

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

<h1>1</h1> <p>Viral Vector Characterization (AAV, LVV, others)</p>	<h1>2</h1> <p>Lot Comparability</p>	<h1>3</h1> <p>Process Development Changes</p>	<h1>4</h1> <p>HCP/Impurities ID & Profiling</p>	<h1>5</h1> <p><i>In Vivo</i> Gene Expression Product Quantitation and Characterization</p>	<h1>6</h1> <p>Confirmation of Gene Editing and Evaluation of Therapeutic Expression Levels</p>
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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).

