" A recent FDA audit clearly demonstrated the value of Document Locator by reducing the time it took us to retrieve requested records in half. "

Bruce Hays
Vice President Operations
The Anspach Effort, Inc.
Palm Beach Gardens, Florida

Customer: The Anspach Effort, Inc.
Industry: Medical Device Manufacturing
Website: www.anspach.com

Critical Issue
Over 500,000 paper records in storage, plus electronic documents stored on a shared file server, were slowing down critical regulated processes.

Solution
An electronic document control solution with digital signatures in compliance with 21 CFR Part 11 that was easy for people to use.

Results
More efficient processes, an ROI that far exceeded expectations, and a reduction in on-site FDA audit time by as much as one-half.

Software and Services
Document Locator
WebTools Module

The Anspach Effort, Inc. Deploys ColumbiaSoft's Document Control Software

The Anspach Effort, Inc. (Anspach) is a leading producer of high-speed power tools used in neurosurgery, spinal and ENT surgery. Their products are sold in over 50 countries. Headquartered in Palm Beach Gardens Florida, they are a division of Synthes, a leading global medical device company with five product groups (Trauma, Spine, Cranio-Maxillofacial, Biomaterials and Power Tools) that develops, produces and markets instruments, implants and biomaterials for the surgical fixation, correction and regeneration of the human skeleton and its soft tissues. Bruce Hays, Vice President Operations, is responsible for manufacturing, procurement, planning, RA, QA, Sustaining Engineering, and document control.

Anspach produces Class I and Class II medical devices that are regulated by the FDA. The company is also ISO 13485 certified. As such their design history files, device master records and device history records need to be retained for up to 100 years for some products. Consequently they generate a lot of documents, both paper and electronic.

The paper records were stored in a sophisticated floor to ceiling Mobile Filing System that rolls on a track. However, when that filled up they began using the third floor of a recent office expansion. Bruce Hays said "we had over 500,000 documents taking up valuable floor space. Plus any time you needed to retrieve a document it usually took 20 minutes to a few hours. On a bad day it could take a lot longer."

The electronic documents were stored on a shared file server. The process for managing these documents was manual. When a new SOP needed to be created or an existing one revised the document was assigned to a revision author who would create or edit the document accordingly. Next the revision author would email the document for review and comment. Once this process was completed the document was printed and manually sent around for each approver to sign. The signed document was then scanned as a PDF by Document Control and electronically filed on their intranet site and the original paper document was filed. Having more than 200 SOP's active at a time further complicated the management of their manual system.

In 2008 Bruce led a team that began the search for an electronic document control system. Anspach needed a system that could digitize paper records, manage versions of documents, route documents for review and approval and was easy to use.

At the conclusion of their search they chose ColumbiaSoft's Document Locator for its robust feature set and its ease of use. Bruce later told us "the thing that sold us on Document Locator was its deep integration into the Microsoft architecture. We knew user adoption was the key factor to implementation success." They also purchased Document Locator WebTools for remote users of the system.

Anspach used a phased approach for their implementation, starting with their paper records. The majority of these documents were device history records, sterilization records and repair records. There were some important benefits to starting with scanning. It didn't require a lot of resources: one person was able to scan and profile their paper records. (A profile is a collection of properties that indexes a document for quick retrieval later.) As soon as documents were scanned into the system users could search and find them in seconds so the benefit was immediate. This got users attention and it opened their eyes to the potential in other areas of the company.

Once phase one was operational, Anspach turned their attention to the electronic documents stored on their network file server. They started with assorted quality documents (SOP's, Work Instructions) and then their engineering documents which consisted of design history files and device master records.

The second phase of their implementation allowed them to take advantage of Document Locator's many powerful document control capabilities. For instance they used Document Locator's folder properties to create business rules at the folder level. This allowed them to enforce what profiles and templates could be used in a folder, what types of documents could be added to the folder, (enable auto naming of documents) and set security by user group. They also used Document Locator's ability to create custom profiles to categorize the different families of products and the SOP's as they imported them into the system. For example engineering documents were profiled with: Document Number, Title, Doc Type, Revision Author, Revision Letter and Effective Date. As these documents were imported into the system, Anspach began using check-out and check-in to manage version changes and workflow to manage the review and approval cycle. Document Locator supports both electronic and digital signatures in compliance with 21 CFR Part 11. Plus a comprehensive document log tracks document access by person, the date and time it was accessed, what actions were performed and logs user notes, comments and password authentication. Bruce said, "A recent FDA audit clearly demonstrated the value of Document Locator by reducing the time it took us to retrieve requested records in half."

What's next for Anspach? Bruce says "the ROI to date has far exceeded our expectations. Our plan is to deploy Document Locator to all departments in the company. We also want to use Document Locator to manage CAPA's, ECO's, Employee Training, Complaint Management and Audits."

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