

Formulation Services



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Comprehensive Guided Media Formulation and Optimization

Custom media can be a competitive advantage in your program development. Led by scientists with training and practical laboratory experience in cell culture media development, Nucleus Biologics provides rapid, comprehensive, and cost-effective solutions for the development of complex media formulations. Leverage our team of expert cell media scientists to develop, refine, and deliver a complete formula tailor-made to your specifications that will scale with your program. A concierge approach to custom media design.

Proven Expertise

Expert formulation scientists with years of experience in the design of cell culture media for numerous specialized cell types.

Full-Service Development

Rely on our team to develop an optimized formula or refine your current formulation with options to manufacture for scale-up.

Optimized Media

Receive a formulation designed specifically for your cell type that targets your desired attributes, all while remaining your IP.

The Nucleus Advantage

Media Ownership

You are no longer beholden to large media manufacturers to support your development. With ownership comes the assurance that your media is always produced to consistent specifications.

GMP Manufacturing

Our scientists always design formulations with GMP in mind, which will ease your transition to market. Media is manufactured in facilities using GMP guidance and in compliance to ISO 13485:2016 to meet the highest standards for quality, performance, and reliability.

Built for Scale-up

Proper planning and well-thought-out media design are critical to success. Bypass obstacles as you scale by developing your media with regulatory guidelines and appropriate quality controls in mind. Additionally, our GMP manufacturing facility can support production of media from 2L - 2,000L.

State-Of-The-Art Facilities

Our facilities feature state-of-the-art cleanrooms and instruments and have the capacity to manufacture 2.5 million liters of liquid and powder media per year to support the development of your discovery.

Better Media, Better Outcomes

Specialized Formulations Achieve Optimal Performance

An optimized cell culture medium can maximize cell performance, bring consistency and reproducibility of results, and drive program success. It has been shown that changing even one component in your media can significantly enhance cell function. Our formulation services have helped develop media to improve a number of aspects, including yield, transduction efficiency, cytotoxicity, etc. We can also help you retake control of your media by developing a formula you own that can perform as good as or even better than your current off-the-shelf media.

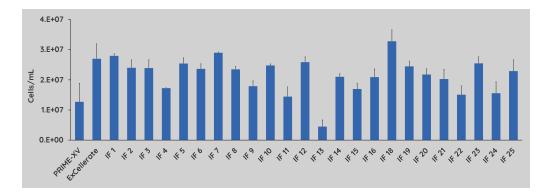


Chart is representative data of multiple tested formula that show proliferation level equivalent or better than the controls (PRIME-XV and ExCellerate™).

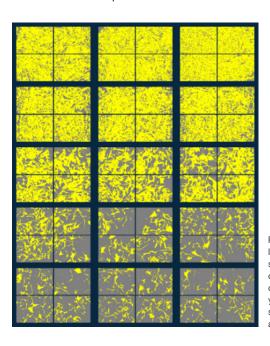
Define What's in Your Media Because Single Components Matter

Cell culture media is a complex mixture of salts, sugars, amino acids, vitamins, minerals, and proteins that drive cell viability and performance by properly mimicking optimized physiological conditions. We begin most projects by analyzing which combination of these components are needed to drive optimal outcomes for your desired CQAs. We employ cutting-edge tools to evaluate the growth needs of your cells in order to define the perfect mixture of components and the exact concentrations in order to generate an optimal panel of formulations to test with your model.

DL-Alanyl-DL-Glutamine DL-Alanine DL-B-Alanine DL-Arginine DL-Asparagine DL-Aspartic acid Thiamine Pyridoxine Pyridoxal Choline DL-Citrulline DL-Cystine γ-Aminobutyric acid DL-Glutamine 2 DL-Glutamic acid DL-Glu and DL-Gln Glycine DL-Histidine DL-Hydroxyproline DL-Isoleucine DL-Leucine DL-1-Methylhistidine DL-Methionine Nicotinamide DL-Phenylalanine DL-Proline Sarcosine DL-Serine DL-Threonine DL-Tryptophan Representative **DL-Tyrosine** o amino acids and DL-Valing vitamin B analysis generated by LC-MS/MS analysis.

Optimized to Your Critical Quality Attributes per Your Downstream Requirements

To test candidate formulations, we employ an array of cell culturing techniques to assess formulation impacts on desired CQAs. Instrumentation such as the Incucyte® allows us to assess cell growth and viability in real-time. In addition, genetic or protein expression kinetics provide valuable information that can guide component decisions. Finally, we are able to assess and compare the incorporation of plant, xeno-free, and even chemically-defined components and formulations to streamline downstream regulatory steps in preparation for GMP scale-up.



Representative Incucyte data showing adherent cells and confluence; quantified with a yellow mask that selectively covers adherent cells

Complete Media Design and Optimization

Media From Design to Delivery

Focus on other goals while our qualified scientific team develops your formula and process from start to finish, then delivers a complete medium designed to meet your defined criteria.

Benefits of our expert-guided formulation services:

- Successful media development for a variety of cell types and cell lines
- Extensive expertise in animal- and serumfree formulations
- Access to cutting-edge analysis tools for data-driven insights
- Average time to media production is 9-16
- Scalable process to ensure seamless transition to commercial manufacturing
- In-house media manufacturing operating under ISO 13485 to take your media from RUO to GMP
- Comprehensive suite of GMP services designed to streamline regulatory and get you to market faster

Step 01

Define Inputs



- Cell type and critical components
- Current protocols, assays, and controls
- Desired CQAs to address

Step 02

Tech Transfer



- Current media formulations
- Current protocols, assays, and equipment
- Biological materials

Step 03

Measure



- Run compositional analysis of current media
- Review existing literature for candidate compounds based on cell type and CQAs

Step 04

Identifu



- Define media configurations and conditions for testing
- Establish small-scale protocols for screening to address desired outputs

Step 05

Experiment and Analyze



- · Perform cell culture assays that align with CQAs
- Perform analytical testing
- Assess data based on established CQA benchmarks

Step 06

Improve, Refine, Reiterate



- Modify/refine formulations based on CQA data obtained
- Iterate experiments to optimize CQAs
- · Report out data and discuss results with customer

Step 07

Deliver



- Deliver all details of 2-3 candidate formulations—your IP
- Option to load and save formulations on NB-Lux
- Instantly order and manufacture at Nucleus Biologics

