

An Arena Solutions case study



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Align Technology, Inc.

Growing Fast While Reducing Cost

AT A GLANCE:

Customer: Align Technology, Inc.

Industry: Medical Device (Class II)

Challenge: Implement a robust electronic document management system to support growth, as well as meet and maintain regulatory compliance.

Solution: Arena

Results: Align cut ongoing compliance cost by more than \$250,000 annually. Change implementation used to take 22 days, but now takes only three to five days.

SITUATION

Align Technology, Inc. (NASDAQ: ALGN) is a medical device company engaged in the design, manufacture and marketing of Invisalign®, the world's leading invisible orthodontic product. Invisalign is a series of clear, removable aligners that both orthodontists and general dentists use to straighten their patients' teeth. With more than twenty million unique aligners made to date, Align is one of the largest manufacturers of mass customized products in the world.

With operations in both Mexico and Costa Rica, Align's entire production process is documented in approximately 1000 highly detailed operating procedures and company SOPs, which must be accessed by more than 500 technical and production staff members. Additionally, another 400 employees from Align's development teams in Russia, and its corporate personnel worldwide, access the production information 24/7.

CHALLENGE

In mid-2002, Align employed about 300 people. But with plans for major expansion, the company's management team identified electronic document management as a vital component for continued growth. The company then hired Meredith Yost, a 25-year industry veteran, to take charge of the document management initiative.

"Our executive team had the foresight to know that a scalable document control function is essential for growing the business," said Len Hedge, Vice President of Operations for Align in Santa Clara, Calif. "If you see implementation times for documentation changes increase, you may have already painted yourself into a corner, as Food and Drug Administration (FDA) regulations do not allow for shortcuts. We knew that investing in document management would be critical."

One of Align's business goals was to reduce the time needed to process change orders. Prior to implementing Arena, Align had managed change orders through manual, paper-based processes, which created a significant backlog and resulted in cycle times of sometimes up to 22 days. Additionally, management wanted to shift the change approval responsibility to the people involved in daily operations rather than relying as heavily on senior executives. Only then could the company increase internal efficiency and position itself for long-term growth.

Align managed production procedures and documentation in folders on a shared, read-only file server where only document control personnel could make modifications. Because all changes required manual updating on both the production folders and the "down-rev folders," personnel were required to duplicate work efforts to ensure referential integrity between documents.

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Employees found it difficult to find the proper revisions of specific documents. Even with the “file search” capability, employees would turn up many versions of a document—only one of which was the effective revision. The wasted time, when multiplied by the number of employees needed to find the effective document, and the number of times per day employees needed to access it, resulted in a high hidden cost.

The Invisalign system is designated as a Class II medical device, meaning that Align is required to follow the FDA’s regulations on manufacturing and reporting. Align also distributes its product to Europe, requiring the company to adhere to ISO13485:2003 regulations. With the complexities associated with the FDA’s Good Manufacturing Practice (GMP) and the European ISO standard, Align needed two full-time staff members in document control to manage compliance. Given the company’s forecasted growth, executives expected Align would need a total of four full-time employees within two years.

It was abundantly clear to Yost that Align needed to migrate from its manual, paper-based documentation and change management processes to a comprehensive and automated document management system.

SOLUTION

Align went through a rigorous vendor selection process before finally selecting Arena as its system of choice. The company dismissed “file-oriented” document management systems because they didn’t support indented bills of materials (BOMs), and also lacked critical part-based “where-used” functionality that would allow back-tracking shared materials across different products.

In the end, Align chose Arena for four clear and compelling reasons:

- Arena provided the breadth and depth of functionality Align needed.
- The web-based architecture enabled easy, convenient and worldwide access for Align’s growing base of end-users.
- The on-demand model freed Align from IT headaches and offered the lowest total cost of ownership.
- The Arena security architecture provided robust, fully compliant and redundant protection for the company’s data.

RESULTS

Rapid growth and improved processes

The use of Arena has supported company-wide growth, enabling a rapid ramp-up from 300 to 900 employees in only four years’ time. Additionally, the shift from an inefficient, paper-based document management system to the streamlined Arena application generated the company a cost avoidance of approximately \$250,000 per year in administrative overhead.

The implementation of Arena has also led to significant business gains across the operations, purchasing and document services departments. Within the operations department, users now enjoy 24/7 universal web-based access to Arena. Moreover, the Arena search capability always returns the effective revision of any item or document, eliminating document mix-ups, satisfying QSR compliance requirements and eliminating wasted time and resources.

A smoother change implementation process has enabled the company to increase efficiency. Using the electronic sign-off process, for example, the change administrator can set a future effective date on change orders, allowing various departments to train their staff before changes become effective in Arena. This means changes are no longer blocked from implementation because training has not been completed. Additionally, with a single centralized view of the product record, users can quickly access the current status of a change order. By viewing this information

Document Management vs. Arena

Feature	Document Management Systems	arena
Unique Numbering (Part/Document)	✓	✓
Item Record	✗	✓
Product Structure (BOM) Management	✗	✓
Versioning	✓	✓
Change Control (Sign-off + Part Update)	✗	✓
Where-Used Analysis	✗	✓
Deviation	✗	✓
Supplier Management (AVL/AML)	✗	✓
Quoting & Costing	✗	✓
External Supplier Collaboration	✗	✓
Closed Loop Corrective Action Tracking	✗	✓

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themselves, they save valuable company time by no longer having to track down and get answers from a specialist. Finally, users receive automatic updates when changes to relevant documents become effective.

The purchasing department has also made advances. Using Arena, fifteen of Align's suppliers have real-time, need-to-know access to specifications. For a Chicago-based manufacturing partner, for instance, the ability to access packaging documents and BOMs ensures the partner uses only up-to-date specifications and quantities.

The document services group has seen significant improvements of its own. Today, the department is able to manage 300% more production documents than with its paper-based, manual process—but without having to add headcount. The document services group also reports a vastly reduced change implementation cycle. Whereas ECOs used to take up to 22 days to process, they now only take three to five days.

BOTTOM LINE

"Arena provides Align with all the functionality we need to streamline critical data management processes, manage compliance and make sure our personnel have vital product information at their fingertips," said Yost. "We have been able to significantly reduce our operational costs while improving productivity. And Arena provides a scalable solution that grows with our business without us having to grow our IT department to support it."

Furthermore, the use of Arena enables Align to continue to stay on top of certain compliance requirements, both domestically and abroad. For example, Align has passed its annual ISO 13485:2003 audit by TÜV Rheinland three times since the Arena implementation. "The auditor was impressed with the traceability within the Arena system," said Yost.

"With the click of a mouse, the complete revision history of any item can be displayed, including what ECO made the revision effective and who signed off." Going forward, Arena will aid Align in its ongoing efforts to streamline core operations, automate document management and continue growing its business.

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- Merideth Yost, Document Services Manager
Align Technology, Inc.

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