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CASE STUDY
Broughton Laboratories

Delivering client success through unique and pre-emptive service – A global analytical GMP business perspective

Delivering uniqueness

Broughton Laboratories are a privately-owned, global Good Manufacturing Practice (GMP) analytical services business that is uniquely differentiated in their ability to provide enduring partnerships based upon client success.

> "We've always been driven by the client, adapting our services to what is required immediately and also in the future. Helping end users to obtain affordable medicines is a big driver."
>
> Paul Moran, Founder and CEO

Central to Broughton Laboratories is their company-wide vision of not only providing high-end results on-time, but offering services that add value to their clients, both now and in the future. This vision has ensured that Broughton has grown since its beginnings in 2006 to now offer several comprehensive, but focused services ranging

Instrument lab at Broughton Laboratories

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from product development, analytical and QC testing, stability studies through to scientific and regulatory consulting services.

With expertise in serving key markets such as the pharmaceutical, animal health and medical devices industries, Broughton Laboratories truly deliver with world leading services – such as specialism in electronic nicotine delivery systems (ENDS) – being the first to provide analytical support for the first-to-market ENDS medicinal product within the United Kingdom.

"We want to maintain our focus on the healthcare and pharmaceutical industries, and firmly believe that we offer a great service when we can be the best in the world at what we do."

Chris Allen, Co-Founder and Managing Director

Expansion to keep up with demand

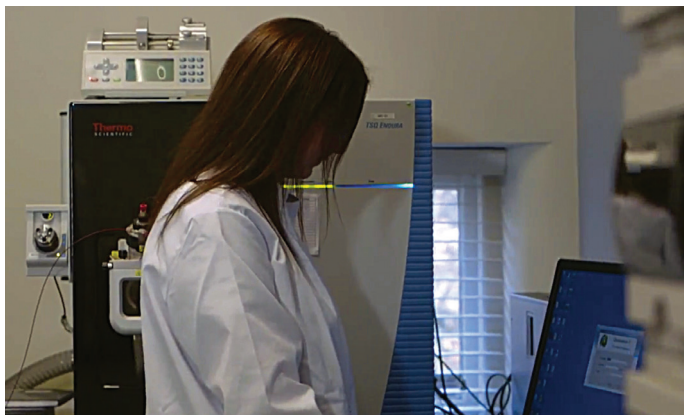
During the set-up of Broughton Laboratories, there was the need to not only begin to equip with the latest separation technologies, but to ensure that these could be controlled effectively while meeting stringent regulations. Several different vendors for both the hardware and software were evaluated; what was a first for Broughton was also a first for Thermo Fisher Scientific, with the deployment of the first two Thermo Scientific™ UltiMate™ 3000 HPLC Systems within Europe – the chosen software to run these systems was Thermo Scientific™ Chromeleon™ 6.8 Chromatography Data System (CDS).

Well over a decade later, those initial systems (still delivering results week in, week out) have been joined by many more UltiMate 3000 systems as Broughton's business has expanded.

With a rapid increase in the use of electronic cigarettes (vaping), regulatory bodies have sought to clamp down on what was an unregulated market. The European Union introduced a Tobacco Products Directive (TPD), and the United States Food and Drug Administration (FDA) have also mandated that vaping products are registered and tested.

With a diverse array of e-liquids (various flavors and base constituents) comes some substantial analytical challenges. Due to this increasing range, diversity and complexity of e-liquids in the globalized e-cigarette market, Broughton Laboratories have had to become more innovative from a chromatography and compound detection standpoint to generate data that meets the rigid requirements of regulatory authorities.

So in order to remove potential interference from flavor compounds, Broughton sought to increase both their analytical capacity as well as sensitivity and selectivity through the use of HPLC coupled with the Thermo Scientific™ Endura™ Triple Quadrupole Mass Spectrometer. The integration of LC-MS/MS within the testing workflow enabled Broughton Laboratories to more confidently detect, verify and quantify more target compound peaks than was possible before.



"Chromeleon CDS is a trusted piece of software that Broughton Laboratories has invested into, working in partnership with Thermo Fisher Scientific, to ensure integration with our innovative LabHQ LIMS platform. This fits firmly with our culture of continuous improvement and giving our clients competitive advantage."

Paul Moran, Founder and CEO

Chromeleon CDS helps Broughton to increase their operational efficiency

To deal with the challenges of higher sample throughput from existing UV and the MS instrumentation as well as incorporation of non-Thermo Fisher instrumentation, Broughton upgraded to Thermo Scientific™ Chromeleon™ 7.2 CDS. With this implementation, Broughton Laboratories were able to double their data processing capabilities in a matter of weeks, meaning data processing was no longer a bottleneck to delivering high quality results to clients seeking to meet regulatory guidelines.

"The fact that Chromeleon CDS didn't tie us to a single instrument vendor, meant we could implement a single, networked software platform which was flexible and scalable enough to grow with us. This was a key benefit. We now have approximately 400 HPLC methods, with many in client specific format; Chromeleon CDS has been able to deal with all of these calculations, we haven't found anything that Chromeleon CDS hasn't been able to do."

Chris Allen, Co-Founder and Managing Director

The halving of data processing time is a testament to the principles of Operational Simplicity™ followed in the development of Chromeleon CDS. By having all the UV and MS instrumentation under one CDS, Broughton has been able to take advantage of all the available productivity tools within the software across all of their instruments including the MS. For example, eWorkflows allow them to streamline and control analysis setup, ensuring that operators always use the correct methods and reports and that the sequence is built correctly, reducing errors and out of specification results. Additionally, integration tools such as the Cobra™ Wizard, SmartPeaks™ Integration Assistant and the built-in dynamic data linking further reduce processing time.

Chromeleon software eWorkflows

When setting up a chromatography analysis you often have to follow guidelines, like a standard operating procedure (SOP). There are many areas where manual sequence creation can cause errors.

eWorkflows provide a template to create a complete, correct sequence with predefined files and a well-defined structure. They minimize the amount of training required and can be used with every instrument controlled by Chromeleon CDS including MS, allowing you to streamline laboratory workflows and use the MS like any other detector. They take you from samples to reliable results in a minimum number of steps.

"Setting up sequences on the LC-MS is really simple and guided through the use of eWorkflows; analysts can come in and select the relevant workflow which contains all the relevant methods which are locked down and validated, only needing to add the samples to the LC as the system automatically brackets samples."

Kerry Malone, Team Leader

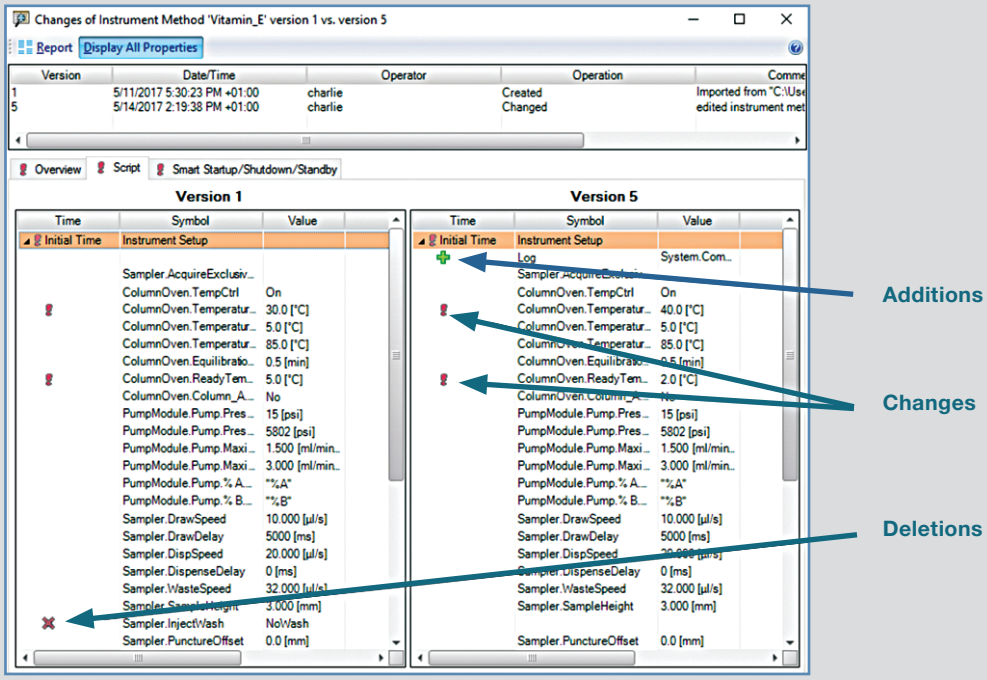
How does Chromeleon CDS facilitate Broughton's culture of quality in maintaining data integrity and regulatory compliance?

With the requirement to meet GMP compliance standards, the use of Chromeleon CDS to control, process and report data is critical to maintaining data integrity; and with several successful MHRA and FDA audits already completed, Broughton is confident that Chromeleon CDS provides the necessary functionality to reduce the burden of ensuring both data integrity and regulatory compliance.

"Chromeleon CDS allows us to audit trail everything that we need to, making it easier when we are audited. The user management system and centralized resourcing means that data access and backup is easily managed, ensuring data integrity."

Adam Neaves, Quality and Compliance Specialist

Reviewing data is more than just looking at the actual raw chromatographic and UV or MS data, there are the associated methods and metadata which need to be considered. Chromeleon CDS provides users with a simple, clear way of reviewing data, along with in-depth audit trails and versioning history to ensure that the process of who did what, when and why can be easily understood for any changes made within the system.



Changes between object versions are easily identified with the version comparison tool.

Audit trail review could be a laborious task given the many different aspects of a system such as data creation, processing, modification, deletion, etc., as well as general entries such as system log-in and log-out. Thankfully, Chromeleon CDS segregates audit trails by relevance making it easier to review and interpret them, and with the ability to compare and view differences between any data object users have clear granularity of events, as well as full traceability.

More than 160 different privileges and an unlimited number of security levels and user roles combine to provide the flexibility to meet any laboratories' workflow requirements, with powerful filtering and search tools which can be used to help identify suspicious behavior (e.g. injections that have been interrupted, aborted or re-injections to potentially obtain the desired result).

Finally, system administrators typically have a large burden placed upon them when it comes to managing a CDS to help drive compliance. Chromeleon CDS goes above and beyond regulatory guidelines to provide the technical controls necessary to demonstrate effective system management with ease, such as auditing to cover administrative and system event changes, including verification checks to identify if attempts are made to manipulate data outside of the CDS.

For more information on services of Broughton Laboratories, please visit **http://www.broughtonlaboratories.com**

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

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