

# Arena for the Medical Device Industry



Establish Automated DMR and DHF Controls  
Provide a Validated Environment for Product Development  
Streamline Quality and Compliance Document Management

Developing innovative, high-quality products in the medical device industry requires effective design and document controls that adhere to regulatory requirements, such as the FDA's current Good Manufacturing Practice (cGMP) and 21 CFR Part 11. Arena helps you meet these challenges and improve the efficiency of new product development.

**A broad range of medical device companies—from class I to class III—rely on Arena to manage product and compliance information in a collaborative environment accessible to all authorized design, manufacturing and clinical trial team members.**

## Customer Success



**Align Technology** is a Class II medical device company whose advanced orthodontic technology is subject to numerous FDA regulations. After experiencing rapid growth, the company chose Arena as a vital component of its continued expansion. Using Arena, Align experienced:

- A reduction in change order cycle time from **22 days to 3-5 days**
- A **\$250,000** annual decrease in compliance administration cost
- A **300%** increase in production document management efficiency
- Three successful **ISO 13485** audits

“The auditor was impressed with the traceability within Arena. With a click of the mouse, the complete revision history of any item can be displayed, including which ECO made the revision effective and who signed off.”

-Meredith Yost  
Document Services Manager  
Align Technology



## ARENA PROVIDES

A centralized device master record (DMR) and design history file (DHF) accessible globally to authorized product team members through an ultra-secure, financial-grade design control workspace

Automated device change processes (e.g., ECN, CAR, SCAR, NCMR) that track revision-controlled design files, BOMs, quality documentation, approved vendor/manufacture lists (AVL/AML) and design notes and instructions

Compliance management tools that support multiple reporting requirements, capture evidence documentation, provide quick visibility to compliance status and instantly generate compliance reports

Built-in system validation (per FDA CFR 820) prior to every release that guarantees that the software and systems used for product development operate in a persistently validated state

## ARENA CUSTOMERS INCLUDE



and hundreds more.

Arena helps medical device companies rapidly innovate new products and maintain compliance with product and process requirements, ensuring traceability of change history throughout the device lifecycle.

**ESTABLISH AUTOMATED DMR AND DHF CONTROLS**

Support standardized design processes across the extended product team and provide comprehensive traceability of all changes to products and product (e.g., quality) documentation

**Features**

- Centralized product information provides an electronic DMR, the DHF, bills of materials (BOMs), item masters, AVL/AML, change history, compliance data, standard operating procedures and more
- Standardized design change process workflows enforce approved procedures and track complete history, including originators, actions, approvals, signatures, decisions and supporting documentation
- Advanced document management, vaulting and edition-control capabilities support ISO9001, ISO13485 and cGMP reporting requirements
- Configurable compliance management capabilities support multiple reporting requirements, such as FDA, UL, CE, and ISO

**Benefits**

- Remove delays and guesswork from product development by providing all team members instant access to up-to-date product information
- Ensure timely review and approval of changes to designs and documentation
- Assemble a comprehensive electronic audit log in support of process compliance requirements (e.g., 21 CFR Part 11)
- Simplify and streamline document management and reporting on product compliance requirements

**PROVIDE A VALIDATED ENVIRONMENT FOR PRODUCT DEVELOPMENT**

Eliminate manual system validation and provide the extended product team access to a persistently validated design and document control system

**Features**

- Comprehensive software and systems validation before every major release supports compliance to FDA quality management system (QMS) requirements
- Installation qualification (IQ) and operation qualification (OQ) protocols (based on the user requirements of medical device companies) are executed by Arena to comply with cGMP and 21 CFR Part 11
- Single application instance accessed by companies and their suppliers and partners requires no additional software or systems for distributed product team members

**Benefits**

- Provide all users instant access to new capabilities of Arena without revalidation concerns
- Leverage Validation Maintenance Service to have Arena execute formal validation protocols, document results and provide records to support FDA, ISO, and other audits
- Provide suppliers and partners consistent access to latest features without requiring them to invest in additional hardware, software or IT staff

**STREAMLINE QUALITY AND COMPLIANCE DOCUMENT MANAGEMENT**

Centrally manage quality and compliance documentation in a revision-controlled repository accessible to all authorized product team members

**Features**

- File details and activity log capture document name, author, creation date, last modification date, action description, action date and affected file edition
- Automated document numbering, vaulting, change management and edition control capabilities enable systematic document control
- Revision-controlled document management provides subscription-based notifications and ensures appropriate review and approval workflows
- One-to-many linking connects any file type to one or more items in any lifecycle stage in the DMR/DHF or to suppliers, requests, changes or other objects

**Benefits**

- Eliminate paper-based document management and file sharing with a secure, centralized document repository and user-based access controls
- Streamline document management to support ISO9001:2000, ISO13485 and other compliance requirements (e.g., TUV, BSI)
- Easily identify the most recent version of a document through comprehensive document revision control and history tracking
- Efficiently collaborate with suppliers and partners on design documentation

Managed by industry veterans, Arena serves a broad array of class I through III medical device companies, in addition to companies in other diverse industries, such as high-tech and electronics, consumer products, clean energy, automotive, industrial equipment and more.

Arena is the solution behind great products from more than 300 companies, such as Align Technology, VNUS Medical Technology, Salient Surgical Technologies, Novare Surgical, Carticept Medical, NuVasive, NeoGuide Systems, NDS Surgical Imaging, and more. Commitment to customers' success is the key to Arena's success.

*"We switched to Arena because the performance of our existing software depended more and more on in-house IT expertise. To be competitive we must remain a lean organization focused on our core business. By using Arena we are able to move critical resources from the IT budget to product development and sales without sacrificing compliance to regulatory agency requirements."*



*Dave Sapuppo,  
Vice President of Manufacturing  
Zassi Medical Evolutions*