arena

arenasolutions.com

Whitepaper

How Med Device OEMs Simplify Validation & Streamline Compliance

Discover the Powerful Benefits of a Cloud-Based PLM Validation Service

Cloud-Based Enterprise Software and Validation Service: Advantages to Medical Device Manufacturers

Because of the difficulty and complexity of validating updates to off-the-shelf (OTS) enterprise software solutions (including those for product lifecycle management, application lifecycle management, quality management, manufacturing execution software, and software defect tracking), many of today's cutting-edge medical device technologies are being managed by old, outdated enterprise software. Validating OTS software after the initial installation and validation can be so time-consuming and labor-intensive, medical device manufacturers tend not to install subsequent software updates, upgrades, and bug fixes, simply because validating each of these improvements proves too daunting and costly a task.

The Problem: Innovative Medical Technology, Outdated Enterprise Software

As staff responsible for quality, project management, and regulatory compliance at medical device companies are keenly aware, non-device enterprise software solutions—used mainly as part of the quality system—must be validated and maintained in a validated state through each and every software upgrade per FDA and federal government regulations. (See sidebar "In Compliance.") This required validation is costly in terms of time, resources, and effort, involving such elements as risk assessment; development and maintenance of software intended uses; validation test cases (IQ/OQ); traceability matrices; validation test plans; execution records with corresponding objective evidence; and validation reports. Because these numerous and complex validation elements are required for every update to the software, medical device manufacturers tend to avoid software upgrades altogether, choosing instead to rely on the original validated software release, which ages and becomes problematic and outdated over time.

Serious Consequences

When medical device manufacturers overwhelmed by software-validation requirements choose not to upgrade their enterprise software, an unfortunate chain reaction is set into motion: after a number of ignored but important software updates, the software's advantages cannot be fully exploited. The software is underutilized by the medical device manufacturer; its new features, functionality, and security updates go untapped. What's more, the software cannot be configured per the company's own updated requirements; therefore, those requirements cannot be fully met, which is a problem posing serious negative business impact. Ultimately, talented Research, Development, and Quality staff become frustrated trying to make an outdated enterprise software solution work for them and creating endless work-arounds in an effort to make old software fit current needs. These individuals may be driven to other, competing companies in order to access the newest software tools and technology, and the medical device company they leave behind suffers.

The following scenario is all too common in the medical-device manufacturing industry:

1. A company buys an excellent, respected, state-of-the-art OTS enterprise-software solution product in 2000. The software features include product lifecycle management.

In Compliance: Key Regulations Regarding Software Validation for Medical Device Manufacturers

Enterprise software solutions, also known as OTS software, that are not medical-device products themselves but are part of the medical-device quality system must comply with FDA and federal-government regulations. The following excerpted regulations may apply to medical device companies who use enterprise software as part of their quality systems:

- **Quality Systems Regulation (April 2014): 21 CFR 820.70 (i): "***Automated processes.* When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented."
- **Electronic Records and Electronic Signatures: 21 CFR 11.10 (a):** "Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records."
- **CDRH General Principles of Software Validation, Section 2 (January 2002):** "Where the software is developed by someone other than the device manufacturer (e.g. off-the-shelf software) the software developer may not be directly responsible for compliance with the FDA regulations. In that case, the party with regulatory responsibility (i.e. the device manufacturer) needs to assess the adequacy of the off-the-shelf software developer's activities and determine what additional efforts are needed to

Continued on next page

2. The company configures the software according to its business needs at the time.
3. The company establishes intended uses (required by FDA) for the software and validates it.
4. This original version of the software, now painstakingly validated, is locked down. The company dares not make any changes to this validated product.
5. The software is off and running and works well.
6. During the next 10 to 15 years, the software vendor releases significant and important software updates—but each one would require a complete re-validation of the software, which the company feels it just cannot afford.
7. It is 2015. The company is still relying on the old, now-outdated, original version of the software. This version no longer meets the company's changed requirements, is being underutilized, and requires cumbersome work-arounds.

It seems almost inconceivable that a company of any sort would willingly put itself in this bad situation, yet many in the highly regulated medical device industry believe they do not have a choice. The costs of assessing an enterprise-software change, developing or updating software-product requirements, creating validation test plans and test cases, executing those test cases while generating the required objective evidence and traceability matrices, and finally, releasing validation reports, all seems too much. That time and effort would need to be culled from the company's core competencies, which is unacceptable in such a competitive, high-stakes industry.

The Solution: Cloud-Based Software and Validation Maintenance

The good news is that medical device manufacturers can, in fact, always have the latest, best versions of their enterprise software with minimal validation effort and cost, and none of the consequences associated with failing to update. **Multi-tenant cloud-based architecture** enables this solution.

With multi-tenant single-instance cloud-based software, all customers (or "tenants") run the exact same software code base via Internet connection, and only one version of this code—the very latest—is hosted by the vendor at all times. As a result of this simplified system, when the enterprise cloud software is updated and validated against the most common intended uses, the results of that validation testing can be leveraged by all tenants.

establish that the software is validated for the device manufacturer's intended use."

- **FDA General Principles of Software Validation: 6.3 Validation of Off-The-Shelf Software and Automated Equipment**: "Most of the automated equipment and systems used by device manufacturers are supplied by third-party vendors and are purchased off-the-shelf (OTS). The device manufacturer is responsible for ensuring that the product development methodologies used by the OTS software developer are appropriate and sufficient for the device manufacturer's intended use of that OTS software. For OTS software and equipment, the device manufacturer may or may not have access to the vendor's software validation documentation. If the vendor can provide information about their system requirements, software requirements, validation process, and the results of their validation, the medical device manufacturer can use that information as a beginning point for their required validation documentation. The vendor's life cycle documentation, such as testing protocols and results, source code, design specification, and requirements specification, can be useful in establishing that the software has been validated. However, such documentation is frequently not available from commercial equipment vendors, or the vendor may refuse to share their proprietary information."

All tenants using the cloud-based software and validation-maintenance option can therefore enjoy the advantages offered by automatic software updates, share the cost of validation, and significantly reduce the required validation scope, since, with that validation-maintenance option, each update is validated by the software vendor against a set of predefined common requirements shared by all medical-device customers.

The improved scenario for the medical-device manufacturer who switches over to multi-tenant single-instance cloud-based software architecture is as follows:

1. The medical device company buys a subscription to a single-instance, on-demand, cloud-based enterprise-software service, equipped with a validation-maintenance option. That company then gains access to the most-recent, up-to-date version of the enterprise software via Internet. No on-site discrete software package is installed.
2. The cloud-based software product includes a comprehensive set of required validation documentation from which the medical device company benefits, including a number of requirements (intended uses) common to medical-device companies: test plans, protocols, validation test cases, traceability, and reports for use as evidence of software validation. The medical device company is spared the time and expense of devising and executing these tests.
3. The software vendor develops, tests, revises and updates the single shared code base as needed. The medical device company never needs to install an update to its own copy of the software product, as no copy exists! The updated code is automatically accessed by the medical-device company via Internet connection.
4. Updated validation documentation of the pre-defined common requirements is produced by the validation maintenance service and shared among software subscribers (the "tenants") each and every time the software vendor updates the software on its server. The medical device company might have a few additional requirements unique to its environment that it may need to validate. Thus, a huge reduction in validation cost and scope is realized.
5. Staff involved with quality, regulatory compliance, and project management can feel satisfied knowing that their goals will be accomplished running only the most current, updated, secure version of the enterprise software, with minimal time and effort spent on validating each new release.

Sample Timetable: Cloud-Based Software Validation

(The following applies to Arena Solutions' VMS. Validation services and documentation offered by other vendors will vary.)

Arena validates each Arena PLM software release against a pre-defined set of intended uses and distributes the following validation documentation to VMS subscribers:

- Product requirements specifications
- Software modification validation impact analysis
- Product requirements traceability matrices
- Software validation test plans
- Installation Qualification (IQ) validation protocol execution records (with objective evidence)
- Operation Qualification (OQ) validation protocol execution records (with objective evidence)
- Software validation reports
- Software validation certificates

One Option to Consider: Arena PLM and VMS

For a medical device company ready to benefit from the advantages provided by multi-tenant cloud-based architecture, experienced software vendor Arena offers its Validation Maintenance Service (VMS) for its PLM enterprise solution. **Arena PLM** is Arena's subscription-based, single-instance, on-demand enterprise-software service run on Arena-managed servers, accessed by subscribers via Internet browser, and featuring both back-up and disaster recovery. Arena continually updates the PLM code base for all subscribers, so that only the most-recent, updated version of PLM is available.

VMS, Arena's validation service, validates all PLM releases for all subscribers against pre-defined common requirements and provides required validation documentation and execution records.

Medical device companies that have switched to Arena PLM and VMS report significant cost and time savings associated with ongoing software validation, and a renewed focus on core competencies. Additionally, these companies have found that the VMS component accelerates the initial PLM enterprise-software implementation and streamlines compliance.

A Smart, Cloud-Based Solution for High-Tech Medical Device Manufacturers

Innovative, high-tech medical-device manufacturers running old, outdated, clunky software to manage projects, product records, and their quality systems are potentially curtailing their own success and growth. A proven, streamlined non-device enterprise-software solution exists in the form of subscription-based multi-tenant single-instance software architecture and a corresponding validation-maintenance solution. With this system in place, all that is needed to easily access and validate all subsequent updates and versions—and have evidence of that validation—is an Internet connection and browser, enabling medical-device manufacturers to support, enhance, and grow their business with the best, most-valuable software tools available.

Bibliography:

1) From Google and Pixar to Innocent and Beyond, by Archie Bland, The Independent, 9 June 2014

2) http://hbr.org/2013/07/the-culture-to-cultivate/ar/1

3) New York Times Article, “The Face of Future Health Care”, March 20,2013, by Reed Abelson

4) Harvard Business Review, “The Culture to Cultivate”. August 2013, by George Halvorson

5) Inc., “Lolly-wolly-doodle-business-model”, June 2014

About Arena

Arena, the inventor of cloud PLM, provides an all-in-one product development platform that unites PLM, ALM, supply chain collaboration, and QMS for the design and manufacture of complex electronics. With Arena, electrical, mechanical, software and firmware engineers can collaborate with manufacturing and quality teams to manage their bill of materials, facilitate engineering change orders, and speed prototyping. As a result, Arena customers can better meet standards while they ensure regulatory compliance, improve training management, reduce costs, increase quality, and collapse time to market. Arena has been ranked a Top 10 PLM provider and won the coveted Design News Golden Mousetrap Award in 2016. For more information, please visit http://www.arenasolutions.com.

Contact

Arena Solutions
Foster City, CA 94404
P. 650.513.3500
F. 650.513.3511

Cloud. Connected. Content. Makes Making Easier.