

Gibco custom media and buffers request form

Section 1: Customer information (required)

INSTRUCTIONS:

Company account number: This number is provided by your internal procurement team. The company account number is also known as your ship to account number or customer account number.

Shipping address: This is not required if you provide your company account number. Otherwise, please complete this section.

Company name:

Company account number:

Billing address:

Contact name:

Shipping address:

Contact phone:

Contact email:

Thermo Fisher Scientific account manager:

Form completed by (if different from contact name):

Section 2: Request type (required)

INSTRUCTIONS:

Request type refers to whether you require a quote, an order, or another miscellaneous requirement (e.g., stability study, specification review).

Custom formulation type: This field refers to whether your formulation is a repeat formulation with no changes, a repeat formulation with changes, or a newly created, first-time formulation.

Prior quote (reference) number: This field is required for repeat requests.

Shipping and delivery requirements: This field is provided to capture specific shipment and delivery requirements. Examples include temperature specifications, type of containers, travel method required, etc.

Price expectation: Please enter information that should be taken into consideration for pricing (e.g., expected unit prices).

Request type:

Reference Cat. No.

Prior quote (reference number):

Custom formulation type:

Requested delivery date:
(dd-mm-yyyy)

Ordering channel:

Price expectation:

Currency

Shipping and delivery requirements:

Standard shipping: Life Technologies Corporation, part of Thermo Fisher Scientific (“Thermo Fisher Scientific”) ships products at ambient temperature by road, air, and ocean where applicable to reduce costs, packing, and environmental waste. Our preferred Incoterms™ rules are Ex Works or FCA shipping point. Other feasible shipping methods are available upon request and subject to additional fees. Please discuss with your account manager.

Section 3: Product information and customization type (required)

INSTRUCTIONS:

Manufacturing: Gibco™ custom products are manufactured in cGMP-compliant facilities registered with the FDA as manufacturers of medical devices, which are and certified to the ISO 13485 standard. Products manufactured using the Gibco™ Media Express™ service offer Gibco™ quality custom media without the time constraints of cGMP documentation. The purpose of this non-cGMP lab is to provide our customers with small volumes of media, much faster than in our cGMP lab, at a discounted set price to allow customers to test various formulations. To meet our low price and quick turnaround time guarantee, we are unable to provide product documentation and QC testing that would come standard in a cGMP order. Further, although we use the same raw materials and processes as in the cGMP lab, we are unable to perform technical support or corrective and preventative action on products produced within this lab.

Product use restrictions: Gibco™ Custom Media and Process Liquids products are for use only in laboratory research or for further manufacturing. Products have not been qualified for use directly in animals, for diagnostic or therapeutic applications, or used directly in humans for any purpose. Uses other than the labeled intended use (e.g., Research Use Only, 'further manufacturing', etc.) may require further evaluation. We reserve the right to accept or decline an order based on the customer's intended use.

Product use classification:

Manufacturing process:

Product format:

If choice for "Product use classification" is "other" please elaborate here:

Yes No Are you the end user for this product?

Yes No Will you be reselling this product as a stand-alone product or as a component of a kit?

Product description (include concentration for liquid formats and reconstitution instructions for powder formats):

Customization type:

Yes No BioProcess Container (BPC) customization required (e.g., different bag film type, port locations, line sets, and end treatments).
Please discuss customized packaging requirements with your account manager.

Yes No Is there the potential to make this product in the Grand Island Large Volume Liquid (LVL) (AOF) facility?

Yes No Do you have the requirement to validate the Grand Island Large Volume Liquid (LVL) (AOF) facility?

Product, BPC, and packaging customization notes:

Section 4: Batch volume and pack sizes (required)

INSTRUCTIONS:

Each batch represents a single lot. You may request up to three batches using this form. Please include all sample, pack size, and volume fill requirements for each batch. **Note:** A single lot can include multiple pack sizes. This is called a consolidated batch.

Batch ranges	Paisley, UK	Grand Island, US	
		cGMP	Non-cGMP
Liquid AO	10–5,000 L	10–2,500 L	1–200 L
Liquid AOF	50–10,000 L	1,900–5,000 L	N/A
		5,000 L–10,000 L	N/A
Powder (AO)	1–4,400 kg	1–8 kg	1–10 kg
		20–100 kg	
		250–750 kg	
		1,500–3,500 kg	
AGT	50–1,500 kg	50–6,000 kg	1–8 kg
Powder (AOF)	50–1,500 kg	20–6,000 kg	N/A
Grand Island LVL facility		750–9,700 L	N/A

Batch 1—please include all sample and pack size requirements.

Quantity: Unit size fill volume: Liquid packaging: Powder and AGT packaging: Total volume:

Batch 1 notes:

Section 4: Batch volume and pack sizes (required), continued

Batch 2—please include all sample and pack size requirements.

Quantity:	Unit size fill volume:	Liquid packaging:	Powder and AGT packaging:	Total volume:
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Batch 2 notes:

Batch 3—please include all sample and pack size requirements.

Quantity:	Unit size fill volume:	Liquid packaging:	Powder and AGT packaging:	Total volume:
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Batch 3 notes:

Section 5: Formulation modifications (for complex changes, please include a separate document)

INSTRUCTIONS:

Formulation modifications: Use this section to capture your formulation modifications (add or remove components, change in concentrations).

UOM: UOM stands for unit of measure required for each component.

CAS Registry No.: A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature. Please include for buffer requests if known.

Change type:	Comp. ID:	Component description:	Qty:	UOM:	Grade:	Animal derived:	CAS Registry No.
1.							
2.							
3.							
4.							
5.							

Molecular weight:	Supplier name:	Supplier part:	Additional notes or requirements:
1.			
2.			
3.			
4.			
5.			

Formulation modification notes:

Section 6: QC testing

INSTRUCTIONS:

Same testing as Cat. No.: available for cGMP only. Use when you want the same testing as the Cat. No. you are modifying or a prior custom Cat. No. ordered. A separate Cat. No. field is provided to capture the catalog or custom Cat. No.

Cat. No.: If clicked yes for same testing, enter in the Cat. No.

Additional tests: Would require additional quote/costs.

QC testing notes: Include any required specification limits.

cGMP testing: Includes pH, osmolality, and sterility for liquid formats, or pH, osmolality, and solubility for powder formats. Includes a standard certificate of analysis (CoA).

Non-cGMP testing: Limited Gibco Media Express testing is available for a fee (e.g., pH, osmolality, sterility, or endotoxin for liquid formats, or pH, osmolality, solubility, or endotoxin for powder formats). Test results are provided without a CoA.

Standard cGMP testing and CoA

Standard non-cGMP testing

Same testing as Cat. No.—please provide Cat. No.

Additional testing

Amino acids

Gas chromatography

pH

Appearance

Glucose

Solubility

Bacterial/fungal screen (sterility)—liquids only

Loss on drying—powders only

Water by Karl Fischer—powders only

Bioburden—powders only

Mycoplasma

Water-soluble vitamins

Conductivity

Osmolality

Other (please specify)

Endotoxin

Performance test applicable for product

QC testing notes:

Section 7: Labeling and documentation

Design my label for me

Custom labeling required (requires label agreement)

Shelf life: The shelf life of this product has not been determined. It is the responsibility of the end user to determine an appropriate shelf life. If requested, shelf life is given as a guide and is not guaranteed by Thermo Fisher Scientific. Please attach stability information if expiration date is required.

Labeling and documentation notes:

Additional notes:

Please email custommedia@thermofisher.com with your request.

All orders made following this request are subject to confirmation of final requirements and related feasibility review, and are also subject to **LIFE TECHNOLOGIES GENERAL CONDITIONS OF SALE** available at thermofisher.com/termsandconditions and **SUPPLEMENTARY TERMS-BIOPRODUCTION PRODUCT TERMS AND CONDITIONS** available at thermofisher.com/content/dam/lifetech/documents/pdfs/bioproduction-product-terms-and-conditions.pdf or upon request. Thank you for choosing Gibco™ custom products.

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