NEW BIOLOGIX

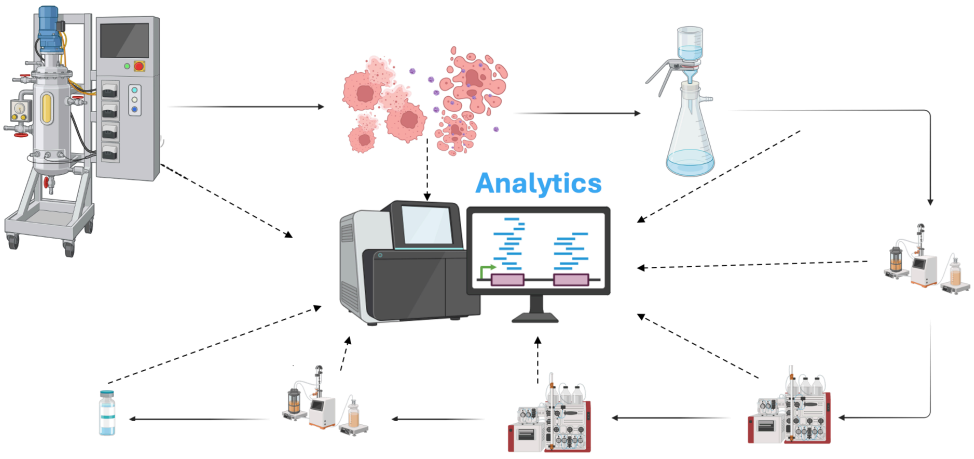
Quality Assurance Matters.

Starting Discovery with the Right Analytics During rAAV Process Development Assures Confidence in Your Final Product

Quality assurance forms the foundation for safety, consistency, and compliance, making it an integral pillar of any successful rAAV discovery and process development strategy. Achieving excellence in quality assurance depends on selecting the right analytical tools.

At NewBiologix, our advanced analytics deliver the confidence needed in final product integrity, meeting regulatory expectations and addressing the critical safety questions for gene therapy.

Our analytics platform rigorously monitors quality at every stage, detecting contaminants and verifying gene integrity from cell lysis to formulation.



1. MASS PHOTOMETRY

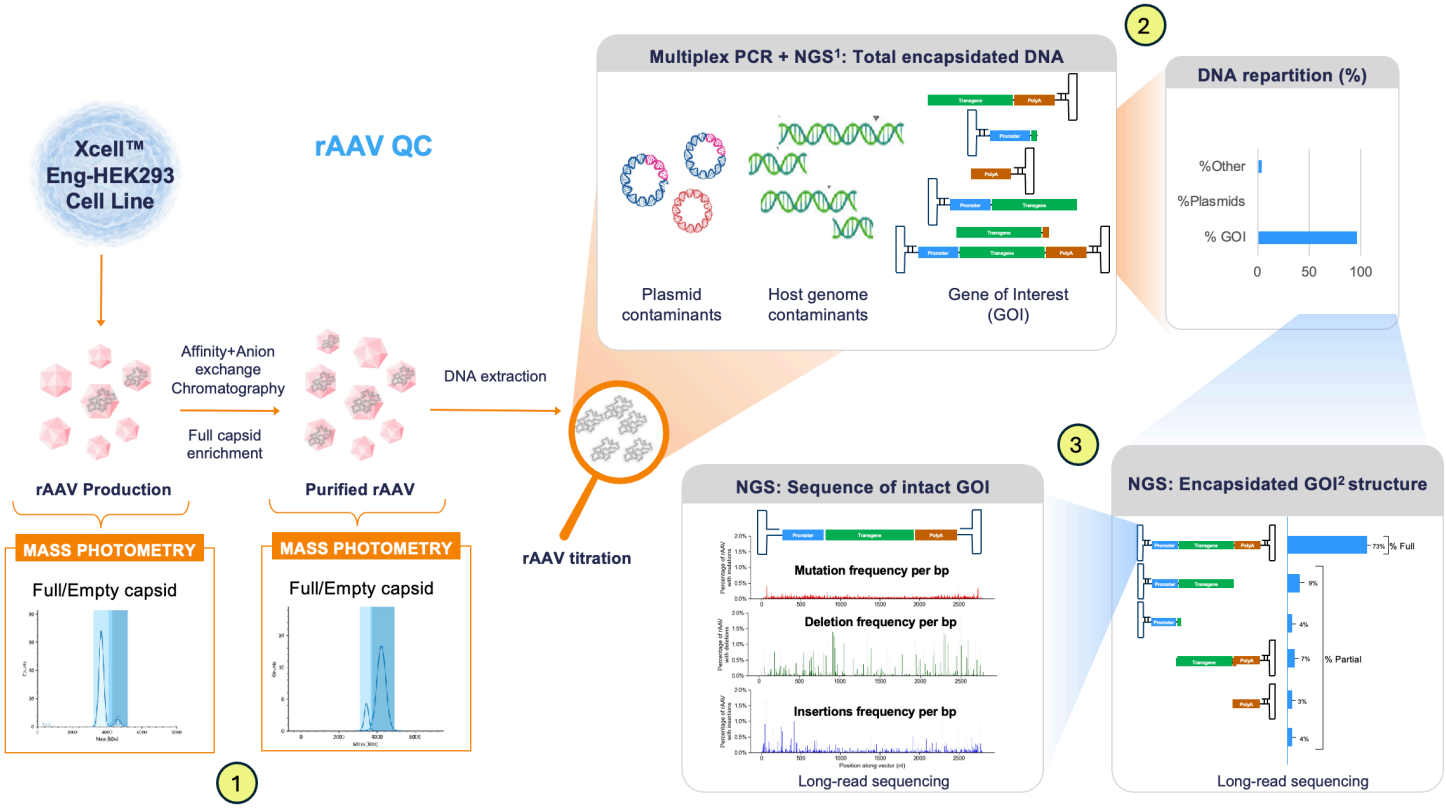
By starting with mass photometry to identify full-to-empty capsid ratios, we accelerate decision-making, enhance process insights, and ensure the production of high-quality, consistent vectors.

2. MULTIDIMENSIONAL PCR

At NewBiologix, we have developed in-house methods using Multidimensional PCR, rapidly emerging as a next-generation standard in rAAV analytics. This approach complements traditional qPCR and dPCR by delivering greater depth, resolution, and interpretability, with a particular focus on genome integrity, a critical factor for clinical efficacy and regulatory approval.

3. NEXT GENERATION SEQUENCING

Next Generation Sequencing (NGS) offers the most comprehensive genomic characterization of rAAV vectors available today. It is essential for precisely understanding what is being delivered to the patient, not only the quantity of vectors, but the exact composition. For regulatory submissions or quality control packages, NGS data adds depth, strengthens the dossier and mitigates risk during regulatory review.



A BREAKTHROUGH HIGH-DEFINITION PLATFORM
Identify Contaminants & Gene of Interest

The combined use of Multidimensional PCR and NGS delivers both precision and depth:

- **Multidimensional PCR:** a fast, reliable QC tool for assessing critical genomic regions
- **NGS:** a comprehensive, base-by-base genomic audit

Together, they enable robust understanding of product quality, meet regulatory expectations, and ensure the development of safe, high-quality rAAV vectors.

WHY QUALITY ASSURANCE MATTERS

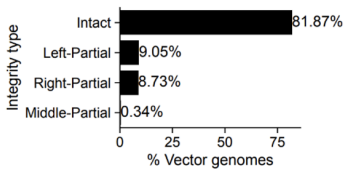
In rAAV production, quality assurance is the foundation for clinical success, regulatory approval, and patient trust. At NewBiologix, we provide the essential tools to establish robust cGMP CMC quality systems and processes that stage for safe, consistent, and compliant vector manufacturing.

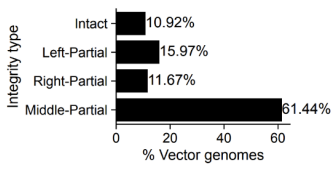
THE MORE INTACT ENCAPSIDATED DNA, THE HIGHER THE POTENCY

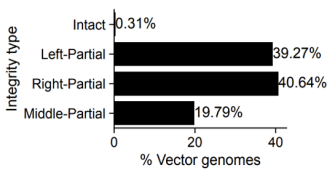
To demonstrate the superior quality of viral particles produced for a Discovery (pre-IND) application using NewBiologix's Xcell™ Eng-HEK293 cell line and chromatography-based purification process, we conducted a comparative analysis against rAAV vectors generated using a commercial HEK293 cell line and (ultra-)centrifugation-based purification methods from two leading CROs.

rAAV Quality by NGS: Encapsidated DNA species

	Xcell™	CRO 1	CRO 2
	rAAV produced at **NBX** using Eng-HEK293 cells and NBX chromatography DSP.	rAAV produced at a **CRO 1** using commercial HEK293 cells and centrifugation downstream process.	rAAV produced at a **CRO 2** using commercial HEK293 cells and centrifugation downstream process.
	% Sequencing Reads	**% Sequencing Reads**	**% Sequencing Reads**
Plasmid backbone	0.9	2.0	1.1
Host cell DNA	0.9	17.1	13.8
Rep/Cap genes	0.1	0.9	1.1
AdV Helper genes	0.1	1.7	0.9
Other	12.1	11.7	30.2
ITR-GOI-ITR (Vector Genomes)	**85.9**	**66.6**	**52.9**







NEW BIOLOGIX

WHAT'S IN YOUR VIAL?

At NewBiologix we deliver trusted quality from the very start, ensuring consistency, reliability, and results that make a difference for patients.

WHEN YOU PARTNER WITH NEWBIOLOGIX...
YOU DO IT RIGHT THE FIRST TIME!

Leverage our breakthrough technologies and expertise to accelerate your gene therapy further, faster.

Ultimate Quality

More Full Functional Viral Particles

Massive Time & Cost Savings

Reproducibility, Reliability & Scalability