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QAI Archives Millions of Global Regulatory Records for Multi-National Specialty Pharmaceutical Provider

Background

To consolidate and streamline processes in their facilities, many large, multi-national pharmaceutical companies have undertaken proactive initiatives, including recording and archiving all paper documentation. One such business, a global specialty pharmaceutical company that discovers, develops, and commercializes products in the ophthalmology, neurosciences, medical dermatology, medical aesthetics, obesity intervention, urologic, and other specialty markets, recently developed and implemented a global regulatory eArchive initiative across its worldwide offices. The specific goal was to create a globally accessible eArchive that could enhance compliance and productivity, increase content visibility and reusability, improve security, and streamline company processes.

Initially, the company – on its own – archived all U.S. regulatory submissions and official correspondence with the FDA at its headquarters. The company utilized U.S. Regulatory Affairs staff and pre-existing, stringent regulatory strategy to plan the archiving of the well-organized files in the central office. From this headquarters project alone, more than 1 million pages were scanned and archived, and space for more than nine cubicles and four offices was regained. Yet, the pharmaceutical company knew that to take the project to a global scale it would need to bring in an outside firm that specialized in scanning, data capture, and archiving projects.

Challenges

The complex scientific and confidential nature of the documents required a team of experts that were not only proficient in document conversion, but also possessed enough background in regulatory affairs to appropriately identify and index the documents that belonged in the eArchive.

To complicate things further, to comply with all regulatory guidelines and aid in the flow of information throughout the company, all site personnel had to maintain access to needed information throughout the process. This increased the speed by which the project would need to be completed at each site, and created the need for collaboration and project documentation portals to access the archives.

There were many challenges to overcome in implementing one of the company's first global archiving initiatives. These included numerous language barriers, local government restrictions regarding document retention, and regulations limiting the movement of documentation through Customs and across international borders. The project's staff also faced specific logistical problems regarding the delivery of physical scanning and documentation equipment to various sites, and the availability of proper power conversion hardware at each location.

Solution

After conducting the initial archive project at its headquarters, the specialty pharmaceutical provider turned to a firm that is well-known in the electronic content management (ECM) sector for providing the hardware, software, and manpower for a full range of document management and archiving projects. The pharmaceutical company found Quality Associates Inc. (QAI), an experienced provider able to supply the services for every component of the project:

- QAI's Information Systems Division would provide scanning and archiving capabilities,
- QAI's Quality Assurance Division would provide scientific and regulatory compliance oversight, and
- DocPoint Solutions (a QAI subsidiary) would provide Microsoft SharePoint software implementation, training, and management.



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QAI's comprehensive approach evolved continually with the project's increasing scale and regular updates from on-site staff. The initial approach called for all documents to be reviewed and indexed in one semi-central location, and then shipped to QAI's Fulton, Md., headquarters for scanning and archiving into the pharmaceutical company's Documentum content management platform. Yet, as the project evolved, on-site scanning was also quickly implemented at each remote location due to local government restrictions regarding document retention.

QAI's solution involved several steps to ensure the data and records were captured and recorded quickly and accurately:

- **Step 1 - Consultation:** QAI worked with the pharmaceutical provider to understand the special needs, concerns, and considerations of the project, especially with proprietary nature of work on a global scale.
- **Step 2 – Data Processing:** QAI's Quality Assurance teams sorted and indexed information to be filed, and then the Information System's teams used high-volume scanners, located at many client sites, to scan and convert archived regulatory records into high-quality electronic records.
- **Step 3 – Data Integration:** QAI and DocPoint Solutions worked closely with the company's staff to ensure that the Microsoft SharePoint portals were properly set up and utilized throughout each site. The teams even wrote a custom software program into the portals to capture the specific index fields for meta-data tags and proper filing. The overall goal was to decrease documentation accessibility downtime.
- **Step 4 – Staff Training:** QAI and DocPoint thoroughly trained staff at each site to use the hardware and software to ensure the continued eArchiving of documentation after the project's completion.

Results

QAI brought the pharmaceutical company into the next century with an innovative and unique solution that created a searchable and accessible eArchive of the company's regulatory documentation. In total, the project encompassed work in more than 30 countries on every populated continent. QAI's staff scanned and archived more than 3 million documents over the course of 28 months, and even more will be integrated and archived by the project's slated completion in September 2010.

Scott Swidersky, Director, Information Systems, Quality Associates, Inc., said, "This global specialty pharmaceutical provider operated more than 100 individual offices throughout the world and faced an enormous challenge, since each office maintained its own paper filing system. The company now has a global repository of regulatory documents that can be easily accessed from any of its remote offices in a fraction of the time previously required."

[Callout Quote:] "This was the most geographically diverse project QAI has undertaken to date. Due to the vast scale and nature of the work at each unique location with this large company, QAI developed a comprehensive, four-step approach that can be implemented – not just for pharmaceutical-related documents – but for any large-scale initiative."

--Scott Swidersky, Director, Information Systems Division, Quality Associates