

## Validation – Simplified Validate Arena Quickly with VMS



### Simplify compliance and maintain Arena validation:

**Spend less time with our complete package of requirements, validation protocols, execution records, reports, compliance knowledge and validation experts.**

A company faced with compliance requirements knows change is disruptive. However, systems must be upgraded, changed and grown to meet your expanding business needs, new technology and industry demands. Arena's Validation Maintenance Service (VMS) lets you spend more time on your core competency, not on validating third party business systems. With VMS, you do the work faster and easier to meet compliance requirements—the first time. Then, continue to benefit from validation documentation with every single release, allowing you to validate changes to your Arena system with minimal disruption.

Arena has been providing its comprehensive Validation Maintenance Service for over a decade. Hundreds of Arena VMS subscribers rely on this service to simplify validation and compliance.

Features	Benefits
<ul style="list-style-type: none"> <li>✓ A comprehensive set of required validation documentation including requirements, test plan, protocols, execution records, traceability and reports for use as evidence of software validation</li> </ul>	<p>Time. Money. Stress. Because soft dollar costs are still costs and time is critical to all businesses, our validation package saves the time and expense associated with devising and executing these tests. The result: a faster path to compliance.</p>
<ul style="list-style-type: none"> <li>✓ Validation documentation is updated with each new release of Arena</li> </ul>	<p>Not only do you benefit from the validation package the first time you validate the software, you continue to benefit with every release as we re-validate and provide an updated full documentation set.</p>
<ul style="list-style-type: none"> <li>✓ Ongoing validation support contact</li> </ul>	<p>Assistance from Arena's compliance team experts.</p>

### WHO BENEFITS

#### Quality Assurance and Regulatory Managers

Benefit from a partnership with Arena's validation expertise and complete validation documentation and methodology. When the system upgrades, the comprehensive documentation package takes you quickly through an updated Arena system validation. *Quicker and easier system validation, giving you peace of mind and reducing costs. All the necessary documentation needed to complete your validation in one place.*

#### Management

Know that your team has the necessary documentation package to validate your critical Arena system easier and faster. *Meet your compliance requirements with more ease by using the comprehensive VMS suite that includes documentation, services and expertise. Arena VMS results in fewer headaches, faster implementation, reduced overhead costs and streamlined compliance.*

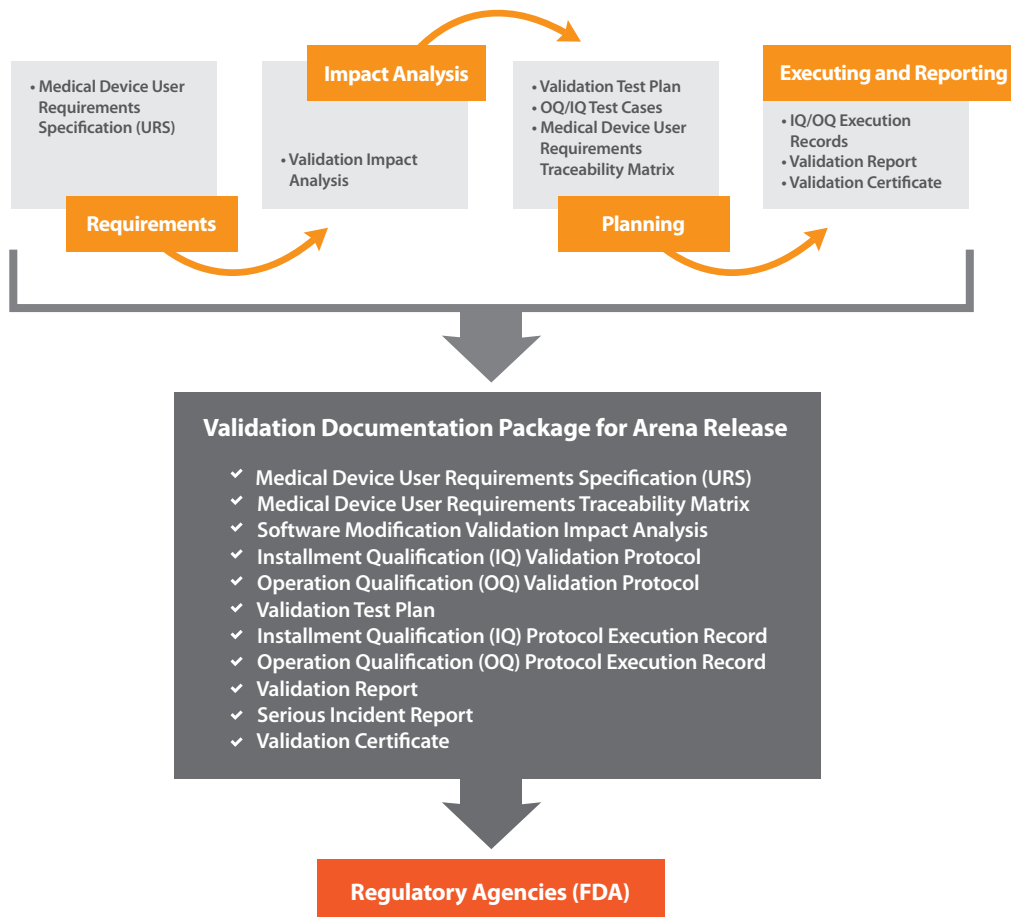
Numerous medical device companies utilize the Arena VMS to quickly complete system validations.

Arena validates software against a pre-defined set of intended uses.

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### HOW IT WORKS

If you have not yet been through a system validation effort or are new to Arena's Cloud solution, you might wonder what's behind the scene. The details make the difference.



*Arena has the inside information you need, made available every release.*

Because Arena is a subscription-based Cloud service, run from Arena-managed hardware with back-up and disaster recovery, your validation efforts are less costly.

With the VMS, you don't need to conduct all the technical system-level testing required for an on-site application. We do the validation testing for you and provide documentation and execution records for every release.

### Arena assists medical device companies in meeting 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. During the design input collection process and throughout the development and quality assurance processes, we keep you in mind – resulting in a product that meets functionality requirements for the change control process. Further, we document our software and environment with protocols, test cases and validation reports. Arena includes the critical elements of change and document management, design control process (DHF/DMR), electronic records, electronic signatures and quality management. Then, for every release thereafter, we complete the software validation cycle and update our VMS package. Let Arena deliver our Validation Maintenance Service so you can focus on delivering products that change the world.