



NEWS RELEASE

Waters Integrates Multi-Angle Light Scattering Detectors with Empower Software for Improved Biologics Quality Control and Simplified Regulatory Compliance

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News Summary

- Saves up to six months on compliant software validation in biopharmaceutical quality control.¹
- Reduces analysis time for biotherapeutic peptides and proteins by 20%.²
- Enhances quality control by providing absolute molecular weight of biologics and avoiding common errors encountered with other techniques.³

MILFORD, Mass., May 6, 2025 /PRNewswire/ -- Waters Corporation (NYSE:WAT) today announced that its Empower™ Software now supports biologics data acquisition and quality control (QC) analysis from Multi-Angle Light Scattering (MALS) and differential Refractive Index (RI) instruments in its Wyatt Technology™ Portfolio. This integration expands the scope of critical quality attributes that a biopharmaceutical laboratory can manage using Empower Software. Additionally, this advancement will simplify the process and digital footprint of acquiring and submitting compliant data to regulatory authorities – from biologics development through QC – saving customers up to six months of software validation time.

Integration supports high-volume quality control testing to ensure the safety of life-saving biologic therapies.

Empower Software is the industry's most established and compliant-ready chromatography data system (CDS), widely adopted globally and used to submit data for more than 80% of novel drugs to regulatory authorities.⁴ The new integration unlocks the ability to use MALS techniques in quality control for biotherapeutics, improving efficiency and Good Manufacturing Practices

(GMP) readiness, while reducing end-user training in compliant settings.

"Today's launch of Empower for Multi-Angle Light Scattering Detectors underscores our commitment from the Wyatt acquisition to integrate advanced analytical technologies into our Empower CDS ecosystem," said Dr. Udit Batra, President & CEO, Waters Corporation. "Specifically, MALS supported on Empower Software reveals high molecular weight species that are not visible to other detectors – reducing the risk of erroneous results in biopharmaceutical quality control. By combining the strengths of compliant software with deep analytical light scattering instrumentation, we are providing customers with a unified solution that enhances productivity and data accuracy – ultimately supporting high-volume QC testing to ensure the safety of life-saving biologic therapies for patients."

The integration of the DAWN™, miniDAWN™, and OptiLab™ Detectors will enable the measurement of more critical quality attributes of peptides and proteins in a single run, reducing analysis time by 20% and providing earlier insights into the stability, safety, and efficacy of biologics.

"As a Contract Development and Manufacturing Organization (CDMO), we anticipate that MALS on Empower Software will enhance our service offerings," said William Wittbold, Senior Director of Operations, at Pace Analytical. "The detailed MALS data is essential for understanding complex biopharmaceuticals. Combined with the reliability of Empower Software, we believe this integration will deliver exceptional value to our customers, ensuring our drug development partners receive the highest quality results."

The capability to integrate the DAWN, miniDAWN, and OptiLab Detectors with Empower Software will be available for peptide and protein workflows in July 2025. Learn more by visiting our [product page](#).

Additional Resources

- Learn more about the **MALS integration with Empower Software**.
- Follow and connect with Waters **LinkedIn**, **Twitter**, and **Facebook**.

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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Contact:

Molly Gluck

Head of External Communications

Waters Corporation

molly_gluck@waters.com

Mobile: +1.617.833.8166

1. In a recent survey of 50 MALS users, responding to the question "How long does it typically take you to validate new software in a GxP lab," the average time was reported as 6 months since it is one software instead of two.
2. In a recent survey of 50 MALS users, responding to the question "How much time, as a percentage of total working time, would you save on average if you could use your primary CDS software (LC software) for MALS data analysis," the average time saving was reported as 20%.
3. White paper **WP1615**: "SEC-MALS for absolute biophysical characterization" describes the challenges associated with determining basic physical properties of biologics in solution, and provides examples of how multi-angle light scattering can reduce the occurrence of erroneous results prevalent in relative measurement techniques. MALS provides absolute results from first principles, avoiding errors of relative measures, and is independent of retention time, reference materials, and column interactions.
4. **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.

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