



NEWS RELEASE

Waters Enhances Alliance iS HPLC System Software, Setting a New Standard for End-to-End Traceability and Data Integrity

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News Summary

- Industry-first smart HPLC system to provide authenticated user access verification on onboard touchscreen for superior security.
- Integration of Alliance™ iS HPLC System with Empower™ Software ensures user actions are identifiable and auditable.
- Minimizes common user errors by up to 40% and enhances audit readiness by providing end-to-end traceability and data integrity.

BRUGES, Belgium and MILFORD, Mass., June 17, 2025 /PRNewswire/ -- 54th International Symposium on High-Performance Liquid Phase Separations and Related Techniques - Waters Corporation (NYSE: WAT) today announced the release of the Alliance iS HPLC System Software version 2.0, a significant advancement that delivers comprehensive, end-to-end traceability and enhanced data security for the pharmaceutical industry. Bringing the same secure architecture synonymous with Empower Software to the Alliance iS HPLC System touchscreen will enhance compliant monitoring and intuitive traceability for customers. Globally, more than 80% of novel drugs have been submitted to regulatory authorities using Empower Software.¹

With this release, the Alliance iS HPLC System delivers leading touchscreen security by offering individual and identifiable access control with user authentication. This innovation further reinforces the system's position as the most intelligent HPLC available today, setting a new benchmark for traceability while enhancing troubleshooting and operational efficiency. It ensures uncompromised data integrity from sample to result.

"Traceability plays an important role in the security and integrity of pharmaceutical data, and the FDA considers the absence of records to be highly significant when data discrepancies are observed," said James Hallam, Vice President, Liquid Chromatography-Mass Spectrometry, Waters Corporation. "Regulators expect to see full audit trails for human interaction with data and systems, and the integration of Empower Software user access control with the Alliance iS HPLC System sets a new standard for end-to-end traceability and data integrity in the QC laboratory."

The integration further enhances the simplicity of the Alliance iS HPLC System, which reduces human errors by up to 40% and enhances productivity in the QA/QC lab through innovative system intelligence that addresses errors before they can occur.²

In addition to its intuitive and secure design, the Alliance iS HPLC Platform has earned the Accountability, Consistency, and Transparency (ACT) Ecolabels from **My Green Lab**, a nonprofit organization dedicated to building a global culture of sustainability in science. The product line was recognized for its sustainable manufacturing practices and error-reducing capabilities, underscoring the Company's commitment to reducing environmental impacts.

Alliance iS HPLC System Software version 2.0 will be available from August 2025.

Additional Resources:

- [Audit trail white paper](#)
- [Alliance iS HPLC Landing Page](#)
- [FDA Title 21 Chapter 1 Subchapter A part 11: FDA Title 21 Chapter 1 Subchapter A Part 11: Electronic Records, Electronic Signatures](#)

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ABOUT: Waters Corporation (NYSE:WAT) is a global leader in analytical instruments, separations technologies, and software, serving the life, materials, food, and environmental sciences for over 65 years. Our Company helps ensure the efficacy of medicines, the safety of food and the purity of water, and the quality and sustainability of products used every day. In over 100 countries, our 7,600+ passionate employees collaborate with customers in laboratories, manufacturing sites, and hospitals to accelerate the benefits of pioneering science.

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References

Presented at the J.P. Morgan 43rd Annual Healthcare Conference. According to internal analysis, ~80% of the drugs filed with the FDA, EMA, and China National Medical Products Administration (NMPA) in 2023 were done so using Empower Software. Source: Waters data and estimates.

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

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