Case study | 003598

Software

High Force Research delivers compliant operations with a CDS that's built for compliance

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 by 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 improved regulatory adherence 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 maintaining the highest level of compliance"
>
> —Stuart Penny, Chief Technical Officer, and a founder of High Force Research

"When we chose Chromeleon software, we were looking at data integrity and 21 CFR Part 11 compliance to satisfy the needs for pharma and life science."

—Stuart Penny

It began with a need for compliance and an industry recommendation

Compliant processes are essential for CROs/CDMOs supporting the pharmaceutical industry. With approximately 70% of its clients in the life sciences/pharmaceutical industry, HFR sought a solution to ensure data integrity and compliance with 21 CFR Part 11. The previously used CDS lacked the essential compliance features. As Penny described, "It wasn't software originally designed for compliance. Compliance features were added on later which made the software difficult to use. In contrast, Chromeleon software is built for compliance from the start, which makes a big difference."

Designed for compliance from the ground up, Chromeleon CDS offers HFR a solution to meet client regulatory requirements by facilitating the process of achieving, maintaining and demonstrating compliance with features such as automated and secure time-stamped audit trails for traceability, administrator-controlled user access and permissions, electronic signatures, and data versioning.

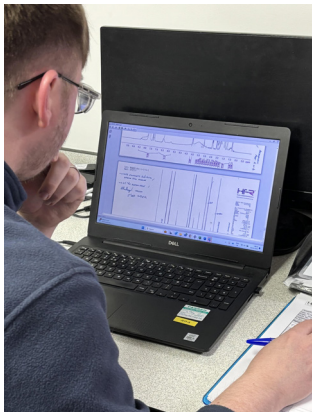
Being a small company with limited time and resources, HFR relied on a key recommendation to help narrow their software search. Penny explained, "We chose Chromeleon software because it was highly recommended by Sterling Pharma Solutions. They spoke very highly of it and being a small company, we don't have the resources to test lots of different software, so a recommendation was important. That's one of the reasons why we chose it."

eWorkflow procedures reduce error and ensure compliance

In general, analytical workflows share a lot of commonalties; there is a sample to be analyzed, data to be acquired and results that need to be reported. However, modern labs often have a wide variety of instruments that require different methods of analysis, sequence structures and calculations, with the added complexity of maintaining regulatory guidelines associated with data integrity and 21 CFR part 11. This all adds up to a lot of risk, potential error and loss in efficiency when investigation is needed, or additional training is required.

"Once a project is validated, we create an eWorkflow template, so it's all locked down to run in production. When you start a sequence, it does everything you need for that analysis. You just select whichever one corresponds to your method. It saves time, but it also eliminates error."

—Jude Humphrey, Senior QC Scientist at High Force Research

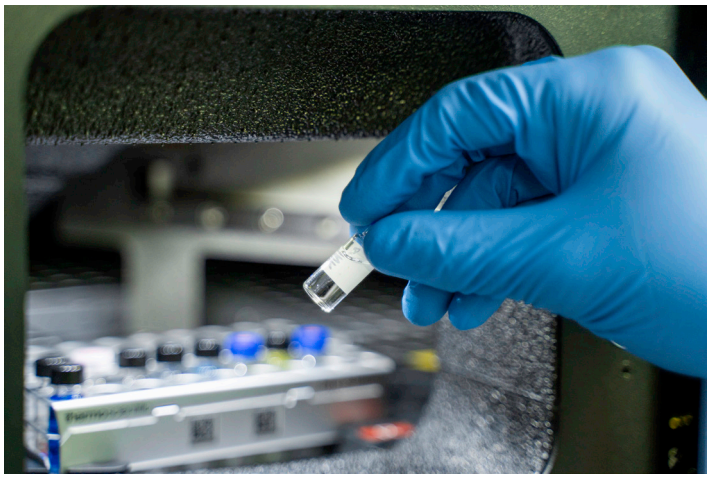


"We used to print all the raw data and compile it into large data packages for review. QA would then manually go through each page, which was extremely time-consuming. If corrections were needed, the entire package had to be reprinted, and all changes had to be fully documented. With Chromeleon software, we feel much more confident knowing it automatically captures everything required for a thorough regulatory review."

—Jude Humphrey

Chromeleon CDS makes life easier for the analyst, increasing efficiency, without compromising compliance. Employing an eWorkflow procedure allows control of all the unique aspects associated with a chromatography or MS workflow. The analyst need only select the instrument, specify the number of samples and the sequence is created, analyzed, data processed, and results generated, all in line with the Standard Operating Procedure. The eWorkflow procedure ensures consistency and reliability regardless of analyst, accelerates data review and can be validated to make sure that only correct methods and templates are used.

For validated methods, HFR uses eWorkflow templates to maintain compliance and ensure that documented procedures are followed. 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. The review process is quick too as you can't really get it wrong. Ultimately, this frees up more time for the analysts so we can increase our productivity throughout the lab," Penny added, "We can reduce errors as well. Errors take up a lot of time, not just the time to re-run samples, but also the QA time involved in investigating as to why the error occurred, which increases workload on a lot of other people. Eliminating errors at the source is one of the key things to make labs more efficient and compliant."



Electronic review reduces paper, streamlines quality checks

Chromeleon CDS provides electronic review capabilities that streamline the process of data review, saving time and making it easy to minimize paper, while reinforcing the criteria for standards like 21 CFR Part 11. "We used paper initially," said Little. "With the old software you'd print the chromatogram for every blank, every system suitability or every sample injection, and if there was a problem with any of that or there had to be a correction, it was quite a lengthy process."

"Most of the work at HFR Bowburn is small scale production to either ISO 9001 or GMP quality standards. Chromeleon software has really helped us to enhance our compliance capabilities and has made the analytical QA review process a lot more efficient."

—Stuart Penny

"I would definitely recommend Chromeleon software. From a compliance perspective, it's an excellent piece of software that gives us complete control over user access and permissions. It plays a key role in helping us maintain compliance here at High Force Research."

—Scott Little, Laboratory Instrumentation Specialist, High Force Research

Little described the lengthy and manual review process that existed prior to deployment of Chromeleon CDS, "It could have previously taken up to half a day to check and review a full sequence." Penny added, "We implemented electronic review in QC to minimize integration errors and to catch any 'out-of-specification' results. If a reviewer thinks something doesn't look right, they can zoom in and have a good look." Humphrey continued, "This saves back and forth time between analysts and QA. It's a lot easier to look at the software and check that the integration is correct than it is on a printout where the zoom wasn't good. The chromatograms are all stored on the system and can be viewed by QA or even by an auditor if needed."

Ensuring compliance and facilitating business growth

HFR's implementation of Chromeleon CDS has greatly improved operational efficiency, enabling the company to grow and remain competitive while adhering to regulatory standards. Penny noted, "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."

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 High Force Research

Established in 1988, High Force Research Ltd. (HFR) 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. HFR collaborates 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 in the life-sciences sector, including pharmaceutical, biotech, diagnostics, and imaging. Work also extends into other sectors including polymers, semiconductors, and fine chemicals.

About Stuart Penny

Stuart Penny is Chief Technical Officer (CTO) 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 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 is 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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