Case study | 003423

Software

High Force Research streamlines operations, ready for growth with Chromeleon CDS

Introduction

High Force Research, Ltd. (HFR) is an independent contract research organization (CRO)/contract development and manufacturing organization (CDMO) that exists to solve client chemistry challenges across multiple scientific industries. Operations are carried out in the company's purpose-built manufacturing facility in Bowburn, UK, which includes two ISO Class 8 laboratories in which multi-stage chemical synthesis according to cGMP standards is carried out. Further capacity at NETPark, Sedgefield, UK, allows initial project research and development activities to be undertaken.

The company fulfills client needs offering dependable, flexible, and affordable high-quality services and products. Toward this goal, the company continues to invest in new equipment, techniques, and processes. Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) is one such investment that has dramatically streamlined operations while enhancing the quality of work, ensuring HFR is prepared for continued business growth and competitiveness.

> "High Force Research aims to enhance and expand our current services for clients, delivering improved results while streamlining our current analytical workflows"
>
> —Stuart Penny, Chief Technical Officer, and a founder of High Force Research

Ease of use influenced the decision

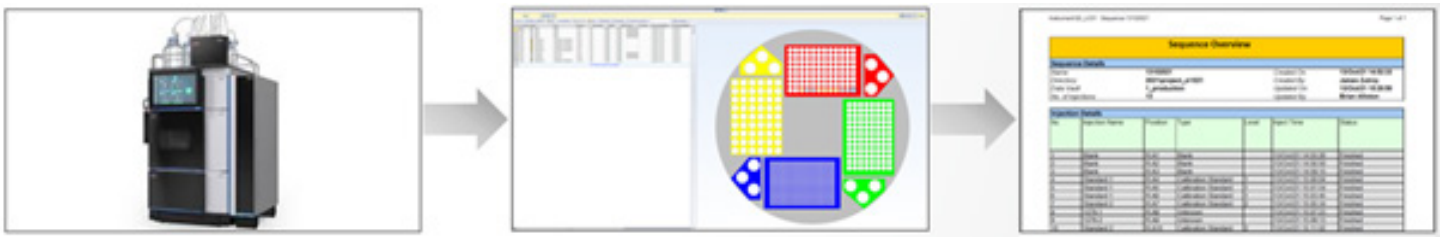
Chromeleon CDS is designed to simplify tasks, reduce errors, and improve lab efficiency. Before HFR finalized its decision to make the transition, Thermo Fisher Scientific staff provided training so users could experience the benefits firsthand. Jude Humphrey, Senior QC Scientist at High Force Research, said, "The technical team at Thermo Fisher initiated an on-site training course, allowing us to gain user experience early. The simplicity, user-friendly nature of the software and assurance of compliance persuaded us to transition, and it has been of great benefit to the department since. As an apprentice at the time of install, it was great to see HFR investing in such great analytical software."

eWorkflow procedures increase efficiency, reduce errors, and make analyses easier

Chromatography workflows are very similar. Samples are injected, separations are performed, signals are captured, and results are generated. Where they differ is in the method details, such as the instrument conditions, injection sequence requirements, and the way results are calculated. These differences create complexity for operators, reducing their efficiency and increasing the risk of error.

Chromeleon CDS solves these problems with an eWorkflow procedure, which contains a set of rules to capture all the unique aspects of a chromatography workflow and guides the operator through a minimal number of choices to create the correct sequence. The operator simply selects an instrument, specifies the number of samples and the software runs the sequence, processes the data, and generates the results, ensuring that the lab's procedural rules and guidelines are followed.

HFR uses eWorkflow procedures to increase the number of samples that can be measured per day. Scott Little, Laboratory Instrumentation Specialist at High Force Research explained, "We used to input data manually and it would take 20 minutes to start the sequence. Now, sequences are set up and ready for review within a few minutes." Little expanded on the benefits of an eWorkflow procedure, "We've added new members into our QC team recently who have all agreed that the Chromeleon eWorkflow procedures are far simpler to use."



"Chromeleon eWorkflow procedures have increased efficiency within the department, allowing fast method upload, with accurate data generation."

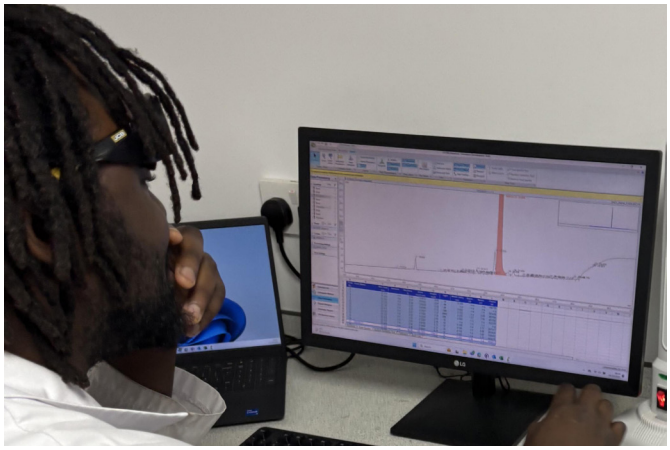
—Jude Humphrey, Senior QC Scientist at High Force Research

Automated integration increases consistency and saves time

Peak detection and integration are fundamental chromatography tasks. Ideally the method applies the same parameters across multiple chromatograms to minimize variation introduced by different analysts. However, finding the method parameters that produce the best results can be challenging, causing many chromatographers to resort to manual integration, which is subjective and labor intensive. The Cobra peak detection algorithm and automated integration features in Chromeleon CDS save time while providing consistency. Little explained the benefits of these features for HFR, "With the guided automatic integration, it minimizes analysts' time looking to determine if the integration is accurate." Humphrey added "People might choose different zoom levels, and then you're not integrating the same way each time, so automated integration is a lot more reproducible."

Easily customizable reports minimize waste

The spreadsheet-based Chromeleon Report Templates address the needs of many labs, they are easily customized and can be saved for future use and modification. Using the software's custom reporting, HFR reduced its reports to just a few pages of information needed by QA and clients. Little explained, "When I was implementing the reports, I looked at minimizing what we print off so that it only included data that's of interest. We went down from approximately twenty pages to a maximum of five pages—a dramatic decrease. This is of huge benefit because it reduces the amount of data that needs to be reviewed by QA, while still allowing critical results to be reported to the analysts and clients very easily." Humphrey added, "We can easily customize reports to the needs of the project and the tests. When we finish developing a method, we'll create a report for that bit of analysis and can often use an existing template."



Ease of use maximizes return on instrument and staff investments

Chromeleon CDS offers a user-friendly interface designed to streamline workflows and guide users effortlessly through tasks, ensuring they move from sample to results in no time. This enhances productivity and maximizes return on investment. Penny highlighted the improved efficiencies when using Chromeleon software, saying, "When you purchase a new instrument, the last thing you want is to also master a completely new software interface. Instruments are costly, so you need them up and running as quickly as possible to benefit your business. And when you bring in someone new, Chromeleon software makes it incredibly easy for them to get up to speed and start contributing right away." Little echoed this sentiment: "When we bring in new instruments, our priority is learning what they can do—not spending excessive time figuring out complex software. Chromeleon software simplifies this, helping us maximize the system's potential from day one."

"Streamlining operations by removing manual processes has been transformative. As a growing organization, we are committed to investing in technologies and systems that enhance our competitiveness and the quality of service we provide to our clients"

—Stuart Penny

"I'd definitely recommend Chromeleon software. It makes the processes within QC labs more efficient if you utilize it on a distributed network, and it has really improved the workload at High Force Research."

—Scott Little, Laboratory Instrumentation Specialist, High Force Research

Increased efficiency and scalability support competitiveness and growth

Growing a business will likely involve deploying more instruments and hiring more staff. Chromeleon CDS is a single-software solution that offers control of over 550 instrument modules from more than 22 different vendors, including Thermo Scientific mass spectrometry instruments, enabling labs to grow without having to learn multiple software products. Penny explained how Chromeleon CDS's scalability facilitates growth, "It's easy to plug more instruments into the same software. As we move forward and expand our chromatography systems, one of the questions we'd ask the manufacturer is, 'Does the instrument integrate with Chromeleon software?' If it doesn't, then we probably won't look at it. You want it all to run under the same system and considering how quickly our QC team have adapted to Chromeleon software, that's important."

About High Force Research

Established in 1988, High Force Research, Ltd. is a privately owned, specialized chemical development company engaged in CRO and CDMO activities. The company has built a solid reputation recognized for its R&D flexibility and innovative approach to complex and challenging projects.

HFR's expertise is in chemical research and development, process optimization, route design, scale-up and GMP manufacture of small molecules for clinical study. They collaborate with multinationals, startups, and discovery groups within academia and industry in synthesizing new materials for proof-of-concept studies. The company's main area of business is predominantly in the life-sciences sector including pharmaceutical, biotech, diagnostics, and imaging; however, work also extends into other sectors including polymers, semiconductors, and fine chemicals.

HFR has two ISO Class-8 laboratories and a purpose-built manufacturing facility where multi-stage synthesis to cGMP standards is carried out. Photo courtesy of HFR.

About Stuart Penny

Stuart Penny is Chief Technical Officer and a founder of High Force Research. An organic chemist by training, he has over 40 years of experience as a laboratory chemist. Stuart introduced GMP operations to HFR and as Operations Director was responsible for overseeing the transition of new chemical entities through development to small scale GMP manufacture. As CTO, he now plays an advisory role in aspects of the team on process development, QA and QC. Before helping to establish HFR, Stuart worked in the fine chemicals industry where he gained many years of experience as a Process Development Chemist in the laboratory, pilot plant and manufacturing operations.

About Scott Little

Scott Little is a Laboratory Instrumentation Specialist at High Force Research. Prior to his three years at the company, he has worked in a variety of fields including pharmaceutical contract manufacturing, oil and gas and engineering. From his previous roles he developed skills around equipment maintenance, qualification, and validation. The primary job responsibilities are ensuring the equipment mainly in the QC lab are maintained and qualified as per internal SOPs and ensuring external providers of maintenance and qualification are scheduled. Other responsibilities include validation of computer systems for 21 CFR Part 11 and data integrity guidelines.

About Jude Humphrey

Jude Humphrey is a QC Analyst at High Force Research, specializing in method development and validation. Over the past five years at HFR, he has progressed from an apprentice to a skilled professional, completing his degree while gaining valuable hands-on experience. Initially trained as an analyst performing routine analyses to GMP requirements, Jude now dedicates his expertise to developing and validating analytical methods for R&D projects and supporting their transition to GMP manufacturing.

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