## GENE THERAPY ANALYSIS

A newsletter from Nitto Avecia Pharma Services



The field of gene therapy holds enormous promise for addressing unmet medical needs. Nitto Avecia Pharma Services will work with you to advance your gene therapy programs with pride, ownership, and responsibility. We have the expertise and instrumentation to perform testing for CAR-T, AAV, and CRISPR products.

### We offer a comprehensive line of platform and flexible programs to support Process Development, Manufacturing and Regulatory Filings.

- AAV-based Drug Product Testing Virus Capsid testing, Protein Expression, and Genomic Analysis
- Raw Material Testing for CAR-T Manufacturing growth media, cytokines, growth factors and enzymes
- Adenovirus / Adenoviral Vectors
- Method Development and Phase-Appropriate Validation
- Pre-clinical to Commercial phase Release and Stability programs to support IND and BLA submission
- Expanded BSL-2 laboratory with a wide range of instrumentation



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#### **AAV** analysis

We have the capabilities for virus capsid testing, protein expression, and genomic analysis. Our MRM/MS-MS can be used to analyze the viral proteome and establish identity.

#### **CRISPR-Cas9** analysis

Our scientists can test components of your CRISPR-Cas9 product, and develop and validate methods to test your final product. We can also offer guide RNA synthesis services through Nitto Avecia.

#### **CAR-T** analysis

We can provide analytical support for all facets of your program. Services include release testing for growth media, cytokines, growth factors, and enzymes. We can conduct product testing to assess purity/impurities, safety (e.g. compendial testing), identity and strength.



#### **Project management**

We provide direct access to our scientists and leadership who partner with you, no matter the size of your organization. A project manager will be assigned to your program to facilitate strategic planning, meetings, weekly reports, and detailed post-project follow up. Our experts can also offer assistance with preparation of IND and BLA filings. If you would like to speak to our scientific team, we would be glad to arrange a teleconference with the Gene Therapy team. Email Kyle Chisholm, Senior Director of Business Developoment at Nitto Avecia Pharma Services at

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