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FDA Software Validation: How Cloud QMS Reduces Costs and Resource Drains

WHITE PAPER

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INTRODUCTION

Medical device companies must overcome many hurdles to get safe, high-quality products to market. While their primary objective—creating safe, innovative, and valuable health solutions—is challenging enough, medical device companies must also navigate a myriad of regulatory compliance issues before products can be sold to doctors, hospitals, and patients. Accelerating the delivery of new products while ensuring compliance requires comprehensive design controls leveraging the best technologies and automated systems to keep quality and product teams aligned to collaborate quickly and effectively.

To ensure patient safety, the Food and Drug Administration (FDA) and International Organization for Standardization (ISO) stipulate that medical device manufacturers establish and utilize a quality system to ensure products consistently meet regulatory requirements and applicable ISO 9001 and 13485 standards. This type of system, or collection of policies, procedures, and processes, is known as a quality management system (QMS) and helps medical device companies establish and document policies and procedures to demonstrate compliance.

> "Implementation was made very easy by Arena giving us complete IQ and OQ documents. The wide range of standard out-of-the-box functionality narrowed the scope of our work even more. This resulted in a very productive and complete PQ while requiring much less management than other IT system implementations I have been a part of.
>
> —Ed Reith, Supply Chain Engineering Manager, EBB

Medical device companies can leverage manual, paper-based, homegrown software, or purchased software QMS solutions. The FDA does not regulate what type of QMS solution is used. Regardless of the type of QMS solution used, companies must demonstrate and provide evidence, or validate that it meets the requirements to consistently deliver safe, high-quality devices to market.

One very important consideration when selecting any QMS solution involves the level of effort and ultimate cost to validate. QMS validation is considered an overhead cost required to satisfy the FDA and get products to market; it is not part of the material and assembly cost, since it is not directly related to producing the physical product.

OLD SOFTWARE, NEW DEVICES

Validating paper-based QMS or older on-premises and document-centric QMS software solutions is labor-intensive, inefficient, and difficult. All this expense pulls valuable team members and resources away from product work. For companies using older types of QMS software, many find the validation process so punitive that they choose not to install software updates and miss out on many new feature enhancements as a result. For paper-based QMS, companies may reach a state of inertia, avoiding updating processes to improve product quality, delivery, or costs due to the burden of manual updates, validation work, and training. In both cases, medical device manufacturers face the daunting task of introducing cutting-edge devices and technologies using old, ill-fitting manual or software QMS solutions.

It is easy for a medical device company to focus excessively on system validation as they navigate considerable regulatory requirements and maintain a constant readiness to address audits that can result in FDA warning letters or adversely affect their business. In 2017 alone, the FDA issued 5,155 Form 483 findings across life sciences companies, and many of those were medical device manufacturers. However, driving design control process support based on fear of noncompliance may only delay time to market and increase costs.

The FDA recently recognized a lack of clarity in regulation requirements for system validation of software solutions. Furthermore, the FDA has launched initiatives to encourage companies to modernize for innovation, break down data silos, and adopt new technologies—in particular, moving to digital data and less burdensome compliance provisions.

As the FDA moves forward to embrace the world of technology and digital data, it stands to reason that medical device companies should as well. Cloud-based QMS software provides the best technology and capabilities for the lowest total cost of ownership and ease of validation. The type of cloud matters when considering computer software validation requirements—with a multi-tenant cloud solution, validation can be much easier to complete.

MULTI-TENANT CLOUD QMS ENABLES STANDARDIZED SOFTWARE VALIDATION

Multi-tenant cloud-based QMS software enables all customers (or "tenants") to run the same software version at all times. With a single version of the QMS software, the cloud software vendor can scale to provide key aspects of validation to all customers.

A multi-tenant software-as-a-service (SaaS) application involves a centralized administration to maintain a common code-based application and run a common instance of an application for multiple tenants (companies). SaaS applications are built to ensure that all confidential data for each tenant is secured from any other tenant.

VALIDATION CHOICES, CONSEQUENCES, AND CHAIN REACTIONS

As quality assurance and regulatory affairs (QA/RA) stakeholders know, software used in designing, manufacturing, testing, and servicing of finished devices intended for human use must be validated not only upon initial implementation, but again with each software upgrade that is applied.

Many deliverables and software validation test plans (or protocols) are needed to establish, execute, and document that each version of the QMS software solution works as intended.

Software validation involves:

- Risk assessment
- Documentation and maintenance of software intended uses
- Validation of test cases
- Traceability matrices
- Validation test plans
- Execution records with corresponding objective evidence
- Validation reports
- Templates

With homegrown or traditional on-premises software, the pains associated with these

Multi-Tenant Advantages

- ☑ Reduces vendor's software development and support costs where savings and economies of scale can be passed on to customers
- ☑ No customer software to purchase, install, or maintain
- ☑ No firewall infrastructure issues or precautions to protect against intrusion to customer's internal systems
- ☑ Backup and recovery are simplified with automated backups and storage by vendor in off-site data center (from customer)
- ☑ Scales from few to thousands of users without additional investment or maintenance in client or server architecture and infrastructure by customer
- ☑ Leverages validation commonality for installation qualification (IQ) and operational qualification (OQ) testing

validation deliverables can quickly exceed a medical device manufacturer's appetite for enhancements and upgrades. This results in key quality stakeholders opting to avoid upgrading the software or possibly upgrading the software without the necessary validation. If software updates occur without necessary validation, the company risks audit issues that could result in serious penalties or business closure.

For traditional on-premises software customers, this creates an unfortunate chain reaction of consequences. When customers choose to ignore multiple important software updates to avoid validation impact, the on-premises solution can no longer be fully leveraged as new features and security improvements are unavailable. Ultimately, quality and product teams become frustrated by the knowledge that they are working harder to make old software fit current needs.

> Although the Arena team was not involved in our FDA inspection, your solution helped us find and retrieve records quickly to address inspection requirements ahead of our schedule. Thank you for supporting our needs and creating a solution that really works as promised!
>
> —Michelle J. Potvin, ASQ CQA, Director, Quality Assurance & Regulatory Affairs, Swan Valley Medical

CLOUD QMS SOFTWARE VALIDATION MADE EASY

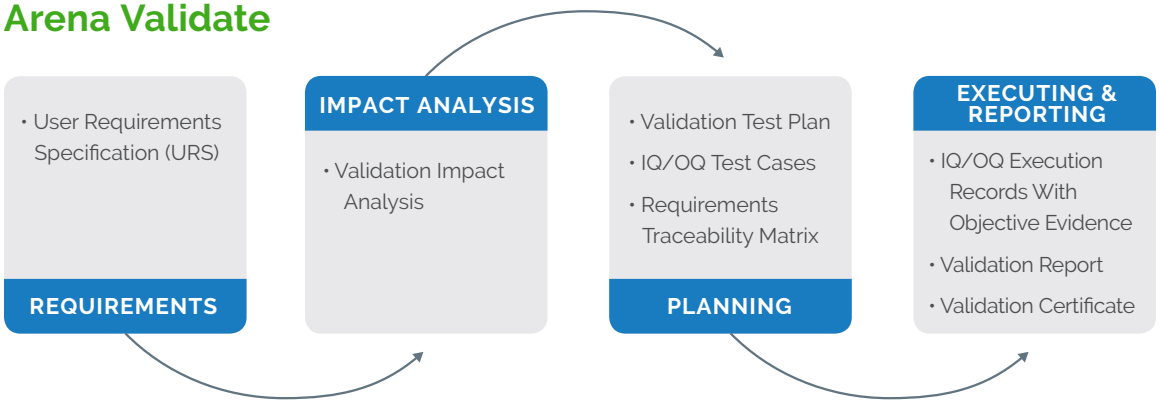
With older on-premises (single-tenant) QMS solutions, software validation is more challenging because each and every customer uses a unique instance of the software application and supporting infrastructure which must be installed, tested, and validated.

View a 1-minute overview of Arena QMS.

Arena's QMS is a cloud-based, multi-tenant solution, architected to provide customer-requested enhancements and value-added new features on a regular schedule. With a level of shared infrastructure for all QMS customers, validation is made easier by leveraging common test protocols for both installation qualification (IQ) and operational qualification (OQ).

Arena Validate is available to all Arena QMS customers. It is supported by a dedicated validation team, allowing Arena to do most of the heavy lifting. This allows customers to focus on reviewing Arena's validation scope and documentation and determining the customer-specific intended uses (required to handle performance qualification or PQ) that will supplement the validation package. In addition, Arena provides performance qualification (PQ) templates, as part of the Validation Setup Packet, to assist customers in determining any additional PQ validation needs. The Validation Setup Packet consists of a collection of templates and reference documents intended to assist new Validate customers in setting up their initial validated installation of the Arena application.

Arena Validate



Arena Validate provides key deliverables to reduce traditional burdens on medical device companies and quality assurance regulatory affairs stakeholders.

With Arena Validate, customers get a simplified validation experience that reduces manual efforts and time-consuming work. Removing traditional validation barriers enables companies to keep pace with the latest technological and functional features and frees quality and regulatory resources to focus on innovation, market responsiveness, and continual improvement to deliver high-quality products.

KEY BENEFITS

According to a study by LNS Research, software validation is one of the top challenges in speeding products from R&D to market for life science companies. Furthermore, they explain that cloud-based technologies are a key differentiator to provide streamlined validation.

Arena Validate leverages the Cloud to reduce medical device manufacturers' validation efforts and overhead. The solution's templated and standardized approach provides validation for every software release against pre-defined common requirements to help Arena's QMS customers address validation regulation with confidence. Customers report significant cost and time savings associated with ongoing software validation plus a renewed focus on core competencies.

SETTING A COURSE FOR SUCCESS

Gone are the days when medical device manufacturers can stick their heads in the sand and hope their software solutions keep up with their evolving new product introduction (NPI) and quality management needs. To maintain a competitive advantage in the global market, companies can turn to Arena QMS to gain the control, compliance, and product development benefits necessary to stay ahead of the pack. Best of all, Arena Validate will ensure that quality and product teams can focus on delivering high-quality, safe, and compliant products to market fast.

To see firsthand how Arena Validate can solve your software validation struggles, request a demo today.

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