thermo scientific

CASE STUDY Sterling Pharma Solutions

Chromeleon CDS delivers efficiency gains and compliance and data integrity improvements to UK CRO/CMO

Brian Alliston, Specialist, Sterling Pharma Solutions

Brian Alliston is currently a Data Integrity Expert and CDS Specialist at Sterling Pharma Solutions Ltd. As the head of the Chromeleon Administration Team and the department's Data Integrity Specialist, Brian supports a multi-functional group of quality control and development analysts in the use of the Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) and the development of training procedures, standard operating procedures, and product-specific report templates. Brian has a degree in applied chemistry from the University of Northumbria at Newcastle and has over 15 years' experience in the pharmaceutical industry working in both QC and development environments.

"Chromeleon CDS is an excellent CDS which has saved our organization both time and money."

—Brian Alliston

ThermoFisher SCIENTIFIC


Sterling Pharma Solutions

Introduction

Sterling Pharma Solutions provide Contract Development and Manufacturing services including innovative process development and optimization, rapid response small scale manufacture for clinical trial supply and full scale commercial manufacture of advanced intermediates and Active Pharmaceutical Ingredients (APIs). The UK site produces clinical trial and commercial quantities of API product from grams to tonnes per annum and is approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and the US Food and Drug Administration (FDA).

Their integrated service offering provides a unique approach to drug substance development and manufacture. Utilizing their dedicated project management structure to bring together Health, Safety and Environment (HSE), Quality, Production, and Engineering expertise along with their highly skilled team of Scientists, enables them to differentiate themselves from the marketplace, ensure delivery, and aid in the success of their customers business.

The Sterling Pharma Analytical Department carries out analysis of raw materials, intermediate process checks, final product APIs, stability testing and clean out samples as well as method development, transfer, and validation activities. There is a high throughput of samples ranging from simple area % purity measurements to complex assay and impurities measurements.

Smoothly does it!

In 2012, Sterling Pharma Solutions, embarked on a mission to replace their existing chromatography data systems (CDS). They assessed CDS software from several different suppliers during a rigorous evaluation project looking at ease of use, compliance, scalability, and possible cost and efficiency gains for the business.

The choice of CDS was made based on several factors. It was important to have one system for the entire company spanning both laboratories that could work with the existing instrumentation. Previously there were two separate CDS, one for each laboratory, each with their own shortcomings on compliance and efficiency, each with their own specialist users and setup, leading to a lack of cohesion between the laboratories. The new CDS would have to be able to unite the laboratories and provide improved compliance, data integrity and efficiency to the whole business.

They decided to deploy Chromeleon 7 Chromatography Data System (CDS) software as a multi-laboratory solution, supporting a total of 58 instruments (25 GCs and 33 HPLCs) across two laboratories (QC and R&D). Brian stated, "We chose Chromeleon CDS for several reasons, the main one being the centralized data storage. Also the fact that both separate parts of the site could operate the same system, the high level of cGMP compliance and data integrity, the ability to create bespoke product specific report templates and the fact we could continue to use our existing instruments."

"The Chromeleon CDS system is very stable, I can't remember any incidence where we have had any major issues or down time. The system stability is a significant improvement over the previous system."

Brian explained; "The transition from our old CDS to Chromeleon CDS was very smooth, with Thermo Fisher Scientific providing all of the support and training required. Level 1 and 2 training was performed on site meaning the analysts were able to hit the ground running on completion of the install. We have recently upgraded to Chromeleon 7.2 CDS and again the transition was smooth, with minimal down time and excellent support from Thermo Fisher Scientific."

After the initial installation, during the intervening 4 years, and with the upgrade to Chromeleon 7.2 CDS, the system at Sterling Pharma has been further optimized to meet the goals set out at the start of the project and to ensure compliance to the latest regulatory requirements. "The support has been excellent, from the initial training to one-to-one sessions with experts helping us overcome any issues and pointing us in the right direction on how best to use the system," said Brian.

Improving compliance and data integrity

As previously stated, the need for improved data integrity and compliance to meet modern regulatory standards was one of the key drivers behind the move to a single CDS, with the business need for increased laboratory efficiency being the other.

The two predecessor CDS systems at Sterling Pharma were unable to meet modern compliance and data integrity standards and neither system could meet the security requirements for electronic data that would allow Sterling to transition to having the electronic data as the primary raw data instead of paper copies. Brian explained: "In our previous CDS, electronic data was backed up and protected but the paper copy was seen as the primary copy. We now see the electronic data as the raw data and we have the confidence that it is secure and enduring for the data life cycle." He continued, "Chromeleon CDS has really improved our data integrity and ticks all of the boxes for compliance with 21 CFR Part 11 and the MHRA GMP data integrity definitions and guidance for industry. As with all quality control labs, we are audited by customers on a regular basis. Compliance to regulations shows we are in control of our processes and give our customers confidence in our abilities to meet their needs."

With the increased regulatory focus on data integrity and compliance in recent years, Brian feels confident that the laboratories are well positioned to meet and exceed these requirements. In the last two years Sterling Pharma has undergone audits from the FDA and MHRA and numerous external customers, all of which been passed with no major citations.

"The audit trails in Chromeleon CDS are very comprehensive and track everything that the user and system does. Our users regularly review the audit trails for each sequence, and with the audit trails easily accessible on-screen and the ability to group, filter and search for events, it is very quick and easy for users to review and allows them to ensure that the correct versions of files, such as instrument methods and report templates, are used for each analysis," said Brian. "The version comparison tool is also very useful allowing us to easily demonstrate what changed between different versions and all changes are very clearly identified. We have even used the rollback tool a few times to reinstate a previous version of a file. Overall I would say that Chromeleon CDS is a very powerful tool for QA review and compliance – it's audit compliant and then some!"

But what about increasing the laboratory efficiency?

Data processing and retrieval were two key areas of inefficiency for Sterling Pharma to address with the new CDS.

The initial impressions of the system were good: "Having previously used several 'older' CDS systems, Chromeleon CDS proved to be a very intuitive system. It has a 'familiar feel' which means it's easy to learn. The user interface is simple and clear and everything is where you would expect it to be," said Brian, "Chromeleon CDS is much quicker in all activities." This intuitiveness and speed significantly reduces training requirements and saves huge amounts of time in the laboratory.

So what about data processing? This has long been one of the most time consuming tasks in every laboratory and this was no exception at Sterling. Use of smart data processing tools such as the Chromeleon CDS Cobra™ wizard and SmartPeaks™ Integration Assistant has helped improve the laboratory efficiency. "Use of the Cobra wizard allows for quick setup of optimum integration parameters giving us consistent integration much faster than either of our previous CDS," said Brian, "Before we were probably a little 'heavy' on manual integration. Chromeleon CDS and the Cobra wizard have readdressed this balance with manual integration becoming the exception and not the norm."

Data sharing and instrument visibility were also improved. Previously, with data being stored on two different, separate systems, and with only a limited number of analysts able to use both, data retrieval could be difficult and very time consuming. The ability to monitor laboratory-wide key performance indicators, such as instrument utilization, was severely hampered. Brian explained "Data retrieval and processing are much simpler than with the previous CDS and with the use of a folder/file naming convention it is possible to locate data quickly and easily." And having a single, centralized system allows the laboratories to easily share instruments and data making method transfer much easier. "We are now looking to use the supplied [Chromeleon CDS Extension Pack] method validation report templates, modified to our needs, to increase the throughput of our method validation activities and provide a clear and consistent report to our customers," explained Brian, "and the ability to monitor instruments from remote PCs is especially useful when the system you are using is in a different building to the one you are based in. This was not possible at all with one of our previous CDS systems."

"Chromeleon CDS has moved us away from the inefficient practices of transcribing data into a spreadsheet and helps us to address data integrity within the lab."

"Use of the Cobra wizard allows for quick setup of optimum integration parameters giving us consistent integration much faster than either of our previous CDS."

Gaining further efficiency improvements

How else did Chromeleon CDS help drive efficiency improvements?

With the previous CDS systems, although it was possible to carry out calculations within the CDS, it was very common to see data being transcribed into spreadsheets to perform calculations. This led to significant inefficiencies since all the transcriptions took time and they also needed to be checked, duplicating the effort. Chromeleon CDS helps by removing the need for manual input of data into spreadsheets to perform calculations. With its built-in spreadsheet reporting engine it offers incredible power and flexibility for reporting along with instant familiarity for spreadsheet users.

Sterling Pharma has a wide range of methods, each with different system suitability and calculation requirements, and with Chromeleon CDS it has been possible to set up method, product and project specific reports. This has and continues to vastly improve their reporting efficiency.

"As the Chromeleon CDS report template is basically a spreadsheet, product-specific templates can be set up reporting the exact data needed for each product removing the need for transcribing and checking data. As you can imagine this saves a lot of time and effort" says Brain. "Chromeleon CDS has moved us away from the inefficient practices of transcribing data into a spreadsheet and helps us to address data integrity within the lab. We are now moving toward a fully electronic system with the intention to use electronic signatures for data review."

What does the future hold?

Having established Chromeleon CDS in the laboratory and streamlined many operations within the laboratories, Brian described his overall impressions and future plans for the CDS.

"Overall Chromeleon CDS is an excellent CDS which has saved our organization time and money. In general the Chromeleon CDS system is very stable, I can't remember any incidence where we have had any major issues or down time. There have been a few network outages but Chromeleon CDS has handled them well and allowed the lab to keep working. The system stability is a significant improvement over the previous system!" He continued, "I find the system easy to use, training new staff is easy and the audit trails are comprehensive and easy to understand."

"Beyond using the [Chromeleon CDS Extension Pack] method validation report templates to increase the throughput of our validation activities as previously mentioned, we are also looking to fully implement and utilize electronic signatures to minimize paper usage. We will be transitioning through a hybrid system (both paper and electronic signatures) while trialling it on an individual process to evaluate best practices."

"We are also looking to implement the use of eWorkflows to further improve efficiency and data integrity in the labs. Using them will enable us to ensure that the correct methods and reports are always being used and analyses are performed in accordance with our SOPs [Standard Operating Procedures] and that will save us time reviewing data."

Find out more at **thermofisher.com/chromeleon**

ThermoFisher SCIENTIFIC