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Whitepaper

Don’t Fear the Cloud

Debunking the Top Three Myths Regarding Multi-Tenant Cloud-Based PLM Architecture for Medical Device Firms

Don't Fear the Cloud: Debunking the Top Three Myths Regarding Multi-Tenant Cloud-Based PLM Architecture for Medical Device Firms

Cloud-based Product Lifecycle Management (PLM) enterprise software is an established, proven technology that offers real, tangible advantages to medical device manufacturing companies of all sizes. So why, after a decade on the market, are these cloud-based PLM systems still regarded with trepidation by some medical device firms? This attitude of mistrust is likely based in a fear of failing to comply with complex regulations and standards and a feeling of vulnerability to hackers and other forms of compromised security. These concerns are legitimate and understandable in the high-stakes world of medical device manufacturing; however, the truth about cloud-based enterprise PLM software does not match the misconception.

In fact, multi-tenant SaaS cloud-based architecture, especially when paired with a validation service, provides ultra-tight security and streamlined regulatory compliance while also formalizing the design-control process and improving both communication and product quality.

Arena Solutions, creator and provider of cloud-based PLM enterprise software and its associated Validation Maintenance Service (VMS), has found during its years of working with medical device manufacturers that the top three misconceptions held by these companies about cloud-based infrastructure are:

1. Cloud is not safe. A medical device company's internal IT department can do a better job ensuring the safety of company data.

2. Cloud-based enterprise software is constantly changing, so keeping required PLM validations up to date is impossible. Regulatory compliance is therefore threatened.

3. Cloud-based PLM architecture may be helpful, and the advantages are apparent, but it will still be necessary to buy and integrate a separate quality management solution for maintaining and archiving all compliance-related documents.

An examination of these three misconceptions exposes them as myths—mostly based in fear and misinformation—that can be identified as such and dismissed, so that medical device manufacturers can move forward and make intelligent, informed decisions about the value of cloud-based enterprise software for their businesses.

It's Time to Debunk: Myths vs. Truths

Myth #1: Cloud is not safe.

Truth: A cloud-based PLM enterprise-software solution, such as Arena's, protects a medical device manufacturer's data with proven financial-grade security infrastructure managed by dedicated full-time security experts. While a medical device firm may have a very talented and highly experienced IT group, the fact remains that corporate IT priorities and skill sets are not primarily focused on 24/7 data security and availability, and are often stretched thin to satisfy such business requirements as e-mail and phone requests, helpdesk tickets, and more.

Enterprise cloud solutions, on the other hand, like Arena PLM, simply offer more advanced security than corporate IT departments do. Because cloud security is the vendor's core business, that vendor's requirements, priorities, and investments are centered on building and maintaining a secure and robust cloud infrastructure. This financial-grade comes with a high cost which when spread across a large install base is not only approachable—but in fact, more economical. This includes employing staff with the right mix of skills (for dedicated operations, data-security, and backup teams), as well as creating appropriate organizational controls and structures.

As a result, cloud-based enterprise software (like Arena PLM) is not just safe, it offers leading-edge safety and security superior to that of traditional off-the-shelf enterprise software and add-on components maintained by overtaxed internal corporate IT departments.

Myth #2: Cloud-based enterprise software is constantly changing, so it is impossible to keep validation up to date.

Truth: All users of a particular multi-tenant single-instance (of software) cloud-based enterprise-software solution, such as PLM, access only the most recent, updated version of that software, which allows the vendor to more easily validate the software updates and share the results of that validation testing with all validation subscribers.

Moreover, Arena validation service validates all PLM releases for all subscribers against a predefined set of intended uses and provides required validation documentation (including requirements, validation protocols, traceability, reports, and execution records) to all validation service subscribers, thereby greatly easing the validation burden for regulated PLM users. In so doing, cloud-based enterprise-software users can materially blunt the cost of validation and significantly reduce the required validation scope.

Additionally, all validation subscribers, including medical-device manufacturers, are notified in advance of upcoming enterprise-software updates, and results of the validation are distributed before the software changes are made. These users enjoy all the benefits of the cloud while maintaining a validated PLM state and, therefore, regulatory compliance, as required by 21 CFR 820.70(i) and 21 CFR 11.10(a). 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.

Myth #3: Cloud-based PLM architecture may be helpful and the advantages are apparent, but it will still be necessary to buy and integrate a separate quality management solution.

Truth: A cloud-based multi-tenant single-instance enterprise solution, such as Arena PLM, is itself an embedded holistic quality management system yielding the tightest integration—as opposed to linking with a disparate third party. By virtue of tying out to the product record, it incorporates and integrates all quality-related data and documents, including all bills of materials, all standard operating procedures, all corrective and preventive action (CAPA) processes, and more.

Within this one cloud-based system is housed all quality-related data and documentation, linked for easy access, visibility, and traceability. For instance, an engineer who is working on the next version of a medical device product will find, when she opens her bill of materials, the CAPA process associated with it. She will have instantly at her fingertips a full history of all the non-conformances that were initiated with past releases of the product; therefore, she can consider this history as she develops the next version of the product. That information will serve as input to her design process and will contribute to proactive, rather than reactive, quality management.

All elements required for medical device manufacturers to achieve and maintain regulatory compliance are built into the cloud-based integrated PLM system, including change control management, product records management (including bills of materials and defective materials reports), quality records and documents management, quality process management (including CAPA, corrective action requests, and supplier corrective action requests), and training records management (including training plans, training matrices, SOPs, and employee training records and reports). These elements can be accessed by all team members, including suppliers, thereby enabling cross-functional teams to collaborate and build quality into the product design early in the product lifecycle and streamline regulatory compliance.

Bringing all of these pieces together in one integrated, cloud-based enterprise system managed by a single vendor reduces expensive non-conformances and enables better communication, a culture of continuous improvement, and increased product quality.

Moving Forward with Cloud Technology

After 10 years of highly regulated businesses adopting holistic and integrated cloud-based enterprise-software systems with great success, it is time to acknowledge that track record and have the skeptics put to rest remaining fears. Medical device manufacturers who choose to embrace cloud technology for the betterment of their businesses find that validation becomes much less burdensome, audits are eased, regulatory compliance is facilitated via built-in quality management, and data security is maintained at an ultra-high level so they have fewer distractions and more energy to focus on their core business.

Simply put: medical-device firms need not fear the cloud. It is perhaps their most valuable tool for reducing risk, increasing quality, staying compliant, and speeding time to market.

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.

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