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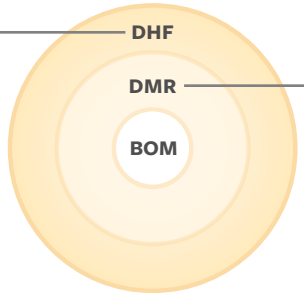
Whitepaper

Providing a Superior Foundation for Your Corporate Quality System

Quality systems for companies regulated by FDA must follow current good manufacturing practices (CGMPs) to comply with the FDA's 21 CFR part 820 regulations.[1] Furthermore, medical device companies have to adhere to ISO 13485 and demonstrate their ability to meet customer and regulatory requirements. Together, the FDA and ISO requirements inform best practices for compliant quality management.[2] In the past, medical device companies had only one solution choice. Today, you have a choice between two foundations for your quality system – a stand-alone document-centric quality management system (QMS), or Arena's BOM-centric system that also has QMS capabilities. So, how do you do you know which foundation is best for you and your company?

In a regulated environment, the key to introducing new products effectively is managing the inter-relationship of all the complexity of your product data, quality processes, and audit requirements consistently and with compliance. It can be difficult to get it right. You must manage the full product BOM with dynamic links to approved manufacturers' list (AML), suppliers, regulatory and environmental compliance information, and engineering changes along with all related quality issues and corrective actions. For medical device companies, regulations require managing the complete design history of a finished device (DHF), which includes the Device Master Record (DMR).

Design History File is a compilation of records that describes the design history of a finished device (e.g. design decisions, meeting notes, design quality docs, and quality records).



Device Master Record includes the relational BOM integrated with the AML/AVL, process specs, quality procedures, software specs, packaging, labeling, installation, and maintenance procedures.

QMS Brief History

Historically, most quality systems for medical device companies or QMS systems have addressed a subset of information to comply with quality regulations. These solutions have been constrained because they provide a document-centric approach to manage quality, training, and even product information.

QMS systems began by focusing on the two key areas of quality compliance for the FDA:

- Documentation Control for SOPs, specifications, and other files
- Process enablement and tracking for auditable processes, including CAPA and training records

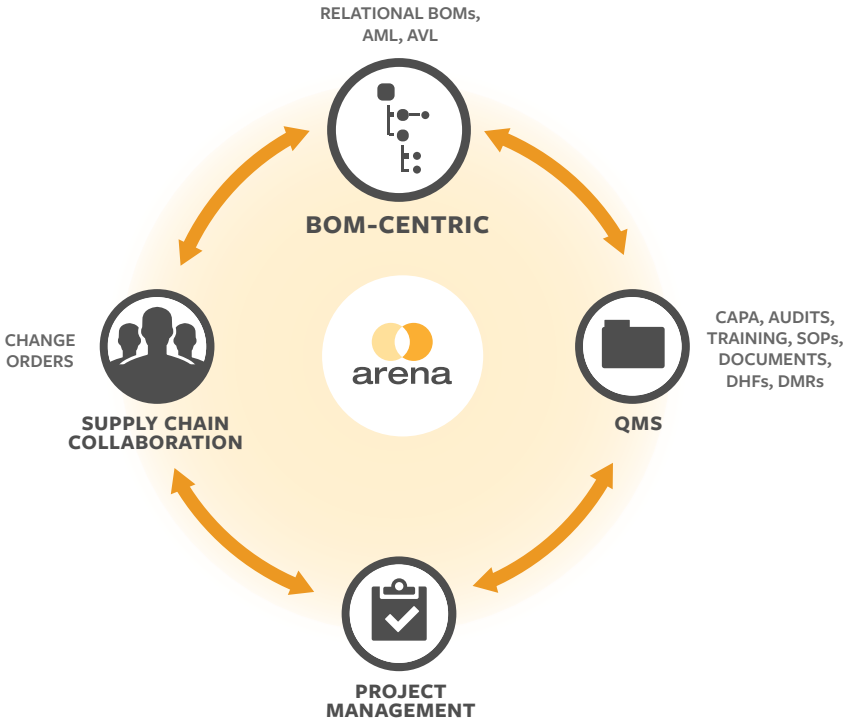
> "Why is it so convenient to integrate quality systems with product lifecycle management? Because the data and records are already there."
>
> Laurence Sampson
> Chief Operating Officer,
> Swan Valley Medical Consulting

Most QMS systems focus on automating the paper-based processes around quality first. Document-centric solutions like QMS fail to capture the comprehensive product record comprised of mechanical, electrical, software, assembly and test procedures, and other documentation in a bill of material (BOM). For product companies, BOMs are used to define the product from the top-level finished good to the lowest level of the assembly. BOMs encompass a relational record with component quantities and units of measure that drive production and supply chain efforts in downstream systems throughout the new product development process and beyond.

While control of quality processes is essential in the medical industry, this document-centric approach may be appropriate for life sciences companies that do not create and manufacture a medical device product. Medical device product manufacturers must be able to carefully track, control, and release product definition changes to market quickly and effectively.

Arena's BOM-Centric Approach

Arena Solutions Product Lifecycle Management (PLM) system controls and drives your new product development process from product concept through end-of-life. To do this, Arena Solutions aggregates your product information into a BOM that describes all of the components, assemblies, and associated documents required to build and ship your product. Managing your complete product record meets quality system requirements while helping you ship quality products on time. This comprehensive BOM-centric approach accelerates your product development process and facilitates product improvement as you strive to reduce cost and continually innovate.



In addition to the standard BOM management you would expect in a PLM system, Arena Solutions provides the other key capabilities that medical device product companies need.

PLM with an Embedded Quality Management System (QMS) Solution

We manage documents, Device Master Records (DMRs), and Design History Files (DHFs) while providing the ability to collect 21 CFR compliant electronic signatures during the review and approval process. For document management, we control specific versions and revisions of drawings, specifications, standard operating procedures (SOPs), assembly and test instructions, and any type of file, including software code. The difference with Arena's QMS approach is that every document is linked directly to the BOM and the specific component or item it relates to. So, everyone can see every document and how it relates to your product.

> "Arena is a one-stop shop."
>
> Kona Medical Systems

Critical Quality Process Support

Arena's Quality module is embedded into the product record so that complaints, issues, audits, and CAPAs are associated with the affected part or subassembly. For DMR management, Arena provides a rich relational structure to capture all aspects of the DMR including the BOM, device/software/process specifications, quality assurance procedures, packaging, and labeling—as well as installation, maintenance, and service procedures.

Design History File (DHF) Management

Leveraging Arena's Project module, you can effectively capture design decisions, meeting notes, design quality documentation, and quality records, while providing a phase gate process to guarantee all information is tracked, controlled, and documented as you move through the design and development process. This unique approach to DHF management provides not only the control you need, but allows you to link to any part of the DMR.

What Arena Does – Digging Deeper

What truly makes Arena unique is the ability to manage linked relationships between DMRs, DHFs, BOMs, individual components, AML/AVL, documentation, product history, and any changes or quality issues. Leveraging information quickly and easily facilitates robust change control, supply chain collaboration, quality management, and key product-related business processes. We will look at these areas in more detail now, considering your business needs and external requirements.

CHALLENGE: Corporate Wide Visibility of Full Product Record & Associated Processes

Engineering creates and documents product designs in a product record, and then everyone else uses this information to verify, validate, source, manufacture, and support the products. But who is everyone else? Manufacturing, quality, regulatory, clinical, purchasing, supply chain partners, packaging, and field service groups. With Arena Solutions, these teams have instant access to the complete product record, which means they perform their jobs more quickly and more accurately. When an issue arises, Arena empowers impacted teams to resolve the issue. For example, if there is a part quality issue, purchasing can easily view the AML to find and select approved alternate parts.

When considering solutions, remember what comprises the product record. The complete product record includes BOMs that define electro-mechanical assemblies with reference designators to identify a component in an electrical schematic, or on a printed circuit board (PCB). The product record is further enhanced with the supporting manufacturers' information (i.e., relational AML/AVL), drawings, specifications, and procedures.

SOLUTION:

With Arena, product companies can eliminate the use of multiple disparate systems. Arena provides one system to manage the BOM and all associated product information, including documentation. This simplifies control, reduces confusion, and increases traceability throughout the product lifecycle.

Additionally, Arena manages training records so managers know which employees have been trained on applicable SOPs, policies, or manufacturing process instructions. Arena provides a single solution to manage training, with links to the related product record policies and procedures.

CHALLENGE: Enterprise & Supply Chain Collaboration

Today's product companies rely on distributed teams of experts to design, manufacture, and support their products. These experts can be direct employees, contractors, or other design and manufacturing partners.

Strategic companies not only use the basic services of these experts, but also capture their wisdom and experience to influence the final product design. This input improves innovation and quality while reducing cost and process

A Different Way: Managing Records Appropriately

Arena does not treat all records in the same way. It understands that documents, change orders, BOMs, suppliers, CAPAs, DHFs, DMRs, and other data records are different unique and interrelated.

ECOs are more than documents or simple forms in Arena PLM. They drive complex workflow approval processes and post-release actions. As an example, when all of your stakeholders have approved any given ECO, the release of the ECO automatically incorporates all BOM redlines to the latest revision. This release can then trigger the transfer of the new items, BOM, supplier, and manufacturer information into your ERP system for planning and production purposes.

In Arena, we maintain the necessary relationships between the change order (e.g., ECO) and its affected parts, assemblies, quality records, and documents. To drive procurement and manufacturing accurately, the ECO's disposition codes—coupled with effectivity dates—allow for optimized planning and production. And the relational BOM includes component quantities and units of measure to drive your enterprise resource planning (ERP) later in the new product introduction process.

Approved manufacturers' parts, suppliers, and supplier information also require unique functionality. Arena's AML capabilities provide management of manufacturer's part numbers, internal part numbers, and the supplier's (or distributor's) part numbers so that your procurement teams can effectively plan and procure parts. With Arena, our AML functionality helps you identify and eliminate the use of duplicate manufacturer's parts, reducing costs through higher volume purchasing.

cycle times. For example, Design for Manufacturing (DFM) processes are compressed when the manufacturer can review designs earlier and give feedback to source different parts or change the design for ease of manufacturing.

SOLUTION:
Arena facilitates teamwork with notifications, dashboards, access control, and a range of collaboration options to share information between all impacted stakeholders. Automated notification can be driven by key actions, such as when ECOs need to be reviewed and approved. Arena controls access so that internal employees and external partners only see the product data needed to do their job.

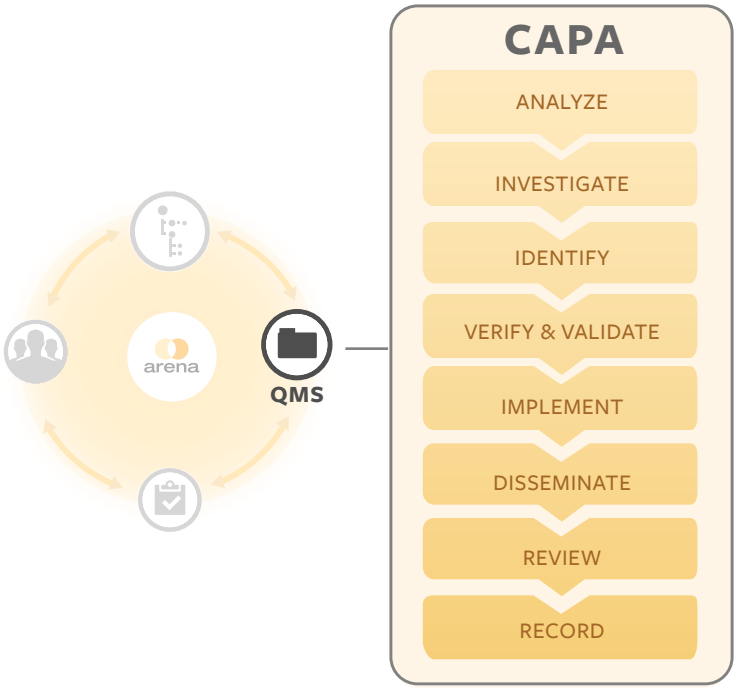
"Product data had previously been divided up into three different databases and systems, which has now been centralized to one system: Arena PLM. This offers the advantage that all product and R & D documents are centrally accessible to engineers and document control. The control and development of our products proceed more efficiently, faster and more controlled."

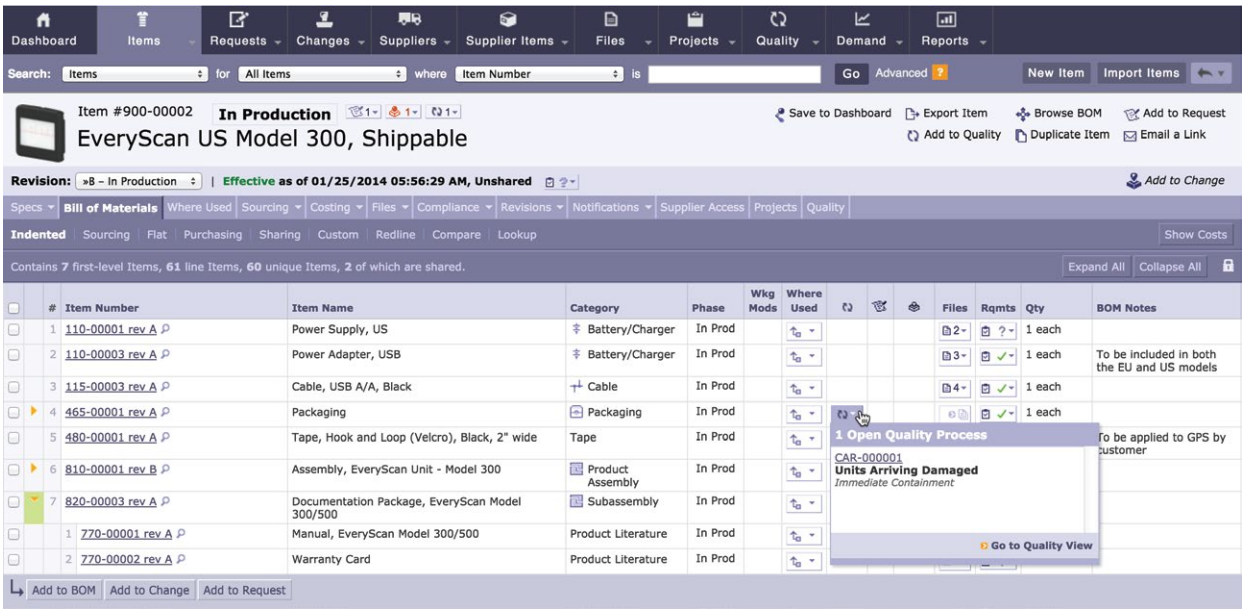
Emiel Gubbels
Director Quality & Regulatory, Argus Imaging

CHALLENGE: Closed Loop Corrective Action Preventive Action (CAPA) Process
For many medical device product companies, the lack of a well-implemented CAPA process is the primary concern for audit issues, observations, or non conformance (NCRs). CAPA is a complicated process with multiple approval disciplines, difficult root cause closure, and multiple quality processes that require a sophisticated ability to traverse product history for time sensitivities. CAPA processes often trigger an engineering change (e.g., ECR, ECO, Deviation, etc.) process to resolve product defects and other issues. A single quality issue may affect one or many products. And, one product may have one or many quality issues. Mastering CAPA processes comes with a big payback directly tied to company success, but it requires a system that supports the process demands.

SOLUTION:
Arena Solutions maintains all these relationships by dynamic links, so users can instantly move from documents, parts, and multilevel assemblies to quality issues or vice versa. Arena provides visibility between the CAPA records and one or more related change orders, which may include the BOM and AML redlines. In this way, internal auditors, quality and regulatory affairs, and other affected groups can instantly access and view all the issues, actions, and steps through to final process resolution in one central system.

Since Arena links quality issues to parts, BOMs, and related ECOs, any provisioned user can view the related CAPA records to understand what changes were required to resolve problems and why.





View of BOM with pending CAR linked directly to packaging

CHALLENGE: Simple Enterprise Software System Validation

Medical device companies are required to validate enterprise software systems that are part of the quality system for their intended use, according to established protocols (per 21 CFR 820.70(i) and 21 CFR 11.10(a)). Regulated companies understand that this requirement means each enterprise system upgrade can have a major impact on business operations. However, enterprise systems must be upgraded or enhanced periodically to meet expanding business requirements, provide technological advantages, and better meet industry demands.

"We've … added in an impact, a root cause analysis, and risk management observation process. Each one of these different processes can call the other ones, or demand that another process be used. They can also be linked together so that when you get an audit, you have a tightly integrated cross-linked evidence chain for whatever problem you're dealing with."

Laurence Sampson
Chief Operating Officer, Swan Valley Medical

SOLUTION:

Arena's Validation Maintenance Service (VMS) is a unique offering that empowers medical device companies and their employees to spend more time on core competencies and much less time on enterprise software system validation. With VMS, Arena validates each Arena release against a predefined set of intended uses that are common to all medical device manufacturers. Arena then distributes the results of validation testing to all validation subscribers. As a result, Arena's regulated customers are able to leverage 100% of the enhancements to yield additional benefits. With Arena, all customers are able to adopt every new software release, while also remaining compliant for a nominal validation cost.

REQUIREMENTS
- Requirement Specifications

IMPACT ANALYSIS
- Validation Impact Analysis

PLANNING
- Validation Test Plan
- OQ/IQ Test Cases
- Requirements Traceability Matrix

EXECUTING & REPORTING
- IQ/OQ Protocol Execution Records
- Validation Report
- Validation Certificate

CHALLENGE: Internal and External Audit Time Shortened

Audits, both internal and external, are a constant reality for medical device product companies. And how well you perform during audits determines not only success of your team and product, but sometimes your company's very existence. One approach to an audit is to engage valuable people resources in the task. These people may be asked to obsessively and manually collect all of the product and process details and become the historians of the DHF/DMR. Yet, this method exposes you to many failure points (e.g., loss of key "brain trust" people, human error, lack of visibility, and communication). It is also a costly process to maintain as your product lines grow and mature.

"Usually you have doc control, you have change champions, you have all these people that have these administrative roles to make sure that we meet the regulatory requirements, and those responsibilities were handled by Arena."

Carl Dupper
Director of Technical Operations, Yukon Medical

SOLUTION:

Arena provides the functionality to achieve and maintain regulatory compliance. Peace of mind during audits is a major benefit of having all your quality actions and change processes linked to the product record. Having the full product design history and product record controlled and tracked in one system provides you with confidence during those stressful audit processes.

What Arena Does Better than Document-Centric QMS Solutions

Provides Corporate Wide Visibility

For medical device and non-regulated product companies, the BOM captures everything required to design, produce, and ship product. From engineering to operations to your supply chain, Arena controls the release of the entire product record by providing access to a single truth.

Enables Enterprise & Supply Chain Collaboration

Beyond visibility, Arena drives effective change, quality, and project collaboration of product record with all impacted stakeholders inside and outside of your company. Arena's cloud solution provides a highly secure way to manage access anytime and anywhere via a web browser.

Unifies Quality and CAPA Process with the Product Record

Arena links CAPA records with the product record and engineering changes (e.g., ECRs, ECOs, Deviations, etc.).

Facilitates Quality Considerations During the Product Development Cycle

Saves time and money by reusing approved manufacturers' parts and other purchased subassemblies. Arena provides dynamic links between all components, quality issues, and records to help engineering prevent recurring quality problems.

Simplifies Enterprise Software System Validation

Arena offers VMS with documented validation test results for every product upgrade to all validation subscribers. This solution is unique and eliminates the fear of upgrading whenever new functionality is available.

Reduces internal and External Audit Time

Arena manages the entire product and quality records, including the DMR and DHF. These records are linked and searchable, shortening audit times.

Arena Provides the Optimal Quality System

Today, medical device companies can choose between a document-centric and a BOM-centric quality management system. Arena Solutions offers the broadest quality system foundation by providing a single system to manage the documents, compliance, quality records, and the complete product design – which often includes mechanical, electrical, and software components.

Arena enables rapid collaboration by providing secure access anytime and anywhere to guarantee all impacted parties are working to the latest and greatest release. Arena PLM links quality issues and change processes to the active product record, and most importantly, the structured product BOM. In this way, PLM enables you to involve partners, suppliers, and contract manufacturers throughout the product development process through delivery of products to the marketplace.

If meeting these critical corporate objectives isn't enough, Arena Solutions also lets you also check the FDA regulation "box." In fact, many commercial non-FDA regulated companies use Arena for their quality processes because it provides a superior foundation to get high quality products to the market fast.

Join our many medical device customers who rely on Arena's comprehensive BOM-centric solution to solve the FDA's quality system requirements and effectively manage your products through the entire product lifecycle.

[1] Retrieved 14 March 2016 from http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations/

[2] Retrieved 14 March 2016 from http://www.iso.org/iso/catalogue_detail?csnumber=36786

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 & 2017. For more information, please visit http://www.arenasolutions.com.

Author

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