



# Your Team, Extended.

Built for developers of tomorrow's advanced therapies, we are a **science-driven consulting company** that provides comprehensive services from non-clinical to CMC.

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Advising Developers of Gene Therapies,  
Cell Therapies, and Biologics.

## About Us

TKD Solutions is an external team of subject matter experts that becomes a full extension of your internal team in every phase of development. Built to solve the challenging problems across the development and manufacturing spectrum, our team runs deep with technical know-how to help wherever you are in your therapeutic's journey to commercialization.

While our technical expertise is unmatched, TKD team members are also selected for their ability to work well with others. We plug in, collaborate, and problem-solve. We can even act as your representative to your vendors, CROs, and CDMOs.

## Our Guiding Values



### Efficiency

For both our clients and the patients waiting for treatment time is everything. We do everything we can to help mitigate delays, and accelerate the path to approval.



### Quality

Quality means taking the time to get it right the first time. From a safety, compliance and regulatory perspective we take pride in the work we do so you can avoid delays.



### Flexibility

Flexibility means meeting you wherever you're at in the path to approval and having the ability to jump in and add instant value.

## Our Consulting Services

Whether you are developing a viral vector, a complex biologic, or a gene-modified cell therapy, you may not have a "platform process" to adopt. That is why our approach combines strategy and execution seamlessly. We go beyond just highlighting what needs to be done; we actively engage, identifying and mitigating risks from pre-clinical through commercial stages.

With our hands-on, science-led approach, we connect you with the right technologies, develop innovative technical solutions, and provide complete documentation without gaps.

- Nonclinical / Early Phase Development
- Process Development
- Manufacturing Science & Technology
- Analytical Development
- Project Management
- Regulatory Affairs
- Cross-Departmental Support

## Your Connection Between Internal and External Stakeholders



## Our Expertise

At TKD Solutions, our team is comprised of scientific experts who have lived through the complexities of nonclinical development and CMC at both small and large organizations. It is with that understanding that we seek to be the support we wish we had for your gene therapy, cell therapy, or biologic in development.



GENE THERAPIES

CELL THERAPIES

BIOLOGICS

**Here are some examples of how advanced therapy developers have plugged us in to move forward their program:**

- Risk-based CMC strategy design and implementation to improve process robustness of approved product
- Development of a QbD approach tailored to a gene therapy program's scale-up needs ensuring successful
- Phase III cGMP manufacturing batches
- Development of phase-appropriate processes and analytical methods for client's in-licensed asset
- Identification and correction of client's cell culture abnormalities during tech transfer
- Selection, management, and oversight of CDMOs



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