Tailored Services Backed by Media Expertise

Outsourcing Media Optimization to Increase Process Robustness and Performance

For drug producers, maximizing yield without compromising product quality requires considering all critical parameters in process development to analyze and improve cell culture conditions. Media performance is linked to several parameters including the manufacturing process as well as the source and quality of raw materials. Optimizing a media formulation is critical to shortening time-to-market and ensuring consistent output. Combining a rational and research-driven approach with statistical methods can enable solutions that are both well-founded and adaptable to your needs.

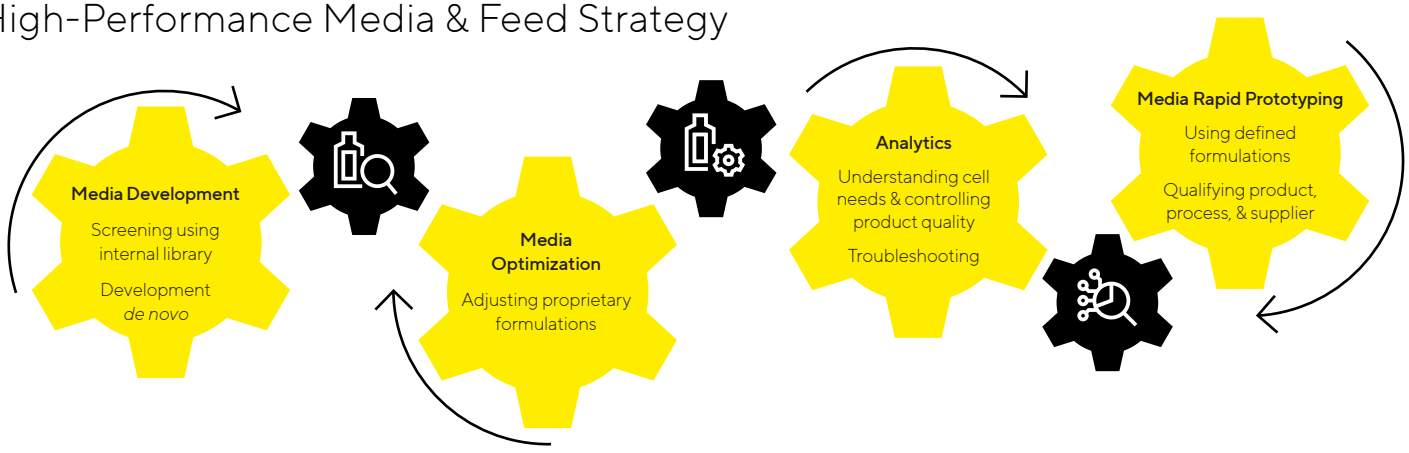
Key Media Development & Optimization Challenges

- Unique process & target expectations require a tailored media formulation .
- Designing the right formulation is time- and cost-intensive.
- Media development depends on specific expertise and dedicated equipment.
- High number of component- and concentration-dependent combinations create additional complexity.
- Access to manufacturing-grade raw materials is crucial for low-risk scale-up.

Comprehensive Capabilities from Benchmarking Studies to de novo Development

- Adherent to suspension cell line adaptation service
- Initial process screening and comparability studies to available solutions
- Media optimization service based on a library of existing formulations
- Iterative de novo development from scratch to match process performance indicators supported by advanced data analytics (MODDE® & SIMCA® software)
- Cutting-edge media analytical methods & equipment including the Ambr® system, supporting an iterative, flexible, & agile approach

Optimizing Process Conditions Using an Integrated, High-Performance Media & Feed Strategy



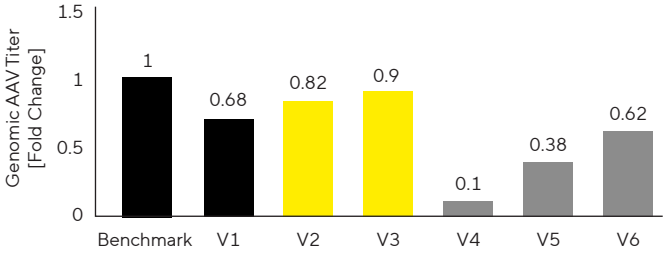
Case Study: Custom Medium Development for AAV Production in HEK293 Cells — Producing > 1.5-Fold Increase in Genomic Titers From Benchmark Study to Final Run

Fresh & spent media analytics to understand current process → Starting **media selection** from scratch or basal formulation → **Cyclic development** testing media variants in the specific process → Final variant confirmation at 2 L bioreactor scale, including **tech transfer**

Frequent expert to expert interactions

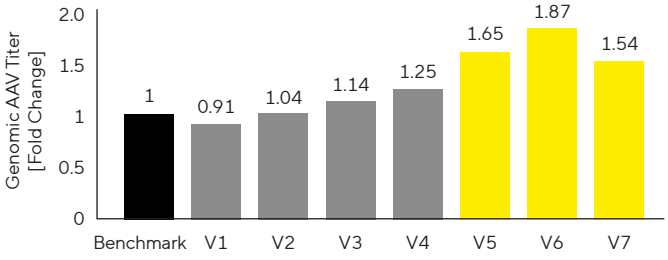
Media variants two and three tested in the first development cycle already showed competitiveness to the benchmark.

Figure 1: *AAV2 production in HEK293 cells at shake-flask scale with 6 media variants from first development cycle. Genomic titer shown as fold change measured by qPCR 72 hours post-transfection in cell lysates.*



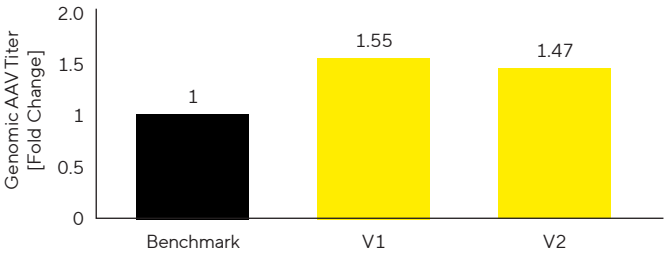
Media variants identified in the second development cycle outperformed the benchmark.

Figure 2: *AAV2 production in HEK293 cells at shake-flask scale with 7 media variants from second development cycle. Genomic titer shown as fold change measured by qPCR 72 hours post-transfection in cell lysates.*



Before sending to the customer, we tested promising intermediate variants in 2 L benchtop bioreactors. Both variants outperformed the initial benchmark.

Figure 3: *AAV2 production in HEK293 cells in 2 L benchtop bioreactors with 2 media variants from final development cycle. Genomic titer shown as fold change measured by ddPCR 72 hours post-transfection in cell lysates.*



Services Available as Standalone or Packaged

Cell line adaptation service
Feed & media optimization service
Feed & media development service
Benchmarking & material testing

Access to our media production capabilities from rapid prototyping to large scale liquids & powders for further manufacturing use.

For more information, visit
sartorius.com