



# GMP Services

Services to Support Your Media Needs  
From Design to Commercialization



The Cell Performance Company™

# GMP Services

## Facilitating an Expedited Path to Commercialization

Consistent, GMP-compliant raw materials are crucial as you transition to the clinic. Prepare your cell culture media and critical laboratory solutions for regulatory approvals, scale-up, and downstream manufacturing. With a comprehensive services offering, we can support and expedite your transition from development to commercialization.

### Robust QMS

Products and services are governed by strict adherence to an ISO 13485:2016-certified quality system and GMP guidelines.

### Complete GMP Solution

Formulate, test, qualify, validate, and manufacture GMP media and other critical lab solutions — a true end-to-end solution.

### Proven Expertise

Receive top-quality support from trained scientists with years of experience in cell culture and the production of liquid laboratory solutions.

## Committed to Your Project Goals and Success

### State-Of-The-Art Facilities

Our state-of-the-art facilities feature multiple manufacturing sites to support your cell culture needs. Our facilities contain over 7,000 square feet of manufacturing space and are outfitted with a total of 7 cleanrooms to produce liquid and powder media.

### Service Menu

Our robust, defined menu of services is designed to specifically expedite and streamline the most common challenges in testing, qualification, validation, and regulatory considerations that require GMP-quality methods and procedures.

### Project Management

With a dedicated project manager, we provide a structured and transparent process with regular updates, fast communication, and detailed scopes of work specific to your requirements.

### Flexible Solutions

Often, the best items are actually off-menu. With years of expertise in producing GMP-quality laboratory liquids, we can help with almost any project. Bring your requests to us and get a specialized scope of work uniquely crafted for your project and needs.

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## Process Development

### Accelerate Scale-up and Scale-out

Accelerate your development and path to manufacturing with our Process Development Services. Our solutions support full-scale GMP manufacturing and compliance with global regulation:

- Raw material testing
- Filter scale-up work
- Shelf-life studies
- And more!

## Qualification and Validation

### Ensure Your Products Meet Quality Demands

Our team of experts can help set you up for success. We can assist with a number of integral qualification and validation processes related to the production and delivery of your product including:

- Establishing fill protocols
- Validation of shipping conditions
- And more!

## Quality and Regulatory

### Streamline and Accelerate Regulatory Compliance

Ensure quality throughout the development and manufacturing process with our Quality and Regulatory Services. Our solutions to help simplify your regulatory processes include:

- Creating manufacturing protocols
- Generating test methods
- Producing batch record documentation
- And more!

### Expert-Guided Formulation Services

Formulation of a cell culture media designed specifically to meet your critical attributes should be the first step in your journey to an efficacious GMP therapeutic. At Nucleus Biologics, we are experts in creating media with the qualities important to your cell culture. Leverage our team of scientists to develop, refine, and deliver a complete formula tailor-made to your specifications that will support your GMP scale-up.



## State-Of-The-Art Facilities

With multiple manufacturing facilities, we provide a vertically integrated solution from powder processing to complete liquid media manufacturing. Our products are manufactured under GMP conditions and governed by strict adherence to an ISO 13485:2016-certified quality system.

- Over 7,000 square feet of manufacturing space
- Segregated GMP, animal-cell free (ACF) manufacturing
- 2.5-million-liter annual capacity
- Five ISO 7 cleanrooms
- Two ISO 8 powder cleanrooms
- WFI spec water system with ozone generation system
- XiltriX environmental monitoring system
- Powder milling and blending



### Our Commitment to Quality

- Certificate of Compliance or Certificate of Analysis provided at delivery
- Manufactured in a GMP environment
- Manufacturing practices certified to ISO 13485:2016