

TISSUE CULTURE RELATED CUSTOM MANUFACTURING & LABORATORY SERVICES



Cell culture media and production capacity are closely interdependent. Therefore, in addition to our ready-to-use standard cell culture related products we offer our clients custom manufacturing and media optimization services. We have entered into agreements with various industrial customers for cooperation in the optimization of specific formulations for specific cell lines and technologies. One specific area of ours is custom manufacturing service focusing on Animal Components - Free (ACF) chemically defined media optimization. Recently BI successfully completed a custom oriented project for the development of ACF media for Vero cells for a large industrial customer in the vaccine area. Currently, for the same customer, we are completing the development of specific auxiliary reagents as a continuation of this project. We believe that our accumulated know-how for a wide range of ACF and SFM products serves as a basis for starting collaboration and media optimization, and to scale up services for any cell lines requested by the customer

Biological Industries (BI) specializes in the preparation of custom media according to the exact formulations and specifications for research in academia and industry. With more than twenty-five years of experience and an impressive reputation for quality, we can provide

- Low volume to large scale production
- Rapid turn-around time
- Easy order/re-order process

All liquid media can be formulated from single-strength; two-fold and five to ten-fold concentrations to meet your special needs and requirements. Each lot undergoes strict and vigorous Quality Control Protocols to verify compliance with the product's specifications

As a part of our fully integrated approach to cell culture related applications, our customer services have become a unique client-oriented application. We offer client-oriented confidential development, material transfer and optimization support for industrial customers

Manufacturing Capabilities

- Liquid formulations: batch sizes from 6 to 1000 liters
- Customized packaging configurations- flexible packaging
- Consistency in small and large batches
- Expertise in SF and ACF media optimization per cell line
- Flexible product delivery
- Worldwide shipping and logistics capabilities

Manufacturing Facilities

- State-of-the-art clean room facilities.
- Animal origin materials from raw materials sourced only in BSE and FMD- free countries produced in a separate clean air facility.
- Autoclave, ultrafiltration, lyophilization, tissue culture, aseptic filling equipment
- Purified water (RO)

QA System Support

- Ongoing technical support
- Raw material supplier qualifications
 1. Elaboration of manufacturing and control SOPs
 2. Validated SOP for gamma irradiation
- Regular media fill
- BI is ISO 13485:2003 certified, a more specific supplement to ISO 9001, which includes medical device requirements relating to: design controls, process controls, special processes, traceability, record retention, and regulatory actions. Please see appendix for our regulatory certifications.

Laboratories Services (QC)

Test	Reference Standard
Sterility test	
Biological Reactivity Test (cytotoxicity)- in-vitro (See chapter 15 – Cell Proliferation Kit)	Current USP
Tests for cytotoxicity: in-vitro methods (See chapter 15 – Cell Proliferation)	(71) Current
Bacterial endotoxins (LAL reagent), kinetic turbidimetric method	USP (87) ISO

Customized Media

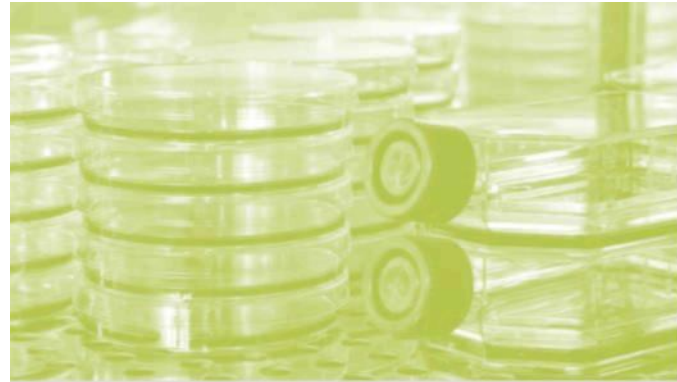
Custom Formulations

Biological Industries specializes in the preparation of custom media according to the customer's exact formulations and specifications. This service is provided both to industrial and laboratory customers. Our Custom-Formulated Media include:

- Balanced Salt Solutions
- Basal Media
- Complex Media
- Serum-Free Media
- Insect Cell Culture Media
- Plant Cell Media
- Powdered Media

BIOLOGICAL
INDUSTRIES

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The minimum quantity required for laboratories is only 12x500ml or 40x100ml. We can provide any media product in sterile bags of various sizes. We supply Sartorius-Stedim bags, but can fill any other type of bag provided by the customer

Liquid Media

- Short supply time: 2-3 weeks
- Lots from 6 liters to 1000 liters
- Single strength (1x), Two fold (2x), Five fold (5x) and Ten fold (10x)
- Quality Controlled

Single-Strength Liquid Media

500ml size bottles	Minimum order of 12	or	100ml size bottles
bottles	Storage temperature 2-8°C		Minimum order of 40 bottles

Two-Fold Concentration Media

500ml size bottles	Minimum order of 6	or	100ml size bottles
bottles	Storage temperature 2-8°C		Minimum order of 30 bottles

Five & Ten Fold Concentration Media

500ml size bottles		or	100ml size bottles
Minimum order of 6 bottles	Storage temperature 2-8°C		Minimum order of 30 bottles

Powdered Media

- Supply time: 5-6 weeks
- Lots from 20 liters to 1000 liters
- Quality Controlled
- Package sizes available on request

We believe that the outsourcing of media optimization development and scale up is beneficial to bioprocess customers. Outsourced optimization services allow R&D customers to focus their technological resources on their core knowledge by eliminating the necessity to formulate media in-house and to invest in aseptic filling facilities and testing capabilities

Price quotations for all of the above services are available upon request.

