

INFOGRAPHIC

# 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

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
Viral Vector Characterization (AAV, LVV, others)	Lot Comparability	Process Development Changes	HCP/Impurities ID & Profiling	<i>In Vivo</i> 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).

