



# CONSIDERATIONS FOR CELL THERAPY MEDIA DEVELOPMENT

**38%** INCREASE GLOBAL CELLULAR THERAPY PIPELINE

**1358** ACTIVE CELLULAR THERAPY TRIALS

Cell and gene therapy development is advancing rapidly and creates unique challenges due to the complexity of developing processes for delivery of a living therapeutic.

Ensuring the **VIABILITY** of collected cells, highest **TRANSFECTION EFFICIENCY**, and **POTENCY** or **CYTOTOXICITY** of cellular therapies should be a top priority during development.



STUDIES SHOW **1 COMPONENT CHANGE** IN MEDIA **INCREASES** POTENCY **TRANSFECTION EFFICIENCY** YIELD

**21 WEEKS FROM FORMULATION TO PIPETTE**

**67%** FASTER THAN TRADITIONAL CUSTOM MEDIA FORMULATION

**SPEED** and **SCALABILITY** are critical to success. Nucleus Biologics' proprietary methods facilitate industry leading custom media formulation and manufacturing speed.

**2L TO 2000L**  
SCALE TO MATCH YOUR DEVELOPMENT NEEDS

**PRODUCT CONSISTENCY** requires robust **QUALITY-CONTROLLED PROCESS** that is adaptable to clinical development. Traditional methods introduce variability that can impact **PROCESS VALIDATION** and complicate **SUPPLIER QUALIFICATION**.



**MANUAL MANIPULATION** INTRODUCES INHERENT VARIABILITY



CUSTOM COMPLETE MEDIA **READY TO PIPETTE**  
cGMP QUALITY

**+1** SUPPLIER TO QUALIFY PROCESS TO VALIDATE

## INDEPENDENT CASE STUDY:

**DMEM** FROM 5 VENDORS  
**0/5** MEDIA TESTED HAD **SAME** COMPONENT CONCENTRATIONS  
**14/24** COMPONENTS **DIFFERED** FROM **CofA**

Many complete media are proprietary formulations; thus, **TRANSPARENCY** is limited. With **INDIVIDUAL OWNERSHIP**, you always know exactly what is in your media.

Over the lifetime of therapeutic development custom media can offer **SIGNIFICANT PRICE ADVANTAGES**. Reductions in labor, time sourcing as well as bulk component purchases decrease costs.

ESTIMATED COST: **HIGH** COMMERCIAL VOLUME

CUSTOM **\$13M**



OFF-THE-SHELF **\$21M**

**5000** PATIENTS **14L** PER PATIENT



EFFECTIVE CELL AND GENE THERAPY STARTS WITH **INTELLIGENT MEDIA**

Finally, an effective custom media that improves performance and consistency begins with **EXPERTISE IN FORMULATION**. Nucleus Biologics has developed innovative systems to facilitate streamlined formulation, customization, and fulfillment of custom media. Formulation can be performed automatically in minutes using proprietary **AIDRIVEN ALGORITHMS** or through **GUIDED SERVICES** employing the expertise of our inhouse R&D team.

For more information about our products and services please visit [nucleusbiologics.com](https://nucleusbiologics.com) or email [info@nucleusbiologics.com](mailto:info@nucleusbiologics.com)



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