# Arena's Cloud-Based Closed-Loop Product Development Offering

***CIMdata Commentary***

*Key takeaways:*

- *Smart, connected products and product-systems capable of adaptive autonomous functioning which can be remotely monitored, diagnosed, repaired, and updated, are increasingly the norm in the market*
- *Innovative connected and intelligent products will drive unprecedented increases in design complexity and software content, while time to market and profit margins continue to shrink due to competition*
- *To mitigate the risk of recalls due to the failure of smart, connected products, it is imperative to enable rapid verification and validation cycles, supported by full traceability of requirements, as well as closed-loop feedback from testing and field trials into the upstream design phases*
- *Arena Solutions is on target for a staged release of a highly scalable, multi-tenant cloud-based closed-loop product development offering for developing innovative connected and intelligent products*
- *Arena's cloud-based closed-loop product development offering has been designed to be cost effective and easy-to-access and use, as well as to help small, medium, and large enterprises competitively develop smart connected products*

## Product Complexity is Accelerating

Connectivity and artificial intelligence are major features of many upcoming software-intensive products. Many smart, connected products are likely to integrate offerings from traditionally distinct industries resulting in systems of systems. The increasing application of sensors, sensor-fusion, actuators, and associated algorithms in products and product systems will drive an unprecedented increase in design complexity and software content, making it even more difficult to ensure dependability while retaining profitability.

Even without connectivity and artificial intelligence, launch delays and recalls due to performance and non-compliance issues with today's relatively less sophisticated electronically-controlled systems can very often be traced to design complexity and software-content. For example, a 2013 U.S. FDA study[1] has determined that software-related recalls measured as a percentage of all recalls in the medical device industry increased from 14% in 2005 to 25% in 2011. This percentage has been steadily increasing since 1983, with software-related recalls as a percentage of overall recalls averaging 6% between 1983 and 1991, 8% between 1992 and 1998, 11% between 1999 and 2004, and 19% between 2005 and 2011. This trend in the medical device industry is likely to grow with the increasing use of robotic microsurgery, remote device operation, diagnostics, and repair, and other advanced technological capabilities because the addition of each of these features necessitates a significant increase in software content.

[1] Simone, Lisa. K., "Software-Related Recalls: An Analysis of Records", Biomedical Instrumentation & Technology, pp. 514-522, November/December 2013.

## Software-Intensive Products Defy Engineering Intuition

The failure modes of software-intensive, control systems-driven products are difficult to imagine *a priori* due to the complexity of their functions and information flows, and consequently, crucial failure modes can easily be missed. Due to the absence of prior knowledge about failure modes, much learning regarding the failure of such new and innovative products is likely to happen as they are conceived and designed in iterations which include verification and validation. Given the shrinking time to market due to competitive pressures, the verification and validation cycles must be accelerated and they must be supported by easy and rapid storage and retrieval of failure knowledge pertaining to systems, subsystems, and components. A product lifecycle management solution that can enable rapid design iterations supported by failure knowledge capture and reuse is necessary to mitigate the launch delay and recall risk of smart, connected products.

## A Flexible & Unified Product Development Solution is Optimum

CIMdata believes that efficient design and development of software-intensive products and product systems necessitates the integration of solution offerings such as application lifecycle management (ALM), and quality management system (QMS) solutions within the framework of product lifecycle management (PLM). In most instances these solutions are disparate, requiring integrations that can prove to be inefficient, expensive, and difficult to maintain and upgrade. A further shortcoming is a failure to enable the accelerated verification and validation cycles which are very desirable.

CIMdata further believes that a single integrated solution is needed, one with the essential elements of ALM and QMS built into a single PLM environment, and one that is easy to access and use, as well as upgrade. The unified nature of the solution should bring together the main features of ALM, i.e., requirements management, traceability, and verification and validation; the core features of a typical PLM environment, i.e., product data vaulting, secure check-in and check-out, configuration management, and change management; and the main features of QMS, i.e., standards and rules, nonconformance tracking, and corrective action preventive action (CAPA). Combined with a cloud-based subscription model brings the flexibility to adapt the solution deployment to changing needs of the business. For example, based on the compliance needs of the organization, the elements of QMS deployed could either be extensive or insignificant.

Arena has developed a secure, highly-scalable, multi-tenant cloud-based closed-loop service around a broad PLM solution suite. The suite provides the ability to quickly and cost-effectively deploy integrated PLM capabilities for innovative enterprises and their supply chain partners. Customers have the flexibility to start with the basic capabilities they need, then add or plug in new, more complex functionality to expand their PLM environment as they require. Arena's supply chain solutions enable enterprises to adapt to changes without imposing major costs on themselves or their partners. In addition, Arena's Quality application incorporates enterprise quality processes tied directly to the product record.

This application maintains a full audit trail of actions taken during the quality review process to enable effective quality management across the entire product portfolio. Companies can either use out-of-the-box quality templates or customize quality processes to meet their individual needs. Personnel working on any product development project can have access to consistent, common quality information and can collaborate on quality issues. This includes authorized suppliers who can launch and run a quality process.

For users needing to better address customer complaints, internal audits, and corrective and preventive action capabilities, Arena's Quality application provides the ability to manage a closed-loop CAPA process linking issues and resolutions directly to the product record. This helps incorporate lessons learned from downstream product development stages, manufacturing, and post-sales service into the design phase for delivering more robust products. In CIMdata's many years of industrial experience, the value of applying robust optimization in the upstream design stages has proven to be undeniable as evidenced by its positive impact on customer satisfaction and recall mitigation. The ability of Arena's solution to leverage knowledge about previously experienced product issues, in the upstream design stage, will greatly help their customers to develop designs that avoid those failure modes.

Arena's strategic vision includes primary elements of ALM and QMS within its existing cloud-based PLM solution to create a closed-loop system lifecycle management offering (Figure 1). The offering when released is expected to provide requirements management that covers the electrical, mechanical, and software content of their customer's products. Some capabilities supported include:

- Requirements management enables an iterative gathering and refining of the product requirements based on the initial assessment of the feasibility of certain product designs meant to satisfy those requirements.
- The breakdown of the requirements into those related to mechanical, electrical, electronic, and software elements of the design is enabled with the maintenance of full traceability back to the original requirements and their derivatives.
- Decomposed requirements are then used to drive verification and validation tests based on the design of test coverage and defect tracking.
- Product testing and detected defects are directly tied to CAPAs, providing closed-loop feedback to future iterations of design or for next level product configurations, as well as for root cause analysis related to warranties and recalls.

CIMdata's understanding of software-intensive products is that their failure modes cannot be imagined upfront and consequently developing designs to avoid them is not possible. However, knowledge about prior occurrence of failure modes either from similar existing products or from previous design iterations can be fed into upstream design phases using closed-loop feedback for developing robust solutions in the next product development iteration.

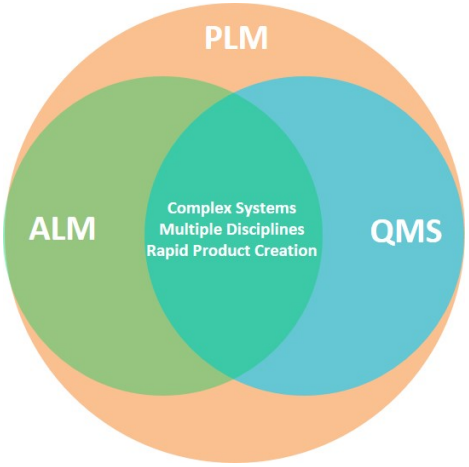


**Figure 1—Arena's Closed-Loop Product Lifecycle Management Offering for Rapid Product Creation**

Arena's closed-loop product lifecycle management offering is designed to also cover the production phase in terms of product configuration management and control, including mechanical, electrical, and software elements. Their performance monitoring and incident management solution governs ongoing support. Ongoing performance monitoring processes are critical to the success of complex products and to prevent the loss of customers, as well as for monitoring performance to find and fix issues before customers are affected by them. Incident management processes are critical, whether they are related to hardware, software, security, or performance issues because they ensure that the analysis and remediation of production problems happens as effectively and as expeditiously as possible. CIMdata has found that this type of analysis and remediation offers valuable insights regarding potential product failure modes which can be applied in the upstream design process and in subsequent product iterations to avoid failure modes upfront.

Arena's cloud-based closed-loop integrated product development offering, which is based on incorporating the key elements of ALM and QMS in a PLM environment, should provide manufacturers and suppliers with the ability to rapidly collaborate and gain knowledge about new and innovative products that are inherently complex due to controls systems and software. In addition, it paves the way for the development of more innovative products that exploit the Internet of Things or other connectivity capabilities and artificial intelligence for autonomous operation.

Arena's customers can deploy the foundational cloud-based closed-loop offering which uses ALM and QMS capabilities within a PLM environment and adapt the desired product development capabilities as their needs evolve. This provides flexibility for small and large organizations to adapt Arena's integrated product development offering to the needs of businesses as they evolve.

## Conclusion

Innovative products increasingly depend upon mechanical, electrical, and software content to deliver their differentiated value. The software content is found to be growing steadily relative to the mechanical and the electrical content. Further, the competitive forces in the marketplace are continuously shrinking time to market. This can, in turn, lead to product dependability issues due to poor understanding of product functioning caused by design complexity and increased, but not well validated software content.

The development of dependable software-intensive electronically controlled products demands many design iterations supported by ALM and QMS capabilities in a PLM environment, which may have been implemented by integrating different, disparate systems. This approach is expensive, inefficient, and inflexible for future adaption based on market needs. A single closed-loop solution for system lifecycle management that includes key elements of ALM and QMS integrated into a PLM environment is needed that can adapt to the needs of the users.

Arena's cloud-based offering for closed-loop product development which is based on their PLM solution that incorporates key elements of ALM and QMS solutions that can be easily accessed by manufacturers and their suppliers, and provides the ability to utilize functionalities tailored to their specific needs, is ideal. Depending upon the compliance needs of the organization in which Arena's integrated product development offering is implemented, the elements of QMS can be extensive or almost absent. For example, a heavily regulated medical device business needs extensive QMS deployment to ensure that the standards and regulations are strictly adhered to, whereas, a consumer electronics company, which has relatively fewer regulations to follow, can operate with a much less significant QMS implementation.

Based on CIMdata's consulting experience, many organizations are still struggling to achieve the efficient introduction of ALM and QMS in a PLM environment in their quest to develop dependable smart, connected products as part of their overall PLM strategy. CIMdata believes that Arena, with its cloud-based closed-loop product development solution, offers a flexible, efficient, robust, and cost-effective backbone that could prove ideal for launching all sizes of manufacturers very quickly into their competitive markets with innovative smart, connected products.

## About CIMdata

CIMdata, an independent worldwide firm, provides strategic management consulting to maximize an enterprise's ability to design and deliver innovative products and services through the application of Product Lifecycle Management (PLM). CIMdata provides world-class knowledge, expertise, and best-practice methods on PLM. CIMdata also offers research, subscription services, publications, and education through international conferences. To learn more about CIMdata's services, visit our website at http://www.CIMdata.com or contact CIMdata at: 3909 Research Park Drive, Ann Arbor, MI 48108, USA. Tel: +1 734.668.9922. Fax: +1 734.668.1957; or at Oogststraat 20, 6004 CV Weert, The Netherlands. Tel: +31 (0) 495.533.666.