ptc

arena

How Strong Design Controls Simplify Compliance and Eliminate Audit Anxiety

WHITE PAPER

INTRODUCTION

Achieving and maintaining regulatory compliance is an imposing hurdle for many medical device manufacturers. Missteps and inefficiencies addressing FDA, ISO, and other regulatory directives can result in costly delays, warning letters, and even business closure. FDA regulated manufacturers must establish and follow quality systems to ensure their products meet applicable requirements and specifications. More specifically, these manufacturers must establish effective design controls to demonstrate devices are safe and effective for their intended uses.

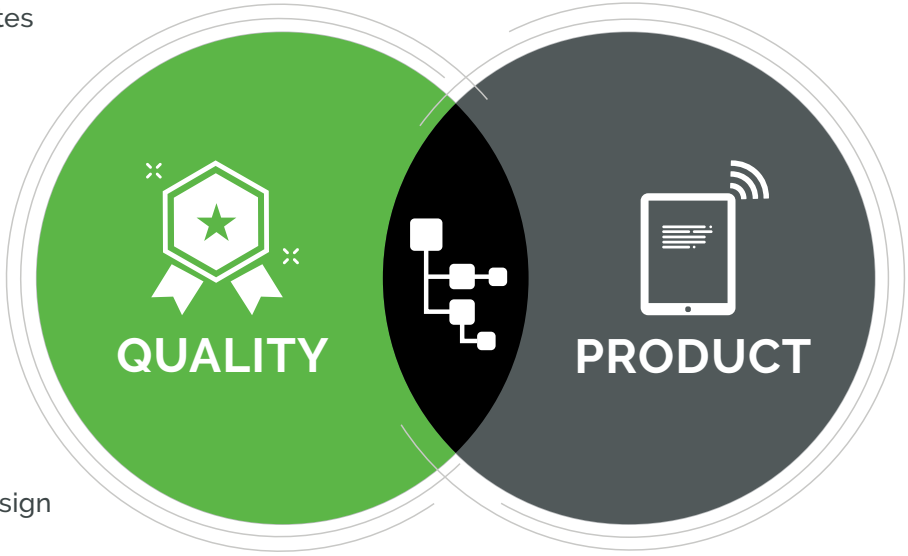
QUALITY MANAGEMENT SYSTEMS

For medical device companies that create sophisticated solutions with electrical, mechanical, and software components, adhering to quality standards throughout the new product development and introduction (NPDI) process requires a connected quality management system (QMS) methodology. This means having a QMS system that is connected to the product record and design process for optimal visibility and traceability throughout the entire product lifecycle. While seemingly obvious, many manufacturers continue to manage quality and product processes in disconnected silos, making it difficult for everyone involved in the NPDI process to work together. So it is crucial to use a single system for design control that connects teams, products, and quality to streamline regulatory compliance.

Design controls are at the heart of the FDA's quality system regulation specified under Title 21 CFR Part 820 and ISO 13485. The FDA specifies the necessary steps and procedures for each design phase. These design controls govern the processes

throughout NPDI. The FDA also defines how manufacturers demonstrate compliance. Medical device manufacturers must produce two pieces of compliance evidence—the design history file (DHF) and the device master record (DMR).

The difference between DHF and DMR can be confusing, particularly as medical device companies develop products in a more digital, and less paper-based world than when the FDA defined some of its foundational regulations and definitions. A key example is the question of where to place certain information such as specifications: as part of the DHF or the DMR? First, remember the FDA requires that manufacturers reference each record only once. Second, as the DMR is actually referenced by the DHF, all DMR content will be linked to the DHF and vice versa—an easy linking for any full product-centric QMS system. Therefore, companies can focus on logical positioning of the "questionable" records based on process flows. If a medical device company creates device specifications, labeling, packaging, or quality assurance procedures earlier in the design and development processes, the company can reference them in the DHF. Or, it can place these later in the DMR definition if created during the design output phase.



A product-centric QMS solution enables complete control and traceability throughout the new product development and introduction (NPDI) process with unified quality and product record management.

THE IMPORTANCE OF THE DHF AND DMR

DHFs and DMRs are critical to demonstrate compliance throughout the entire product lifecycle. Both types of records are for:

- Documenting dynamic records that continually change (with traceable revision control)
- Submitting regulatory submissions to the FDA and international regulatory bodies
- Preventing nonconformances and product recalls

The DHF and DMR

Design History File (DHF): This is a collection of records that describe the design history of a medical device. The FDA specifies requirements for the DHF in Title 21 CFR section 820.30 as follows.

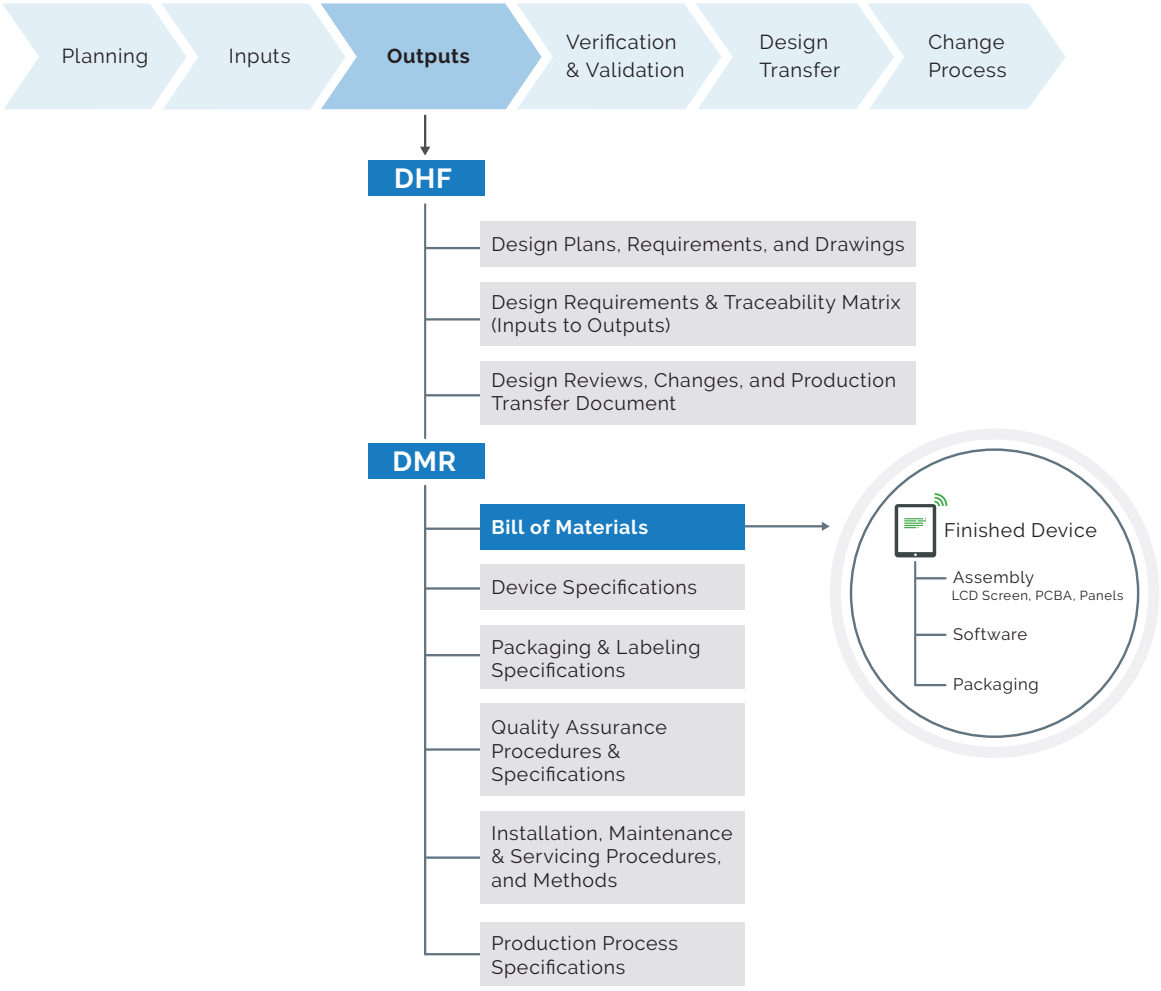
> *Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.*

Device Master Record (DMR): The DMR is comprised of drawings, instructions, and other records used to produce a product. According to FDA Title 21 CFR section 820.181, manufacturers shall ensure that each DMR is prepared and approved in accordance with 820.40:

> *The DMR shall include, or refer to the location of, the following information:*
>
> a. *Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;*
> b. *Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;*
> c. *Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;*
> d. *Packaging and labeling specifications, including methods and processes used; and*
> e. *Installation, maintenance, and servicing procedures and methods.*

Design Controls

To demonstrate compliance and proper design controls, companies must be able to effectively manage the DMR and DHF in context with each other and the entire product record. To manage the entire product record, you must have the ability to manage a complete bill of materials (BOM) for electrical, mechanical, and software parts.



When medical device companies are audited by the FDA, they may be subject to any of the following actions if they fail to comply with any quality system regulations including DMR and DHF management:

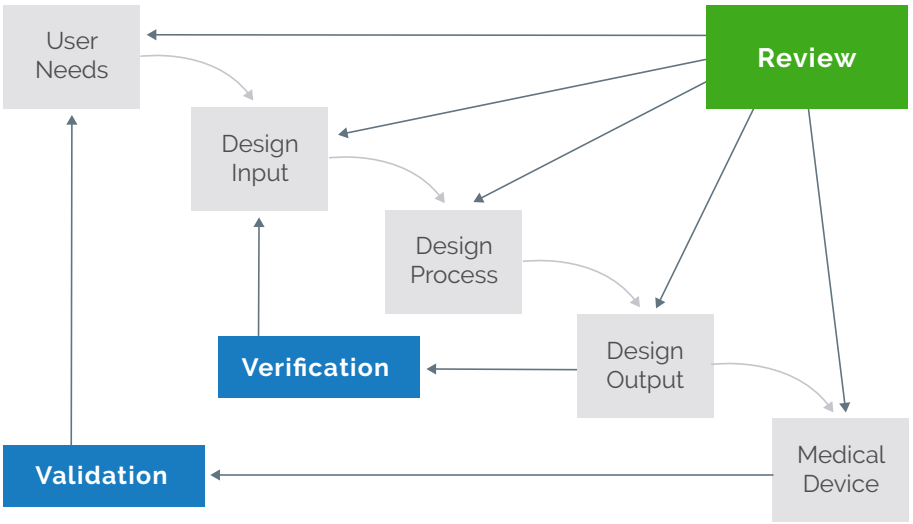
- Increased audit schedules
- Failure to approve new products
- 483 Observations
- Warning letters
- Product recalls
- Plant closing
- Civil penalties, fines, and even jail time in extreme cases

ENABLING DESIGN CONTROLS

Every part of the design process must be supported by a document in the DHF, and every document and component in the DMR must be well controlled. Design controls requirements stipulated in 21 CFR 820.30 include:

- Design and development planning
- Design input, including intended use and user needs
- Design output, including evaluation of conformance to design input requirements
- Design review
- Design transfer ensuring that the device design is correctly translated into production specifications
- Design changes
- Design history file (DHF), a demonstration that the design was developed according to the approved design plan

FDA Design and Development Overview Process Flow



Issues with design controls are magnified when the right tools for managing design and quality are not in place or not connected. Paper-based systems are one such example, causing countless errors, bottlenecks, and inconsistent information. And while document-centric QMS tools go a step further by automating some aspects of document management, their limited functionality leaves quality, design, and other key components of the product record disconnected and inaccessible.

In contrast, Arena's product-centric QMS approach ensures the entire product record (e.g., parts, BOMs, AML, drawings, packaging, specifications) and quality record (e.g., CAPAs, DHFs, DMRs, NCMRs) are connected throughout the entire product lifecycle. This connected QMS methodology enables full traceability for all key stakeholders from engineering to quality to operations and the entire supply chain. This creates stronger design controls and gives everyone more confidence to face and address FDA or other audits.

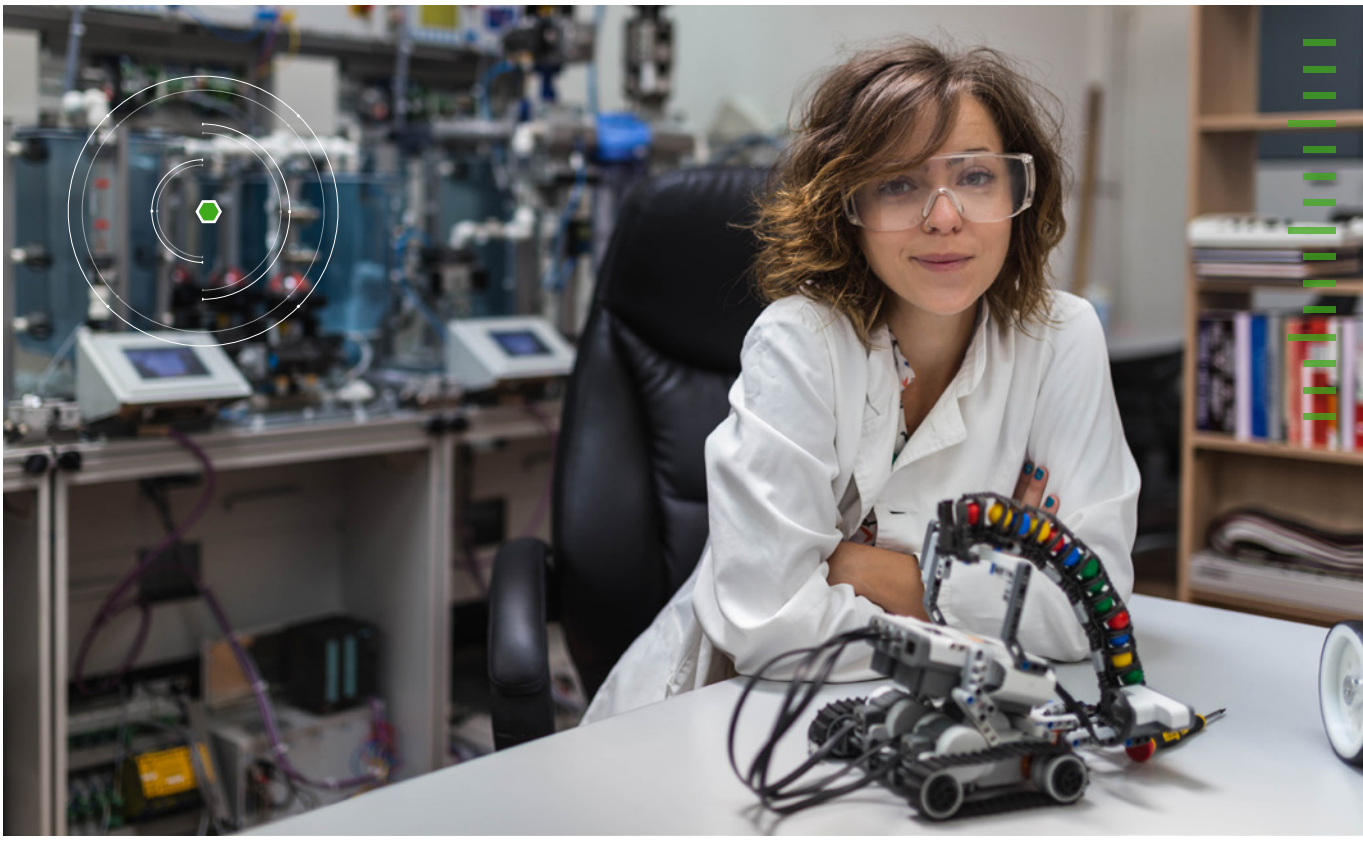
THE BENEFITS OF CONNECTED QMS

With Arena QMS, a DHF can be easily created from predefined templates that adhere to your established SOPs and broader quality system framework. This ensures consistency and control and links quality and design from the very start. Having these elements linked streamlines compliance and allows you to easily demonstrate that your products and processes meet regulatory requirements.

The benefits of connected quality and design also extend throughout the entire supply chain, mitigating challenges created by dispersed partners and teams that span multiple time zones and locations. Centralizing the BOM, DHF, and DMR along with associated product design and quality system records keeps everyone on the same page to reduce confusion and costly mistakes.

ADOPT A BETTER APPROACH TO MEET FDA DESIGN CONTROLS

With Arena's product-centric QMS solution, medical device manufacturers can achieve and maintain regulatory compliance by bringing quality, product, and all teams together in a single connected QMS solution. This gives key stakeholders in quality assurance and regulatory compliance the confidence to address internal and FDA audits anytime. To learn more about how Arena QMS can help your company streamline NPDI processes and streamline compliance, contact Arena today.



ptc arena