Introducing a New Era in HPLC

Fraser McLeod, Vice President of QA/QC for Waters Corporation, explains how Waters next-generation Alliance™ iS HPLC System will revolutionise productivity and efficiency for modern QC labs.

Q: Waters Corporation has a rich history of supporting QC laboratories. Has the business observed any changes in the challenges faced by QC labs over the years?

A: Waters introduced its first commercial HPLC system 50 years ago, helping pharmaceutical QC laboratories to ensure tens of thousands of prescription drugs on the market are pure, safe, and work as expected.

At this time, many of the biggest challenges experienced by QC labs were based on the scientific capabilities of the separation technology, such as the kinds of columns that can help meet their needs. For modern QC labs, the story is slightly different.

In recent years, we closely collaborated with hundreds of QC managers and bench analysts to fully understand their challenges and find out specifically what they need today from a state-of-the-art HPLC system to help their labs perform at their best.

We learned that the challenges experienced most often are based on the relentless demands faced from both a scientific and business perspective to do more with less, manage high staff turnover, and deal with growing levels of sample complexity.

All these factors, and more, can increase the chance of errors, such as forgotten samples, incorrect solvent levels, incorrect tightening of system fittings, or not verifying correct system performance. These errors can have a significant impact on efficiency and productivity in the lab, and the associated costs incurred when investigating them.

We also heard a lot about the desire for improved usability and simplicity, so that managers can help analysts get up to speed quickly with new instruments, especially as they navigate from legacy methods and onto new technology.

At a time when challenges like these are mounting, we recognized that the need for simplicity in the QC lab has never been greater, to support their evolving scientific and business needs.

Q: How does the newest HPLC launch from Waters address these challenges in QC labs?

A: The Alliance iS HPLC System has been developed by Waters specifically for QC labs, with a suite of features and solutions designed to minimise errors and improve system usability.

The system prevents up to 40% of common errors* by performing pre-run verification of the correct column, vials, and plates, as well as solvent levels and expiration dates. Tool-free fittings prevent leaks, and clearly labelled and organised solvent lines and auto-recognition of Waters eConnect HPLC Columns prevent user errors when setting up the system for analysis.

We have also added several new hardware components designed to maximise reliability and ease of use. The intuitive touchscreen interface provides guided workflows, troubleshooting and maintenance, ensuring consistence and ease of operation. Quick and easy access to the Waters Help Center, directly from the instrument touchscreen, also makes it much easier to address errors in real-time and minimise unscheduled downtime.

The usability elements also address a big piece of the efficiency puzzle: training new hires. Modern QC labs can experience high staff turnover, as increasing numbers of analysts move onto other roles, creating a constant need to train new hires. The intuitive simplicity built into the Alliance iS HPLC System makes it easy for new hires to quickly become proficient in executing routine processes with minimal avoidable errors.

Overall, this suite of features will save QC labs valuable time and money, plus protect them from the risk of investigations.

Q: Does the Alliance iS HPLC System work with other products from the Waters ecosystem?

A: It was important to us to develop a system that could connect with other key solutions in the Waters portfolio to offer a cohesive and seamless operational experience to QC labs.

The Alliance iS HPLC System is uniquely built for Empower Software, which is the most used software in QC labs today. Waters Empower Software Suite helps the entire laboratory operate more efficiently, with the industry's most advanced data acquisition, management, processing, analytics, and reporting capabilities. The Empower 3.8.0 release provides exclusive capabilities for the Alliance iS HPLC System, including:

- Method Matching
- Column Tracking & History (with eConnect HPLC Columns)
- Pre-run Checks
- Empower System Audit Trail
- Touchscreen Interactivity

Additionally, waters_connect System Monitoring provides intuitive and centralised access to detailed Empower Software instrument information via the waters_connect Cloud Platform, without compromising security or compliance. This helps QC labs to maximise productivity and utilise resources more effectively from anywhere, anytime.

The Alliance iS HPLC System and Empower 3.8.0 release also support Waters new eConnect HPLC Column technology, designed to ensure complete column traceability and facilitate post-run troubleshooting. Ready-to-use from the box, eConnect columns are securely fitted with a NFC-enabled eConnect device tag, ensuring they are always automatically identified, verified, and tracked by the system. Analysts and managers can easily track column usage and make sure they're always using the right column.

Using the combination of status lights, touchscreen interface, Empower Software, integration with waters_connect System

Monitoring, and smart column technology; the entire QC lab can access an instant view of system status and access real-time information for informed decision-making.

Q: How can the Alliance iS HPLC System reduce the compliance burden felt by QC analysts and managers?

A: QC labs need their systems to support both legacy and new methods that can be operated repeatably anywhere in the world, all while meeting essential regulatory requirements. This inevitably places a large burden on the analysts to ensure errors are minimal and processes are followed meticulously.

To address this and help QC labs meet global compliance needs more effectively, the Alliance iS HPLC System includes features that are designed to reduce the number of quality incidents that occur in their labs, as well as the amount of time spent investigating quality incidents – all the while empowering analysts to access results much more quickly.

QC labs can rely on repeatable global method performance with enhanced temperature control in the sample manager, column manager, and detector, plus reduced adsorptive carryover and eliminated volumetric carryover.

When coupled with Empower Software Solutions and eConnect HPLC Columns, analysts can access new features such as the Intelligent Method Translator App (iMTA). This enables analysts to create an Alliance iS HPLC System Instrument Method directly from a Waters or other third-party LC system. Basic chromatographic conditions are automatically transferred, and the new Empower Software instrument method can be reported, providing trace-ability to the originator method for compliance. This is complemented by Method Matching technology, which can warn users if the column installed is not matched to the selected method.



For enhanced compliance tracking, users can access a System Audit Trail, where actions performed on the touchscreen interface are automatically logged into Empower Software.

Q: How would you say the Alliance iS HPLC System differs from other HPLC innovations?

A: The two biggest differentiators of this system are its intuitively simple operation, and ability to reduce errors by up to 40%*. All the features we included in the design were geared specifically towards addressing usability challenges and error reduction.

To make sure interaction is as smooth and seamless as possible for users, a considerable amount of industrial design research and planning went into this product, reflected in features such as the color-coded solvent tubing clips, status lighting, and intuitive touchscreen. This instrument represents the highest level of usability we have achieved for a single product at Waters.

We were very mindful about in-corporating features targeted at reducing errors but without putting any extra burden on analysts with extra steps, and instead reducing errors in a way that naturally supports the user's workflow. The system is designed with intuitive mechanisms that provide fast feedback, plus health monitoring tools that enable teams to dive deeper into crucial performance parameters in real time.

Ultimately, our priority was making sure that operating the Alliance iS HPLC System would be as seamless as possible. We see this as perhaps the most innovative overall element we're introducing to the HPLC market with this instrument.

Q: How do you think the future looks for Waters in terms of HPLC innovation?

A: Waters has been established in the chromatography field for decades, and



we know how to create instruments that perform. However, we believe the new vector of usability, simplicity, and error reduction we have achieved with the Alliance iS HPLC System will help to take HPLC innovation to the next level.

We have made great strides towards demonstrating our longstanding commitment to solving the problem that matters to our customers by creating an instrument that can reduce common errors in QC labs by an impressive 40%*. However, we know that this still leaves the door open to reduce errors by a further 60%. This is where we will continue to focus our efforts and is where we expect to make many more great strides in the years to come.

* Estimate based on Waters' market research in 2022 after surveying 56 global pharmaceutical company QC labs.





Fraser McLeod

Fraser McLeod is the Vice President and General Manager for Waters QA/QC Business Segment. In his role, he runs a team that develops and commercializes solutions that are predominantly used in QC labs and is responsible for all Waters chromatography instruments as well as the NuGenesis and Empower Software Solutions. Fraser has worked in the life sciences industry for more than 25 years focusing on new product development and business transformation strategies.