Drug Discovery and Development

Success Story

Agilent OpenLAB Enterprise Content Manager helps to reduce cycle times and makes electronic records easier to find and retrieve

To comply with U.S. FDA 21 CFR Part 11, and be able to readily access and retrieve their secure files, the pharmaceutical company featured in this story chose Agilent OpenLAB Enterprise Content Manager (ECM) software. Today, with the aid of Agilent OpenLAB ECM, the company’s analysts are able to search scientific findings with their web browser, using simple English commands to access and retrieve entire sequences of scientific information in seconds. In the past, this seemingly simple activity took hours, or even days of time, and required help from the vendor of their previous data management software.

Searching for a simple, but effective, solution to securing data

Two years ago the pharmaceutical company featured here sought a solution to close the compliance gaps associated with the lab records in their analytical development group. At the time, the company had another vendor’s content management system, which they had validated but not implemented. While their analysts had been trained on this data management software, they were not actually using the system.

The business need was clear to the management team:

1. Records must be stored in a manner so that unauthorized record modifications would be prevented.
2. If unauthorized modifications should occur, these changes needed to be readily detected.
3. The company needed help in organizing data and making information readily available — for both knowledge workers and compliance purposes.
4. The solution must integrate with the company’s systems, archiving raw data files from a variety of lab instruments, including ChemStation data files from the network.

Rather than upgrading their other vendor investment, the company instead chose to move to Agilent OpenLAB ECM to comprehensively address the needs of the business. Agilent OpenLAB ECM is a secure, centralized, web-based repository for electronic records that can collect, organize, index, archive and share many different types of information, including raw data files and reports, analytical spreadsheets, Microsoft Office documents, research notes and various biological images. Intuitive and easy to use, Agilent OpenLAB ECM was built specifically as a web-based software tool for companies needing to meet compliance requirements. The manager of analytical informatics at the company characterizes Agilent OpenLAB ECM as “a simple, but effective solution” to their challenges. At the time of their decision, the manager further believed “Agilent OL ECM is easier to support, easier to manage, more flexible, more feature rich, priced competitively, secure, and would help to comply with Part 11 and Sarbanes Oxley”.

At the time, the company had another content management system in-house, which they had validated but not implemented. While their analysts had been trained, they were not actually using the system.

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Manager of Analytical Informatics
ECM enables the company to apply analyst time to the highest valued use

At the company, a typical investigation begins when an analyst discovers a new characteristic of a compound. They will then start to check to see what happened with other related compounds. Previously, this could take months and months. Now it takes weeks – and the time is spent examining records – not searching for them. A search with Agilent OpenLAB ECM now takes the same amount of time as a typical Internet search. One capability critical to the company was the ability to retrieve an entire Agilent ChemStation data sequence efficiently. Agilent OpenLAB ECM does this readily by zipping an entire folder of ChemStation files together. This process was critical to enabling analysts to search effectively with no administrative intervention. This functionality has now been fully automated with the newest releases of Agilent ChemStation products (LC, GC, GC/MS and LC/MS). Files are transferred directly to and from Agilent OpenLAB ECM.

Two hours of training sets stage for analysts to be productive

The lab’s 24 analysts were given a single training session and one handout for Agilent OpenLAB ECM with step-by-step instructions on retrieval methods. With this fresh start and new capability, the drug development staff was off and running. In contrast, the company’s previous software had required two six-hour days of training, and with no records archived thereafter the success of this training investment was questionable. Since implementing Agilent OpenLAB ECM, the company has been able to eliminate the person hours previously needed for archiving data, resulting in a savings of over $30K a year, returning those dollars directly to the bottom line. More importantly, of course, is the search capability of the scientists, who no longer have to submit forms for administrative assistance to complete a search for critical records, ensuring higher productivity and contributing to a faster cycle.

ECM is intrinsic to the company’s industry best practice

The company is focused on providing high quality products, using an analytical method leveraging Agilent’s LC/MS ChemStation system to determine the strength and purity of their products. In doing so, they believe they have built an industry best practice which allows them to test their compounds with higher precision and greater accuracy.

Agilent OpenLAB ECM helps manage the records of this innovative process, consolidating the Agilent ChemStation hierarchical file folder into a single zip file, containing the entire sequence of records. The company can then archive and retrieve these aggregate records for further investigation and testing. The company’s process not only saves time, but also confirms the quality of records.

ECM, the trusted repository

In short, Agilent OpenLAB ECM has brought multiple benefits to the company:

• U.S. FDA 21 CFR Part 11 compliance
• Compliance with Sarbanes Oxley
• Analysts are able to put their time to productive use, relieving them of the burden to find a system administrator to run a retrieval for them
• As a result, data searches are completed in short order, with a positive impact on cycle time
• The company has saved on costs of archiving files, eliminating the human resource cost estimated at $30,000 annually
• The company’s personnel have confidence in their records
• While the solution today is limited to analytical development, it could expand, very likely soon to research.

About the company

The company featured here, an innovative and emerging leader in drug discovery and development, is focused exclusively on the therapeutic target, RNA. It’s mission is to develop products from its RNA-based technologies, such as antisense.

Today the company has 1500 patents and a broad antisense pipeline with compounds in all phases of preclinical and clinical development. They are working on treating a wide variety of health conditions, including metabolic, cardiovascular, ocular and inflammatory diseases, and cancer.