

6 Analytical Strategies to Consider Before Submitting Your Cell and Gene Therapy Application

Cell and gene therapies have the potential to provide long-term therapeutic efficacy, but their development is both risky and cost-intensive. Strategic application of advanced analytical techniques can help improve the selection of candidates and guide development decisions, leading to a greater number of safer, more efficacious cell and gene therapies completing development and entering the market. It is important to keep in mind the phase-appropriate regulatory demands while applying excellent science and the best practices of the industry.

Recommended Analytical Strategies



Viral Vector Characterization (AAV, LVV, others)

Lot Comparability

Process Development Changes

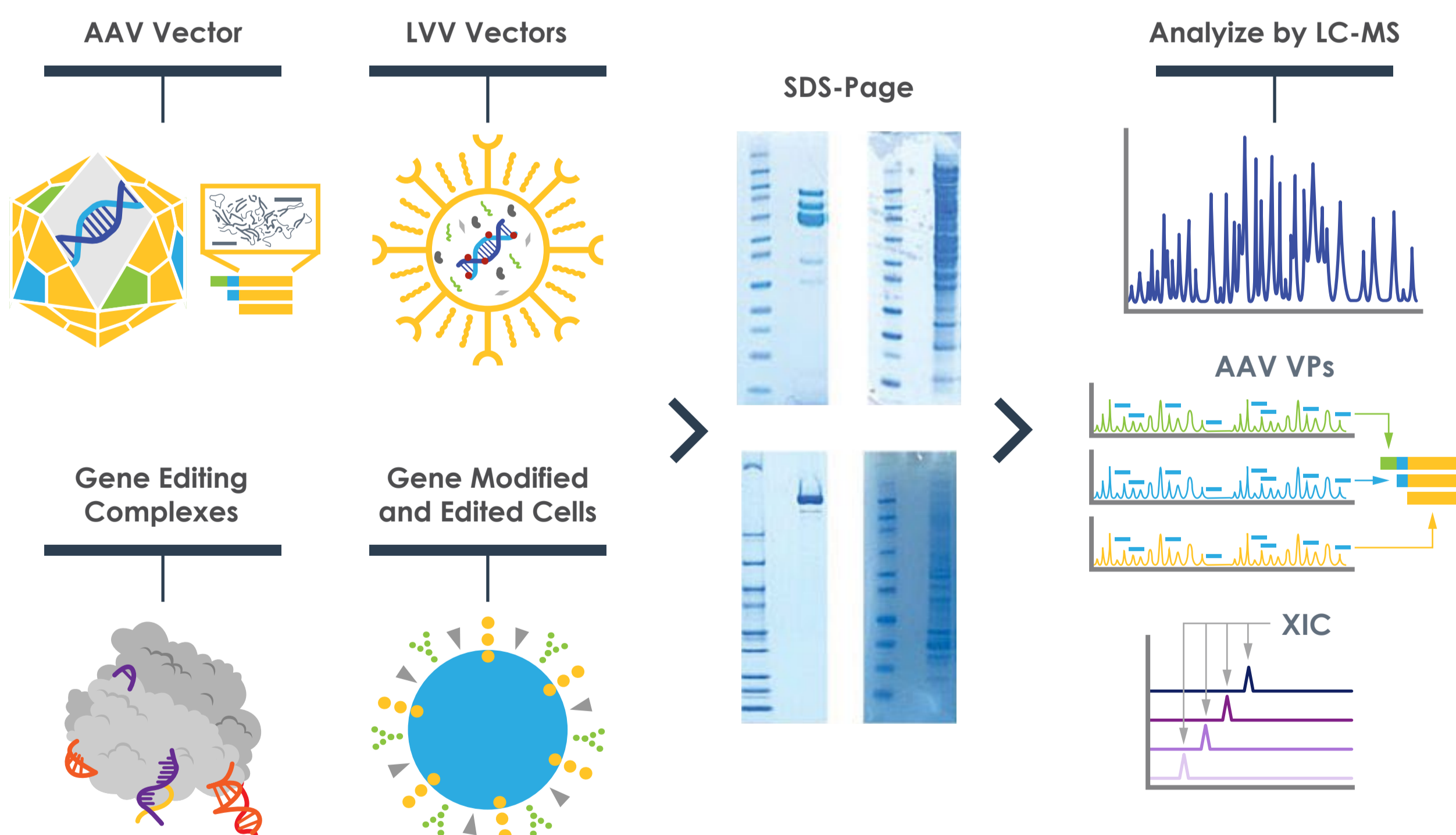
HCP/Impurities ID & Profiling

***In Vivo* Gene Expression Product Quantitation and Characterization**

Confirmation of Gene Editing and Evaluation of Therapeutic Expression Levels

Advanced Analytics for Gene Editing Technologies

We apply analytical approaches to enhance the development of cell and gene therapies. LC-MS can be used to identify and quantify therapeutic protein components, such as AAV capsid proteins, as well as process and product-related impurities (right).



Our team can assess vector proteins, as illustrated by this diagram, which depicts four common gene therapies (left) and the use of SDS-PAGE to visualize the differences in complexity (middle).

BioAnalytix • Protagen Protein Services

ADVANCE. DE-RISK. ACCELERATE.

Contact our team to learn how we can help advance and accelerate the development of your cell and gene therapy products.

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