

COALESCE: TOP LEVEL QUALITY IMPLEMENTATION AND FLAWLESS AUDITS



THE CHALLENGE/SITUATION

CEO Dave Ahern founded Coalesce with some ex-colleagues in 2009 with the aim of providing medical and drug delivery device development services to the pharmaceutical industry.

Before launching the company, Coalesce had designed the quality management system (QMS), with the intention of eventually becoming certified to ISO13485, a standard for medical device development.

They decided to operate the quality system for a few years, with the intention of refining and aligning the system according to how they ran the business before applying for certification.

Initially, they used an Excel based documentation system which, whilst it was fit for purpose, would not satisfy the requirements of 21 CFR Part 11, the FDA's Regulation on Electronic Records.



For example, the system provided no user-friendly way to lock documents, so while revision history was available, documents were not impervious to interference. More rigour was needed, and this set the team off on a search for a document management system (DMS).

Coalesce decided to find a DMS that was scalable, flexible, and compatible with their operations processes.



Breath-actuated Inhaler (BAI)



Dry powder inhaler (DPI)

HOW DID COGNIDOX HELP?

Cognidox's modest size, and knowledgeable and technically proficient senior management gave it the edge over global competitors particularly during the commissioning and data migration process. Ahern commented that, "There was a great deal of flexibility with how the system could be set up so that it would meet our specific needs. It meant we didn't have to completely reconfigure our working practices"

The team had to migrate all of its legacy data into Cognidox. This included every single document that had been created by, or received by the company since its inception. The company now has more than 12,000 documents in Cognidox. The migration process was straightforward and now everything from technical documentation, to delivery notes and invoices, resides within the central repository.

Coalesce decided to apply for certification against ISO:13485 and had their first audit conducted by BSI within two months of going live with Cognidox.

Ahern attributes this to the well-established quality processes, as well as the rigour and flexibility provided by Cognidox, stating that, "The auditors were very impressed with the structure of the QMS and DMS."

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Dave Ahern



IMPLEMENTATION AND BENEFITS

"We received certification at the first attempt with no minor or major non-conformities. We breezed through the audit process, and I think a lot of that is down to the fact we had adopted Cognidox."

Dave observed the ease of adoption of the tool amongst his employees. The intuitive interface and process flow meant that users could be made proficient with minimal training. People adapted intuitively, and very quickly.

Dave also advocates the search facility which makes the entire workflow more fluid. "The search facility sits at the top of the interface at all times and is extremely powerful and quick, and the advanced search facility is excellent."

A hierarchy of categories can be associated to a document, and without the search functionality, it might become time-consuming browsing for documents.

The search facility makes it easy, quick to find anything within the thousands of documents.

"The search facility sits at the top of the interface at all times and is extremely powerful and quick, and the advanced search facility is excellent."

Dave Ahern

COMPANY INFORMATION

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