

# Your dedicated partner in bioprocessing bulk liquids

Complete solutions for more control, choice, and confidence



## Our commitment to your process

For over 50 years, production facilities have turned to our trusted Gibco™ media, feeds, buffers, and bioprocessing liquids to enhance product performance. Our products are designed to meet your specifications, including flexible BioProcess Containers (BPCs) in the size of your choice. By combining our standard and custom products with our worldwide supply chain distribution centers—for example, through the Doe & Ingalls\* logistics program—we can offer you superior solutions for your process with the continuity of having one consistent supply partner.

\* Available in North America.



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## More offerings for more choice and control

Meet the challenges of your most demanding applications with formats, formulations, films, BPCs, and packaging designed to support a broad spectrum of bioproduction needs.

#### **Format**

- 1x liquid
- Concentrate technology\*

#### **Formulation**

- Custom formulations
- Customer-owned formulations (OEMs)
- Catalog formulations (specific changes can be requested)

#### **Films**

- Thermo Scientific<sup>™</sup> Aegis<sup>™</sup> 5-14 film—for high-value applications
- Thermo Scientific™ CX5-14 film—one of the most widely used films in the industry, proven for over 10 years
- Thermo Scientific<sup>™</sup> ASI<sup>™</sup> 26/77 film—a two-layered film for high-value applications, proven for over 10 years
- Continuing to support legacy films (9101, BF1400, etc.)
- Customer-specified films
- \* Not available in Paisley, Scotland.



#### Thermo Scientific™ BioProcess Containers (BPCs)

- Standard BPC offerings: 1 L, 5 L, 10 L, 20 L, 50 L, 100 L, 200 L, 500 L, and 1,000 L (50–1,000 L all have top and bottom drain options)
- Custom configured BPCs, including choice of ports, connectors, filters, and other components from an extensive component library
- Common solvent extractables report available upon request

#### **Secondary packaging**

- Variety of sizes and configurations for outer shipping containers
  - UN-rated drums for hazardous distribution
  - Fiber or plastic corrugated shipping boxes from 1 to 20 L
  - Top- and bottom-drain plastic drums from 50 to 200 L
  - Returnable pallet containers from 500 to 1,000 L (50–200 L sizes also available from Paisley, Scotland site only)
- Find out more about our liquid media packaging at thermofisher.com/liquidmediapackaging

## One supplier, countless solutions

### Choose from our comprehensive catalog

Meet your bioproduction needs with a wide range of proven products, from best-in-class buffers and bioprocessing liquids (Figure 1) to time-tested Gibco™ media.

- Gibco<sup>™</sup> Water For Injection (WFI) for Cell Culture
- Gibco™ Dynamis™ Medium
- Gibco<sup>™</sup> CD OptiCHO<sup>™</sup> Medium
- Gibco<sup>™</sup> CD CHO Medium
- Gibco™ CHO CD EfficientFeed™ A Liquid Nutrient Supplement
- Gibco™ CHO CD EfficientFeed™ B Liquid Nutrient Supplement
- Gibco™ FunctionMAX™ TiterEnhancer
- Common and custom buffers

## Boost your bioprocessing with custom capabilities

Optimize feasibility, scalability, and reproducibility with extensive services that can be tailored to suit your workflow.

- Custom BPC engineering—sizes, films, components library, and secondary packaging
- Formulation—catalog or custom specification
- Prototyping—early development and formulation prior to scale-up
- Manufacturing—Gibco™ Media Express (GME) and cGMP
- Gibco™ bioproduction services technical consultation
- Custom labeling and documentation
- Custom solutions for storage and global distribution
- Multi-compendial raw material library

## Buffers and bioprocessing liquids\*

Acetic acid

Citrate buffer

**EDTA** 

Ethanol\*\*

Glucose/sucrose

Glycine

HEPES/MOPS

Histidine

Hydrochloric acid\*\*

PBS/DPBS

Sodium bicarbonate

Sodium chloride

Sodium citrate

Sodium hydroxide

Sodium phosphate

Tris/bis-tris

WFI

Figure 1. Examples of common buffer and bulk process liquids.

<sup>\*</sup> List is not comprehensive for all capabilities.

<sup>\*\*</sup> Grand Island, NY, USA site only.

### Manufactured for excellence

Trust our worldwide commitment to enabling the utmost confidence in your supply.

## Our global reach helps ensure the quality and availability of supply

- 5 manufacturing sites worldwide: Grand Island, NY; Paisley, Scotland; Logan, UT; Millersburg, PA; Cramlington, UK
- Over 8 million L of products manufactured per year to meet customer demand
- Accurate customer-demand forecasting ability helps maintain lead times
- Continual process improvement initiatives help increase efficiency
- Our facilities operate in compliance with ISO and cGMP guidelines, and our large-volume liquid facility in Grand Island, NY was built to comply with EudraLex Volume 4, Annex 1, Manufacture of Sterile Medicinal Products guidelines

# Equipment—we're continually expanding our liquid capabilities for both animal origin (AO) and animal origin–free (AOF) requests, offering:

- Batch sizes from 10 L to 10,000 L
- Ability to manufacture corrosive solutions and alcohol-containing solutions at our Grand Island, NY site

## BPCs—we put our BPC products to the test

 Our BPC products are tested against industry physical and biochemical standards to ensure the flexible container will maintain product integrity and performance

#### More confidence, fewer risks

#### Supplier qualification

Thermo Fisher Scientific has established a low-risk supply chain to meet demand, with maximum transparency, and minimal variability. Suppliers and raw materials are selected based on several criteria, including completion of a technical questionnaire, audit, and successful specifications testing of multiple lots.

## Continuous risk management is performed through a risk-scoring matrix—suppliers are categorized based on their individually assessed risk:

- Approved: successfully meets audit and testing criteria, as well as having strong historical performance
- Under evaluation: supply challenges have been encountered, and we're working with the supplier to rectify
- Discontinued: supplier discontinues the product or Thermo Fisher chooses not to use

#### **Customer harmonization program**

We have created and implemented a customerexperience program incorporating five workflows. Each workflow consists of a series of steps designed to deliver an improved and harmonized customer experience.

- Inquiry to quote
- Approval packet preparation
- Order transparency
- Order execution
- Customer experience



#### Logan, UT

- BPCs
- Single-use technologies
- Class 10,000/ISO 7 clean room



#### Millersburg, PA

- BPCs
- Single-use technologies
- ISO 13485
- FDA-registered

#### Raw materials low-inventory alert program

A GMP-validated management execution system is used in production to prevent formulation errors. The production environment controls dispense accuracy to 0.1% variability and ensures retrospective traceability.

#### **Finished product QC testing**

Our QC department offers the following finished product testing options:

- pH
- Conductivity
- Bacterial/fungal screen (sterility)
- Amino acid analysis
- Appearance
- Glucose
- Mycoplasma

- Water-soluble vitamins
- Osmolality
- Endotoxin
- Performance test (when applicable)
- Range of compendial compliant assays available
- Programs to develop testing and can validate custom assays



#### Grand Island, NY

- Cell culture media, regents
- Sera
- ISO 13485
- FDA-registered
- Annex 1 environment



#### Cramlington, UK

- BPCs
- Class 10,000/ISO 7 clean room



#### Paisley, Scotland

- Cell culture media, reagents
- ISO 13485
- FDA-registered

## Real-time stability program: custom formulation testing available

Our most thorough testing program is available to customers who require extensive testing of products, including custom formulations, as well as detailed catalog stability data.

We provide frequent and thorough product stability testing (Figure 2).

#### Quality you can rely on

Our quality department supports over 100 customer audits and technical visits per year between our Grand Island and Paisley facilities.

#### **Expert support, every step of the way**

## Gibco™ BioProduction Services and field application specialists

Optimize your manufacturing workflow with expert process-development strategies. Our global team of highly experienced consultants and scientists will work with you to create customized solutions for any bioproduction challenge.

#### Program management office (PMO) services

Our program management specialists are ready to provide guidance and technical expertise at each stage of your project. Your dedicated PMO team is available to provide order status updates, information on product applications, and tailored support.



Process liquid stability data													
Product description (Concentration)	Storage conditions	Duration	Stability tests										
			Appearance	Conductivity	Endotoxin	Normality	Osmolality	Hd	Sterility	Glucose	Glycine	Nitrate	Total organic carbon
Sodium hydroxide (3 M)	15–30°C	0 mo 3 mo 6 mo 12 mo	\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}	√ √ √	✓	\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}				
<b>EDTA</b> (0.5 M)	15–30°C	0 mo 3 mo 6 mo 12 mo	\( \sqrt{1} \)		\frac{1}{\sqrt{1}}			\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}				
Glucose (50%)	15–30°C	0 mo 3 mo 6 mo 12 mo	\frac{1}{\sqrt{1}}		\ \(  \)		✓	\ \(  \)	\ \(  \)	\ \(  \)			
<b>PBS</b> (10x)	15–30°C	0 mo 3 mo 6 mo 12 mo	\frac{1}{\sqrt{1}}				✓ 	\frac{1}{\sqrt{1}}	\ \(  \)				
Tris (20 mM) NaCl (1.5 M)	15–30°C	0 mo 3 mo 6 mo 12 mo	\( \sqrt{1} \)	\ \(  \)	√ 		√	\frac{1}{}	\frac{1}{\sqrt{1}}				
Glycine (100 mM)	15–30°C	0 mo 3 mo 6 mo 12 mo	\frac{1}{\sqrt{1}}	\ \(  \)	\ \(  \)		✓ 	\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}		\(  \)		
WFI quality water	15–30°C	0 mo 3 mo 6 mo 12 mo	\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}	✓		1	\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}			\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}
MES (50 mM) NaCl (200 mM)	2-8°C	0 mo 3 mo 6 mo 12 mo	\( \sqrt{1} \)	\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}			\frac{1}{\sqrt{1}}	\frac{1}{\sqrt{1}}				

Figure 2. Frequency and parameters of stability testing and product output.

## We're with you every step of the way

Find industry-leading solutions across the entire workflow

You don't need to work with multiple vendors to get what you need. With applications that span the drug development process—from drug discovery through large-scale commercial production—we'll be your single source for a broad range of solutions.



Cell line development and media optimization



Mixing, cell culture, and fermentation



Harvest and collection



QC and analytics







CHO cell lines



Analytical services



Media optimization services



Cell culture media, feeds, and enhancers



Single-use fermentors, bioreactors, mixers



BPCs



Integrity testing solutions



Single-use heat exchanger



Large volume liquids



Harvest and separation products



**BPCs** 



Single-use heat exchanger



Single-use aseptic sampling system



#### **Purification**







QC and analytics



Analytical columns



Automation solutions for nucleic acid sample preparation



Chromatography resins



Affinity ligands and resins



Transfer assemblies



Host cell DNA, host cell protein, and protein A quantitation



Large volume liquids



Single-use mixers



Storage and transport



Single-use BPCs, manifolds, and containers



Single-use fermentors, bioreactors, mixers



Single-use filling system



Single-use frozen handling system



In the complex world of biotherapeutics manufacturing, you need a partner who can meet any demand with consistent supply. That's why we're dedicated to providing you with integrated solutions for all of your core operations, from upstream cell culture to downstream purification.

#### More locations to serve your needs

Access high-quality solutions and expert support services from any of our global facilities.

For a free technical consultation or a complimentary product sample, call 800-955-6288 or email us at gibcoservices@thermofisher.com

#### Grand Island, New York

United States of America +(1) 800-955-6288 custommedia@thermofisher.com

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Find out more at thermofisher.com/bioprocessliquids

