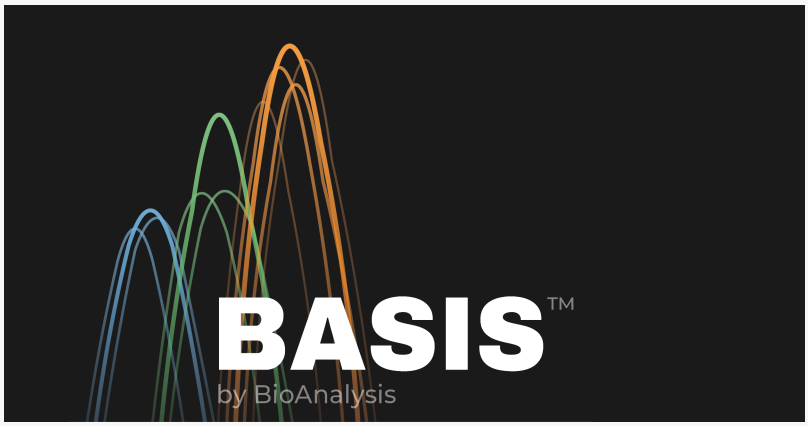
BioAnalysis Launches BASIS 2.0, Next-Generation GMP-Compliant AUC Software for Analytical Ultracentrifugation

BioAnalysis launches BASIS 2.0, its next-gen GMP-compliant AUC software for gene therapy. Higher throughput, one-click workflows and full regulatory compliance.



PHILADELPHIA, PA, UNITED STATES, March 3, 2026 /EINPresswire.com/ -- BioAnalysis LLC, a collaborative research organization specializing in analytical services for gene therapy and biotherapeutics, today announced the launch of BASIS 2.0, the next generation of its proprietary GMP-compliant software platform for Analytical Ultracentrifugation (AUC).

> We built BASIS 2.0 to dramatically increase throughput, simplify the workflow, and maintain the scientific rigor that regulatory agencies expect."
>
> *Lake N. Paul, PhD, Founder and CEO of BioAnalysis.*

BASIS 2.0 builds on BioAnalysis's position as one of the first organizations to offer 21 CFR Part 11-compliant AUC services for gene therapy development. The new version introduces significant enhancements designed to accelerate timelines and reduce risk for sponsors navigating the path from development through regulatory submission.

"Gene therapy teams face enormous pressure to move quickly without compromising quality or compliance," said Lake N. Paul, PhD, Founder and CEO of BioAnalysis. "BASIS 2.0 was built to address exactly that challenge. We've dramatically increased throughput, simplified the workflow, and maintained the scientific rigor that regulatory agencies expect."

When you work with BioAnalysis, BASIS 2.0 delivers:
• Higher Throughput: Parallel analysis of multiple data sets simultaneously increases processing capacity

• One-Click Workflow: Direct instrument communication enables operators to download and analyze data in a single click, reducing manual touchpoints and potential error sources
• Built-in Methods: Instrument methods integrated directly into the software provide enhanced convenience and security
• Expert Oversight: Raw data surfaces at key checkpoints, ensuring trained analysts can identify issues that automation alone might miss
• Full Compliance: Comprehensive audit trails and data integrity controls aligned with FDA 21 CFR Part 11 requirements
• Comprehensive Validation: Full Computer Software Validation (CSV) performed and maintained by BioAnalysis, eliminating the need for clients to write and execute their own CSV

Analytical Ultracentrifugation is widely recognized as the gold standard for empty, partial, and full capsid quantitation in AAV and other viral vector products. Accurate capsid characterization is a critical quality attribute for regulatory filings, directly impacting assessments of therapeutic potency, dose accuracy, and patient safety.

Lake Paul, PhD | President and Founder of BioAnalysis

"We've seen too many organizations struggle with GMP workarounds for AUC. Manual data handling, non-validated software, pieced-together audit trails," added Dr. Paul. "Even when instrument manufacturers offer GMP software, each lab is still responsible for its own Computer Software Validation. BASIS 2.0 eliminates those headaches while actually improving the science."

BASIS 2.0 is available exclusively through BioAnalysis's analytical services, not as a standalone product or license. The BASIS 2.0 platform integrates seamlessly with SEDFIT, the globally recognized AUC analysis engine, and supports projects across non-GMP and GMP environments.

About BioAnalysis LLC
BioAnalysis, based in Philadelphia's Kensington neighborhood, is a collaborative research organization providing analytical services for gene therapy and biotherapeutics development. Founded in 2019, the company combines scientific excellence with community impact, serving clients worldwide while actively creating opportunities in the life sciences industry for local community members. Specializing in biophysics, chromatography, and mass spectrometry applications for gene therapy and biotherapeutics, BioAnalysis offers deep expertise in method development, cGMP validation, and testing. The company is guided by five core pillars: Scientific Excellence, Client Partnership, Rapid Delivery, Value Always, and Community Impact.

For more information, visit www.bioanalysisllc.com.

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