



Waters Corporations/ Wyatt Technology

ABOUT

Waters Corporation, a global leader in analytical instruments, separations technologies, and software, focuses on accelerating the benefits of pioneering science to improve human health and well-being. For over 65 years, we have partnered with our customers to ensure the safety of the medicines we take, the purity of food we eat and the water we drink, and the quality and sustainability of the products we use every day.

Overview of the company:

- ≈ 7,600 employees worldwide
- 35 countries of operation
- 12 manufacturing facilities
- 100+ countries with our products available

Organizations throughout the pharmaceutical and life sciences industry are increasing their investments in pharmaceutical and biopharmaceutical development as global demand increases for new and life-saving therapies. In these rapidly-evolving fields, there is a widespread need for application-appropriate, high-value technologies for large and small molecule analysis.

Strategic characterization technologies provide unique insights into the development potential of large molecule therapeutics. A first-line analysis of complex biotherapeutics that is rich with information can save significant time and development costs during production. Waters latest innovations are designed to address the multi-faceted analytical needs of large molecule characterization – from innovator biopharmaceuticals, to biosimilars, to antibody drug conjugates – and to keep pace with the regulatory changes that impact development laboratories.

In biopharma, where therapies are larger and more complex, such as proteins, antibodies, and mRNA vaccines, Waters delivers advanced technologies for detailed molecular analysis. These tools help scientists understand structure, purity, and stability, which are essential for ensuring product safety and effectiveness.

Waters offers a comprehensive portfolio of analytical solutions, including liquid chromatography systems, mass spectrometers designed for routine and advanced analyses, multi-angle and dynamic light scattering instruments (Wyatt Technology), and specialized instruments for aggregate and particle characterization (Halo Labs).

In the pharmaceutical space, where small-molecule drugs are chemically synthesized, Waters offers tools for precise analysis, impurity detection, and quality control. These solutions help labs improve efficiency, meet global regulatory requirements like FDA and EMA standards, and accelerate time-to-market.

Beyond instruments, Waters provides complete support through software, training, services, and expert guidance. From early research to final manufacturing, Waters helps optimize lab performance, simplify complex processes, and maintain regulatory compliance.

By turning complexity into clarity, Waters empowers pharma and biopharma teams to bring better treatments to patients, faster and more reliably.

INDUSTRY TALK



Felix Gloge – Senior Bio Account Manager

Light Scattering (SEC-MALS and DLS) – Fundamentals and applications in academic and biopharmaceutical research

*Light scattering has become a cornerstone in the physical characterization of macromolecules, nanoparticles, and colloidal systems. **Static Light Scattering (SLS), commonly implemented as multi-angle light scattering (MALS), and Dynamic Light Scattering (DLS)** provide complementary, label-free insights into molecular weight, size, and interactions in solution. Their ability to probe native systems non-destructively has made them indispensable in academic biophysics and biopharmaceutical development, where molecular stability, aggregation, and conformational behaviour are key concerns. In practice, MALS coupled to HPLCs or FPLC provides molecular weight and conformation across chromatographic peaks, while DLS (cuvettes or microwell plates) characterizes size distributions and aggregation propensity. Combined, they offer a complete picture of macromolecular size, shape, and solution stability.*

Structural Biology and Biophysics: *In structural biology, light scattering is widely used to assess protein oligomerization, complex formation, and sample homogeneity. SEC-MALS provides absolute molecular weights to confirm assembly states, while DLS quickly identifies aggregation or conformational transitions under changing environmental conditions. DLS is routinely employed to evaluate protein stability before crystallization, NMR, or cryo-EM studies and to screen buffers or additives that enhance thermal and colloidal stability.*

Applications in Biopharmaceutical Research: *Light scattering techniques have become integral to biologic drug development, enabling detailed characterization of therapeutic proteins, antibodies, viral vectors, and nanoparticle delivery systems. Their non-invasive*

nature and absolute quantitation make them ideal for assessing critical quality attributes (CQAs) during formulation, process development, and quality control.

Protein Aggregation and Stability: *Aggregation can compromise efficacy and immunogenic safety. DLS is the most sensitive technique for detecting early aggregation, following changes in hydrodynamic size and polydispersity during stress or storage studies. SLS, through the A_2 parameter, complements DLS by revealing the nature of intermolecular interactions. Combined, they support formulation optimization to enhance protein stability and shelf life.*

Molecular Weight and Conjugate Characterization: *SEC-MALS provides absolute molar mass measurements essential for characterizing modified or conjugated proteins (complexes, ADCs, glycosylated proteins etc.) and nucleic acid complexes. It accurately determines drug-to-antibody ratios (DARs) and identifies aggregates or free components without calibration standards. For viral vectors such as AAVs or lipid nanoparticles (LNPs), SLS quantifies size (M_w , radius of gyration), particle concentration (/ml), while DLS evaluates size (R_h) and dispersity, supporting both process development and regulatory documentation.*

Vaccines and Nanoparticle Formulations: *Particle size and uniformity influence the immunogenicity and delivery efficiency of vaccines and therapeutic nanoparticles. DLS provides rapid analysis of size, polydispersity index (PDI), and colloidal stability, while SLS confirms aggregation state and concentration. These measurements are now routine in vaccine formulation screening and process scale-up.*

Conclusion: *Static and Dynamic Light Scattering, particularly through SEC-MALS and DLS, have evolved into versatile, complementary tools for understanding molecular behaviour in solution. They provide absolute molecular weight, hydrodynamic size, and interaction parameters, bridging the gap between academic research and industrial biophysics.*

In academia, they illuminate the fundamental principles of macromolecular assembly, solution behaviour and colloidal interactions. In biopharmaceutical development, they are critical for ensuring the stability, efficacy, and safety of biologics, vaccines, and nanoparticle therapeutics.