

A large, light blue, semi-transparent DNA double helix structure is the background of the entire page, winding across the frame from the top left towards the bottom right.

Common Challenges and Solutions to Support AAV Manufacturing

The expert team at Franklin Biolabs has been at the forefront of AAV vector production for cell and gene therapies for over 20 years. Drawing on this deep expertise, we've identified several of the top challenges researchers face when working with AAV vectors. Click to explore how our team overcomes these challenges and delivers thousands of high-quality, reliable AAV vectors to researchers worldwide.

Challenge 1: Scientific Support

Problem: Reviewing your project to identify knowledge gaps and maximize productivity.

Solution: Franklin Biolabs offers comprehensive consultative design support that enables predictive productivity, based on the experience gained from 10K+ unique preps.

Our consultative approach supports:

- Proper capsid selection
- Optimal promoter choices
- DNA construct attributes
- Analytics
- Estimated productivity and yields

Our experience has shown that early design optimization is critical for downstream performance and regulatory suitability. By removing guesswork, we support scientists in making the appropriate choice for their vector constructs.



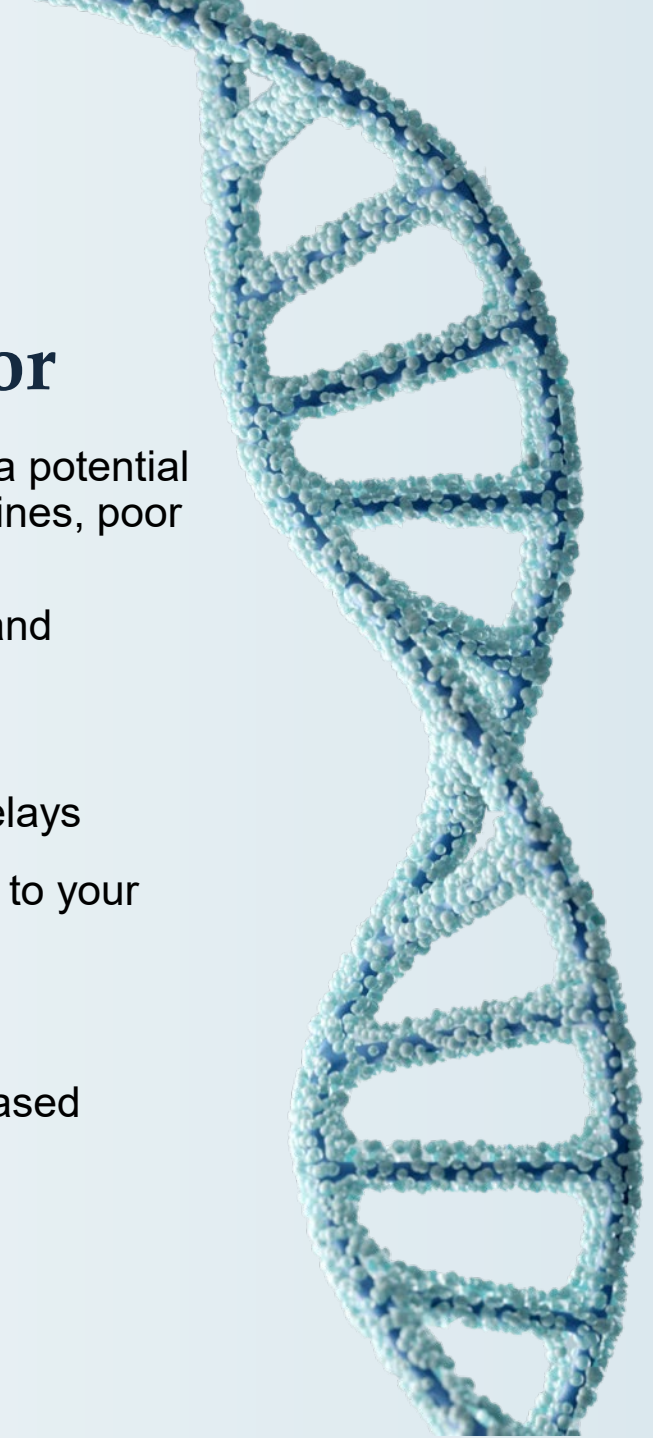
Challenge 2: Stable Supply of High-Quality Vector

Problem: Our experience has shown that not having stable access to high-quality vector is a potential delay in moving the project forward. Typical supply issues include inconsistent delivery timelines, poor product quality, and a lack of transparency from the vendor are common concerns.

Solution: Franklin Biolabs offers reliable access to in-house materials that offer consistent and repeatable performance >98% of the time.

Our proven system offers you:

- Access to end-to-end services, which will shorten timelines and eliminate subcontractor delays
- Rapid access to materials, coupled with standardized processes, ensures that you adhere to your project timelines
- Consistent performance (>98% of our past projects were delivered as expected)
- Access to high quality materials that ensure analytical optimization (custom assays, cell-based potency, quantification & titer)
- Real-time updates to your order status



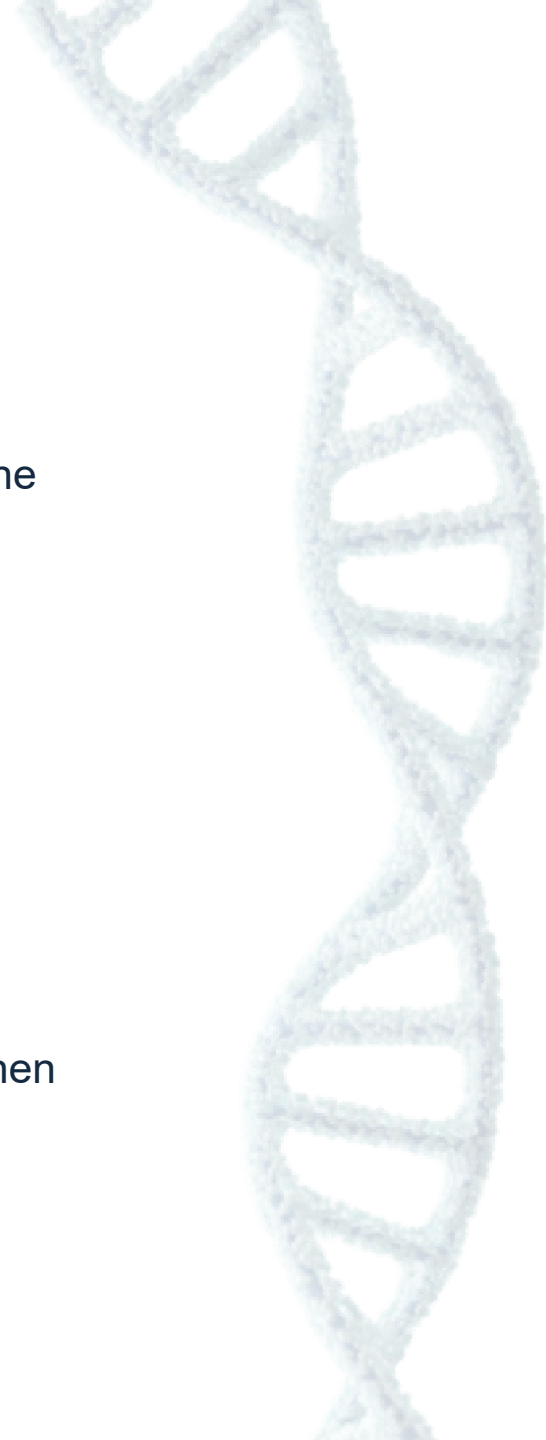
Challenge 3: Vector Manufacturing Costs

Problem: High vector manufacturing costs often prevent experiments for potentially life-saving gene therapies.

Solution: To help researchers overcome costly projects, we provide guidance on vector design, appropriate manufacturing scaling, and vector productivity.

We ensure that you maintain costs by:

- Consulting on the identification of the best performing vectors
- Implementing operational improvements ensure appropriate scaling
- Offering flexible a la carte services to support your analytics needs
- Execution of Lean Lab principles that minimize waste
- Providing insight into process improvements that maximize the productivity of vectors, which then enables investigators to benefit from lower manufacturing scales.



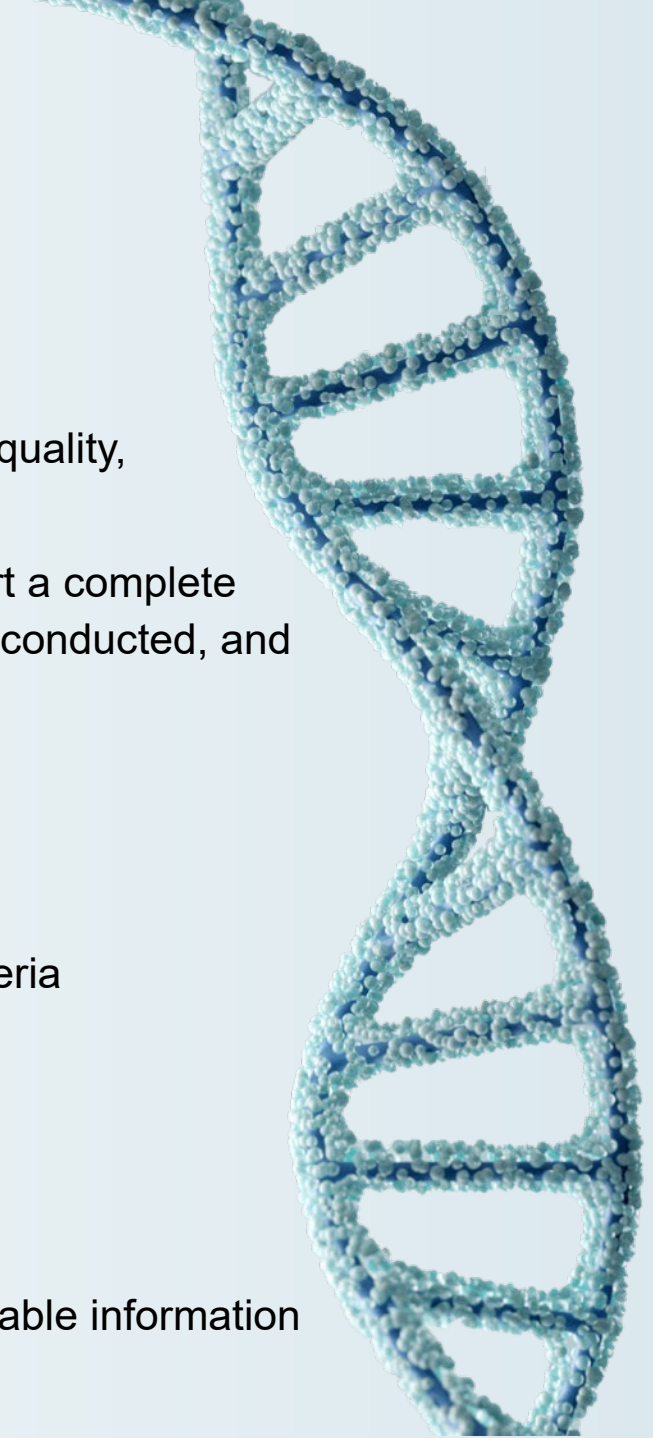
Challenge 4: Documentation and Controls

Problem: Researchers need full traceability to ensure data integrity, reproducibility, product quality, regulatory readiness, and publication.

Solution: Our deep understanding of the nuances encountered in manufacturing will support a complete documentation package that will assist in proving the project is scientifically sound, ethically conducted, and regulatory compliant.

Our ability to execute documentation at the highest standards ensures:

- Full traceability for all:
 - Protocols and training
 - Equipment environmental monitoring, calibrations, maintenance, and performance criteria
 - Production metrics
 - Financial and inventory assets
- High data quality through the implementation of ALCOA+ documentation practices
- Witness verification programs that ensure data accuracy
- Continuous improvement in documentation practices to ensure the capture of critical traceable information





Review and Wrap Up

At Franklin Biolabs, our proven AAV experience allows us to embed solutions from project onset that can accelerate your programs' journey to the clinic and help your project succeed.

Our proven history of success includes:

- Providing support for INDs in 6 drugs in the last 3 years
- >700 publications
- >50,000 citations
- Development of over 2,000 unique capsids outside the standard naturally occurring serotypes.

Our experience has shown that every researcher doesn't have the same needs, so we have specifically built customizable solutions that allow for end-to-end support at every step of your project.

To learn how Franklin Biolabs can support your projects, contact us today.

www.franklinbio.com

