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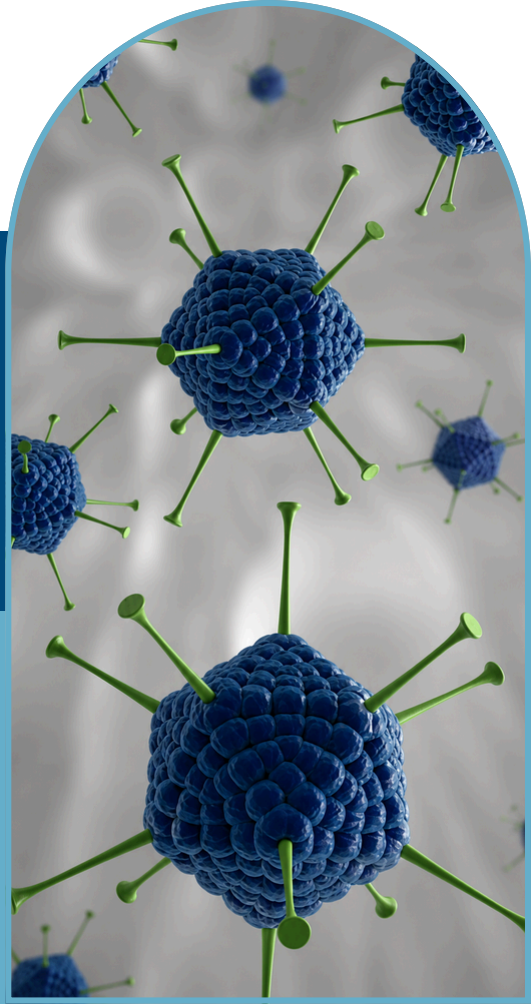


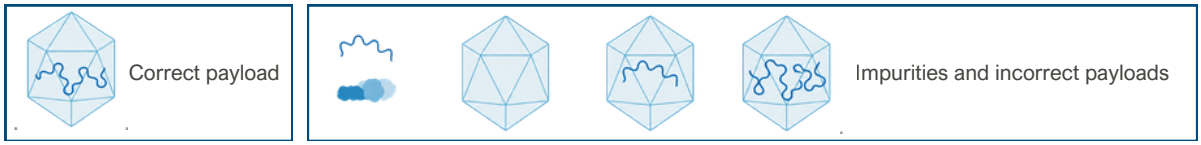
Characterizing AAV Payload with Confidence:

GMP-COMPLIANT svAUC FOR FULL, PARTIAL, EMPTY, AND OVERFILLED CAPSIDS

A biotechnology company developing an adeno-associated virus (AAV) gene therapy needed to accurately characterize vector payload as the program advanced toward GMP manufacturing. One of the most critical quality attributes for AAV products is the proportion of empty, partially filled, full, and overfilled capsids. These populations directly influence product potency, dosing, manufacturing consistency, and regulatory acceptance. However, conventional analytical techniques provided only partial information, making it difficult to obtain a complete picture of vector quality. To generate a comprehensive and GMP-compliant assessment of AAV payload, the company partnered with Solvias.

THE CHALLENGES

Full-to-Empty Capsid Ratio Is a Critical Quality Attribute
The therapeutic performance of an AAV product depends not only on vector concentration but also on the proportion of capsids successfully carrying the intended genetic payload. Empty or partially filled capsids contribute little or no therapeutic benefit while increasing product heterogeneity.

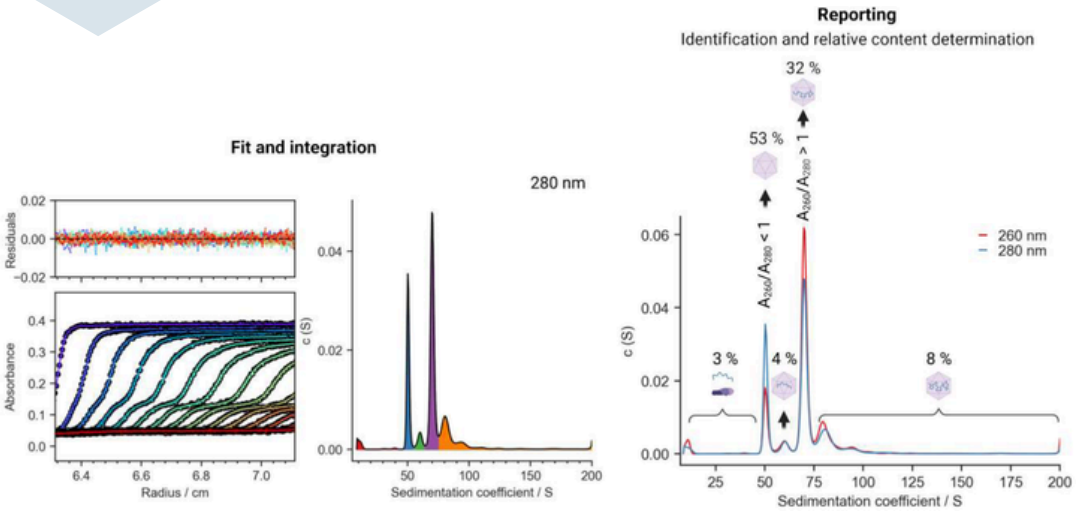


Limitations of Individual Analytical Techniques
Common orthogonal methods provide valuable information but often characterize only part of the particle population. Relying on a single technique may leave uncertainty about the true composition of the product.

GMP Readiness
As development progresses, analytical methods must deliver reproducible, traceable, and regulatory-ready data suitable for GMP environments while maintaining confidence in data integrity and lifecycle management.

OUR COLLABORATIVE APPROACH

Sedimentation Velocity Analytical Ultracentrifugation (svAUC)
Solvias implemented GMP-compliant svAUC to characterize AAV samples directly in their native formulation buffer without requiring a solid matrix (as SEC would) or freezing protocol (as cryo-TEM would). During the centrifugation experiment, the absorbance at 260 and 280nm was recorded, which after data fitting and peak integration allows the species to be identified and the relative content to be determined.



GMP-Compliant Data Workflow
The analytical workflow incorporated validated software, electronic traceability, standardized operating procedures, controlled data review, and expert interpretation to ensure data integrity and regulatory compliance throughout the analysis. Every critical component of the workflow, including the measurement cells used during centrifugation, was individually qualified and fully traceable, ensuring confidence in the reported results.

THE RESULTS

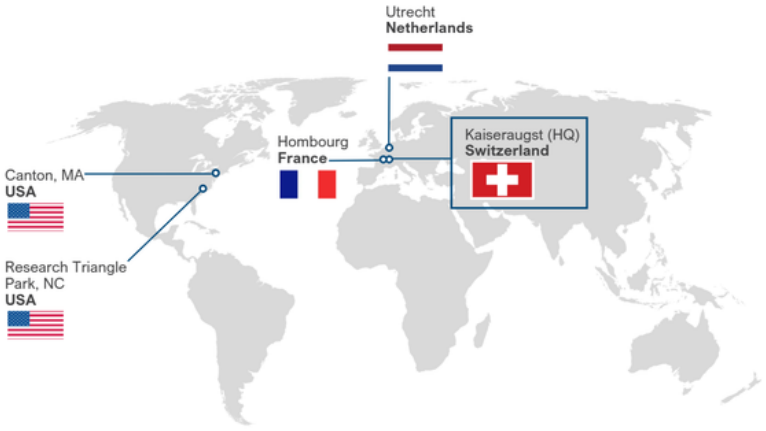
- Accurate quantification of empty, partially filled, full, and overfilled capsids while simultaneously detecting process-related impurities in a single experiment.
- Regulatory-ready analytical package supporting process development, characterization, and batch release.

CONCLUSION

This case demonstrates how GMP-compliant sedimentation velocity analytical ultracentrifugation enables comprehensive characterization of AAV vector populations while preserving native sample conditions. By combining svAUC with a fully compliant data workflow, Solvias helped the customer generate a robust, regulatory-ready understanding of one of the most critical quality attributes in gene therapy development.

WHY PARTNER WITH US?

- CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 23K m^2 of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



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