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PLM Best Practices for Medical Device Manufacturers to Ensure Quality

Contents

medical
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PLM Best Practices for Medical Device Manufacturers to Ensure Quality

It is well known in the medical device industry that the success of a company is driven by its ability to bring innovative, cost-effective products to market quickly. And, in today's global medical device market, proactive strategies are needed to ensure compliance with the regulatory requirements in global markets. As the Food and Drug Administration (FDA) and other regulatory bodies have embraced the concept of total product life cycle (TPLC) management, it has become the gold standard for guiding a medical device from concept to completion.

> "Arena offers a simple and affordable product that allows medical device companies to manage their development process including DMR, DHF, docs, procedures in FDA and CE standards."
>
> — Oren Cohen,
> VP Engineering

NEURONIX

One report explains the "shifting financial, regulatory and globalization landscapes call for closed-loop product management strategies that can keep up with the increasing innovation tempo and complexity of medical devices, while at the same time, lower cost, increase quality, and facilitate compliance with regulatory requirements."[1] Noting that TPLC is aimed at enabling accelerated innovation and improved product characteristics, the report also goes so far as to attribute better company performance to the TPLC process. According to the report, FDA's vision for total product life cycle ensures that "every stage of the life cycle feeds into and connects with all others."

To improve product quality, reduce cost, and increase business, the report recommends that device companies focus on improving coordination and collaboration among key departments in the company. Further, the report suggests that doing so requires using appropriate software applications that enhance visibility, data access, analysis, and process improvement. Such software ensures that all parties have access to the same—and most up

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Why Arena PLM?

Arena invented PLM in the cloud and has over 70,000 global BOMControl users who have processed 2,000,000 change orders, 6,000,000 design files and 20,000,000 item records enabling engineering and manufacturing teams with their extended supply chains to simplify bills of materials (BOM) and change management (CM) for companies of all sizes.
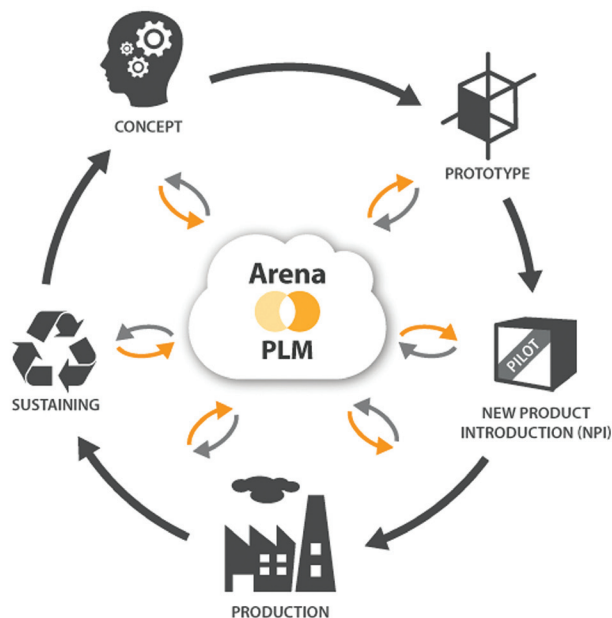
Benefits of Product Lifecycle Management (PLM):

- Collapse time to market
- Reduce prototyping costs
- More accurate and timely request for quotes
- Maximize supply chain collaboration
- Less scrap & rework
- Improve product quality
- Reduce ECO Cycle Time
- One version of the truth for your supply chain
- Streamlines compliance & audits

to date—information. TPLC enables device companies to manage the process from the concept and design of a product's life cycle through commercialization and ongoing safety monitoring.

TPLC encourages collaboration and facilitates cooperation. Achieving a successful design and regulatory compliance with TPLC is virtually impossible with traditional manual processes—such as spreadsheets—because manual processes don't provide an environment that enables the interaction essential to TPLC. Product life cycle management (PLM) provides that structure and the fail-safes that create this interactive environment. With PLM, medical device companies are able to predict quality issues that affect not only compliance but also cost.

Manual processes can inhibit good product design and quality because development processes lack integration. Each department has its own distinct systems to support its needs and this is exacerbated as oftentimes they work in functional silos. Serial design models, such as stage gate and waterfall, are no longer

sufficient. The TPLC model, by contrast, is iterative. It ensures all individuals involved in product development are included in the process.

Device manufacturers need solutions that not only archive and manage data, but also facilitate the sharing of product and process data within the company, as well as with suppliers and partners. A TPLC approach focuses on sharing information throughout the development of the product and its entire life cycle. In TPLC, product development follows a logical progression and incorporates the required interactions between all stakeholders.

A successfully implemented TPLC program not only leads to the development of high-quality medical devices; it fosters a culture of innovation. TPLC ensures the design of a medical device will be effective and ensures the device will be designed with the patient in mind.

Further, TPLC enables medical device companies to integrate and consider all factors that will influence the design and manufacturability of a device. This includes supplier qualification, which is critical to ensuring

[1] "Total Product Lifecycle Management: Lowering Costs while Increasing Quality," June 2009: FDA News.

Quality System

Arena PLM

- Corrective & Preventative Actions
- Production & Process Controls
- Equipment & Facility Controls
- Records, Documents, & Change Controls
- Material Controls
- Design Controls

Business-Software. com Ranks Arena as the Top 10, only cloud, and also the most affordable PLM solution.

consistency. Factoring in corrective and preventive actions (CAPA) is also central to TPLC. To prevent recurrence, root causes must be evaluated. Moreover, it is essential to build in quality at the early design stages.

To design a quality product requires looking at the whole system overall. It is important to have historical data and other related documents easily accessible, which is nearly impossible without a centralized system. It allows different groups to collaborate early. Cloud PLM provides a centralized system for maintaining design control documents—e.g., design history files (DHFs) and device master records (DMRs), product records, and quality system records (including CAPA).

FDA AND TPLC

FDA has encouraged device manufacturers to move away from the traditional waterfall model to TPLC, in which FDA has said the stages of product development must not only overlap but must also be connected.

FDA's TPLC database integrates both premarket and postmarket data about medical devices. The database pulls from other CDRH databases including Premarket Approvals (PMA), Premarket Notifications (510[k]), Adverse Events, and Recalls. The searchable TPLC database is refreshed as each of the individual data sources is updated. The TPLC database provides data by a generic category of a device, not by individual submission or brand name. In the future, FDA plans to further refine the database to be specific to individual products with information from its Clinical Trials Database. Currently, the TPLC database integrates the data by a three-letter code associated with a generic type of medical device.

FDA has also begun to develop guidance documents that help manufacturers prepare their submissions with TPLC in mind. For example, "Total Product Life Cycle: Infusion Pumps—Premarket Notification [510(k)] Submissions Guidance Document" was developed to assist the industry in preparing premarket notification submissions for infusion pumps. It helps identify device features that manufacturers should address throughout the entire product life cycle. In this case, the recommendations are intended to improve the quality of infusion pumps in order to reduce the number of recalls and infusion pump Medical Device Reports (MDRs). FDA believes that these recommendations will help mitigate risks and reduce future risks associated with infusion pumps.

IMPROVING DESIGN QUALITY

Paper-based files are difficult to develop, approve, and maintain. During the design process of a medical device, every design change, document revision, and discussion has to be documented. It is essential to have a complete change and document history. Every time a document is revised, the team must collaborate and approve the new revision documented per

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the appropriate standard operating procedure (SOP), ensuring the process maintains exacting change and document history. These processes can be cumbersome and time consuming with a paper-based system and are susceptible to human error.

In general, there are three types of documents: 1) quality system records—company SOPs, work instructions, business processes, quality system management; 2) product records—bill of materials (which can be extremely complex), drawing revisions; and 3) user manuals, assembly instructions, test processes, material certifications, datasheets, design files, and other product-specific documents. One of these components can trigger a revision change or even a new part number depending on form, fit, and function change rules of the item itself and possibly up the bill of materials (BOM) hierarchy to the parent part number depending on need for visibility. All documents are interdependent on one another. Such processes are very difficult to manage manually, especially across multiple products, but product variants are made relatively simple to manage with PLM.
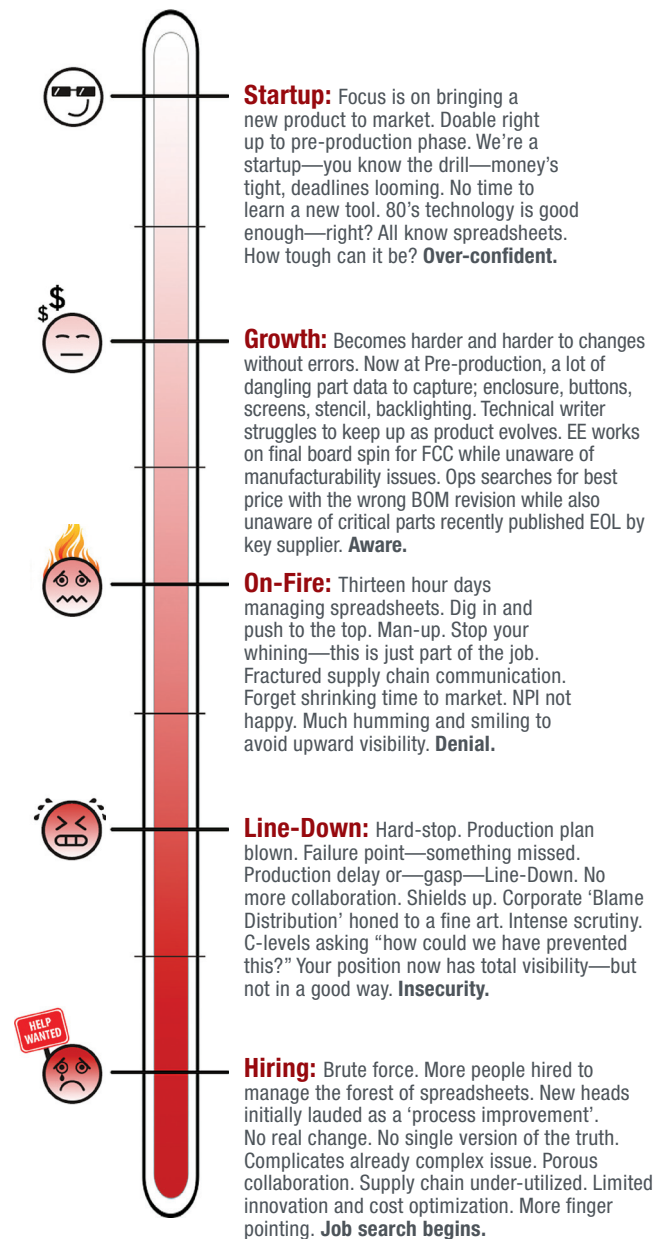
Companies must follow a design control process in which they establish and maintain a design history file DHF, DMR, etc. per quality system regulations. PLM easily controls all of the required quality system documents (design history file, device master records, per quality system regulation including validation and verification (V&V), risk management documents, etc.) and product records. PLM's configurable routing and electronic signatures allows manufacturers to significantly reduce engineering change order (ECO) approval time.

To understand how PLM can improve quality, it is important to review and understand design controls—the procedures to control the design of the device in order to ensure that specified design requirements are met. Design control elements include design and development planning, design inputs, design outputs (information showing that the device was developed according to the design plan and design inputs), design reviews, design verification, design validation, design transfer, and design changes.

Fatal Inaction

Still Using Spreadsheets?
You must have a high tolerance for pain if you're still using spreadsheets to manage your quality and product data. Many fast growing medical device manufacturers often consider product lifecycle management (PLM) solutions too late. Does this sound familiar?

Startup: Focus is on bringing a new product to market. Doable right up to pre-production phase. We're a startup—you know the drill—money's tight, deadlines looming. No time to learn a new tool. 80's technology is good enough—right? All know spreadsheets. How tough can it be? **Over-confident.**

Growth: Becomes harder and harder to changes without errors. Now at Pre-production, a lot of dangling part data to capture; enclosure, buttons, screens, stencil, backlighting. Technical writer struggles to keep up as product evolves. EE works on final board spin for FCC while unaware of manufacturability issues. Ops searches for best price with the wrong BOM revision while also unaware of critical parts recently published EOL by key supplier. **Aware.**

On-Fire: Thirteen hour days managing spreadsheets. Dig in and push to the top. Man-up. Stop your whining—this is just part of the job. Fractured supply chain communication. Forget shrinking time to market. NPI not happy. Much humming and smiling to avoid upward visibility. **Denial.**

Line-Down: Hard-stop. Production plan blown. Failure point—something missed. Production delay or—gasp—Line-Down. No more collaboration. Shields up. Corporate 'Blame Distribution' honed to a fine art. Intense scrutiny. C-levels asking "how could we have prevented this?" Your position now has total visibility—but not in a good way. **Insecurity.**

Hiring: Brute force. More people hired to manage the forest of spreadsheets. New heads initially lauded as a 'process improvement'. No real change. No single version of the truth. Complicates already complex issue. Porous collaboration. Supply chain under-utilized. Limited innovation and cost optimization. More finger pointing. **Job search begins.**

 Cloud PLM provides a centralized system of electronic records so that everyone has access to the same version of any document and everyone sees the latest revision of a document.

According to CFR 820.30(j), "Each manufacturer shall establish and maintain a design history file (DHF) for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part." A DHF becomes a compilation of records that describes the design history of a finished device.

All elements that are controlled by PLM are required by 21 CFR Part 820. Part 820.40 Subpart D requires device manufacturers to establish and maintain document control procedures in which document review and approvals are required and approvals are to be properly documented. All document changes are required to be reviewed and approved, and the document change history must be maintained. Part 820.30 Subpart C also requires device manufacturers to establish and maintain a design control procedure. Part 820.181 requires device manufacturers to establish device master records. The DMR must be prepared and approved in accordance with the document control procedures in Part 820.40.

The DMR is a compilation of records containing the procedures and specifications for a finished device (e.g., device specifications and drawings, standard work specifications, production environment specifications, quality assurance procedures, packaging, labeling, installation procedures, and so on). It is essentially the end result of your design output, as DMRs are the final technical documents. Design output information shows that the device was developed according to the design plan and design inputs.

PLM enables device OEMs to share bills of materials and all necessary files with suppliers. When the same component is needed from different manufacturers, it is easy to communicate the requirements. For example, a company can indicate that it has a new design to review, and suppliers can immediately access those records and can even participate in change review processes including approval/rejection signoffs.

PLM AS A TPLC TOOL

Medical device companies face many challenges in product development. Not only must all processes be documented, but these processes must be followed, and all outputs must be documented per the design control processes (e.g., DHF, DMR, etc.). Implementing a cloud-based PLM solution to address TPLC management decreases time to market for medical device companies. It also reduces the cost of development because PLM formalizes all of the processes required by FDA including design control, document control, and change control processes. Because PLM enables electronic signatures, it's easy to obtain approval and move through change control faster.

Collaboration is the backbone of PLM. With PLM, especially a cloud-based PLM system—which can be accessed from anywhere at anytime—collaboration is seamless. Cloud PLM provides a centralized system of electronic records so that everyone has access to the same version of any document and everyone sees the latest revision of a document. It enables device companies to move through product life cycle phases faster than with traditional processes as it reduces the chances for mistakes that result from human error during manual data entry.

Another benefit for medical device companies is that PLM streamlines audits and compliance. With PLM, design history file documents and device master

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records are searchable, traceable, and linked. It's easy to locate and present files to FDA and other regulatory bodies as soon as they are requested. With PLM, the document route can be configured per the company's quality procedures. PLM makes it easy to demonstrate that SOPs are being followed because it specifies the steps and procedures that make up each design phase. PLM provides change history. As many companies now have a global presence—people working from home offices, multiple locations, suppliers, and manufacturers alike—PLM enables seamless access in a centralized system. All stakeholders view the same information and update the same documents, and approval can be accomplished in a timely manner.

For medical device manufacturers, internal quality management systems must consist of SOPs, work instructions, and policies in which employees must be properly trained. PLM makes it easier to maintain these quality management measures because they can be documented, and each change is tracked in a centralized system.

PLM serves as a critical tool during audits as well. To ensure compliance with applicable regulations, auditors might ask to review any number of documents stemming from any phase in the design and development life cycle. The PLM software allows for quick and easy retrieval of requested documentation.

Another benefit to PLM is the ability to integrate supplier information in such a way that they, too, are part of the process. For example, PLM enables medical device companies to rank suppliers based on cost, product availability, and other factors. With such information in the system, device companies can determine how fast a supplier can provide a prototype, for example, and this provides for control over vendor costs and production times.

CLOUD-SPECIFIC BENEFITS
PLM itself enables companies to move their paper-based systems to on-premises solutions with an installed client configuration. PLM software, even if it's not in the cloud, provides great benefits; however, cloud-based systems provide yet another level of

"As Align has grown into one of the world's largest mass manufacturers of a highly customized medical product, we've relied strongly on the functionality of Arena PLM. We now have more than 850 users logging in to Arena PLM to access the latest product information and operating procedures. By automating our document control function through Arena PLM, we were able to deal with a larger volume of changes and have reduced our change implementation cycle time without increasing headcount."
— Len Hedge, VP, Operations for Align Technology

ALIGN TECHNOLOGY

accessibility. If a company is operating in the cloud, users need only access to the Internet and a Web browser thereby removing global barriers to collaborate.

The beauty of cloud PLM is that you don't have to install or configure anything on in-house servers. The cloud enables users to simply go to a specific URL, enter a username and password, and access the centralized system of electronic records for the company. That's it. There are also cost-effective benefits. With cloud PLM, a medical device OEM doesn't have to allow for IT support or invest in extensive infrastructure. As a scalable solution, new users can easily be added (or subtracted) by simply assigning the new user a username and password. The cloud-based PLM supplier provides the financial-grade infrastructure with multiple backups and security.

Because the system is in the cloud, medical device companies can implement it quickly, and they're assured they have the latest version of the software. As the PLM software is updated with new features, it's available to the entire customer base instantly, meaning all of the users are working off the same version. To ease the validation burden on device manufacturers and help them ensure compliance with applicable regulations such as 21 CFR Part 11, PLM providers often include validation maintenance services in which each release is validated in-house against a well-defined set of intended uses for each release. Customers are then provided with validation documentation to confirm that updates to the software have, in fact, been validated and that the PLM conforms to its predefined intended uses.

Productivity. A key benefit of cloud-based PLM is its document control features. In the cloud, 10 cross-functional stakeholders who need to sign off on a change can be at 10 different locations worldwide, and the change is seamless. PLM provides automatic notification to approvers who can approve the change through electronic signature. Getting physical signatures—even if you have an office across the street—is a time-consuming task. Medium- to large-sized medical device companies have a complex approval matrix defining who must sign documents, and this process can be drawn out with paper-based systems. PLM reduces the chance of human error.

With cloud-based PLM, everything is searchable, enabling access to research documents and previous versions of documents. Documenting a device's history helps to demonstrate compliance and significantly reduces audit time.

Communication. Because PLM is a cloud-based software as a service (SaaS) delivery model, all personnel need access only to an Internet browser to operate the system and access any documents or records. With everything in one system, critical personnel can make an informed decision and can initiate cross-functional collaboration. Issues can be identified and addressed early in development. In medical device development, this is also cost-effective because it is much less expensive to correct mistakes in the beginning of the product life cycle than later on.

Time-to-market. PLM is designed to enable medical device companies to deliver a product to market quickly. PLM fosters innovation and collaboration because it improves the feedback loop during the total product life cycle, thus ensuring better design at the front end of the process. Historical information prevents repeating errors, and the PLM system provides immediate access to all data necessary for designing the product. Such access to all of the data from each design phase improves the design process.

ARENA: EXPERTS IN PLM FOR MEDICAL DEVICE MANUFACTURERS

The electronic tracking of product development required by TPLC is not easily accomplished with the dated paper-based waterfall or stage-gate systems. Arena Solutions' cloud-based PLM software makes it possible to ensure that all relevant parties—including suppliers— are able to communicate and participate on a given project in real time. Arena focuses on assisting medical device companies in meeting 21 CFR Part 11. Its cloud-based PLM system serves as a tool to execute electronic records and signatures and provides procedural and technical controls to ensure a secure environment. Arena's electronic record management solution creates, modifies, maintains, archives, retrieves, and transmits secure electronic records.

Arena's PLM offers the additional benefit of enabling the consolidation of all compliance information in one centralized location. Arena has created an ultra-high security infrastructure that ensures that all firewalls and encryption devices are tested rigorously. Its multi-tenant, single-instance architecture extends to protect intellectual property and secures information from inappropriate access. Arena's extensive investment in a high-grade production networking system also provides near perfect system availability and fault tolerance.

CONCLUSION

Getting an innovative, cost-effective product to market quickly requires collaborative interaction of all key stakeholders throughout the product design cycle. As TPLC takes hold, medical device companies must embrace these new systems to compete. It reduces costs associated with late-stage redesign, it reduces regulatory delays associated with inefficient document control, and it improves communication among team members. FDA already expects this higher level of product development, and soon may demand it. ∎

AT-A-GLANCE

	arena	Pricey PLM
Native Cloud Architecture	✔	
Item Master	✔	✔
Bill of Materials (BOM)	✔	✔
Change Control	✔	✔
File Management	✔	✔
Approved Manufacturers List (AML)	✔	✔
Engineering Change Requests	✔	✔
CAD & ERP Integration	✔	✔
Validation Quality Management	✔	✔
Auto-Document Parts	✔	
Demand Analysis	✔	
Project Management	✔	✔
Compliance Management	✔	✔
Supply Chain Licenses	$	$$$$
Supply Chain Collaboration	✔	
Bidirectional Integrations	✔	✔
INVESTMENT	$	$$$$

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Patented. Proven. PLM
Over 70,000 Global BOMControl Users

Change Orders	002,055,617
Design Files	006,419,985
Item Records	020,037,956

Why Arena?

Click on the thumbnail on the left to listen to **How to Speed Innovation at Lower Cost in a Global Regulated Environment**

Speakers: Arena/Arthrex

About Arena Solutions

Since Arena pioneered cloud PLM applications over a decade ago, over 70,000 Arena BOMControl users have processed 2,000,000 change orders, stored 6,000,000 design files and created 20,000,000 item records. The company's broad product offerings enable engineering and manufacturing teams and their extended supply chains to speed prototyping, reduce scrap, and streamline supply chain management. Arena cloud PLM applications simplify bill of materials and change management for companies of all sizes, and offer the right balance of flexibility and control at every point in the product lifecycle—from prototype to full-scale production. Based in Foster City, Calif., Arena has been ranked as a Top 10 PLM solution, Top 5 Supply Chain Collaboration solution and also holds a spot on the San Francisco Business Times' Best Places to Work List for 2013.