



# Bulk process liquids for bioproduction

Capabilities and catalog



A dynamic background image featuring a large splash of water in shades of blue and white. The water is captured in mid-air, with numerous droplets and bubbles visible, creating a sense of movement and freshness. The overall color palette is a range of blues, from light sky blue to deep, dark navy tones.

## One-stop solution for your bioproduction needs

Bioproduction is a rapidly changing market with many challenges. Since manufacturing processes can vary widely, it takes an experienced, technologically exceptional partner to anticipate potential needs of manufacturers and to offer flexible options, especially for companies who are looking to outsource. To address these requirements, Thermo Fisher Scientific has developed a broad portfolio of bioprocessing liquids and containers, both standard and customized, to provide a high level of quality for your workflows.

A vertical decorative image on the left side of the page showing a dynamic splash of water with various sized bubbles and droplets against a light blue background.

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# Introduction

For over 50 years, bioproduction facilities have turned to our trusted Gibco™ media, feeds, buffers, and bioprocessing liquids to enhance cell culture and product performance. By combining our standard and custom products with our worldwide supply chain distribution centers, we can offer superior solutions for your process with the continuity of having one consistent supply partner.

Recent trends in bioprocessing have shown a shift from powdered culture media and buffers, to fully finished bulk liquids. End users have found that liquid culture media purchased from an outside supplier tends to perform better than media mixed in-house from powder or other concentrates. In addition, liquid media manufacturers have far greater control over their product, and that helps you achieve higher product consistency and quality [1]. We provide this expertise to help you streamline your bioproduction workflow. In addition, the capital investment needed for state-of-the-art mixing equipment, new capabilities, and continual process improvement can be cost-prohibitive for smaller operations; partnering with us helps to reduce those costs to you and provides you with a strategic advantage. The value is increased even further during early product formulation when chemical consistency is paramount, or when conducting business in developing countries where facilities that are compliant with current good manufacturing practices (cGMP) may not yet exist [2].

Bulk process liquids and buffers increase biopharmaceutical process efficiency and reduce risk by simplifying and standardizing workflows.

## Features

- Manufacturing capacity
- Cold warehouse space and distribution
- Support resources
- Process optimization

## Benefits

- Manufacturing extension
- Lot-to-lot consistency
- Dependability
- Ability to forecast costs
- Access to our resources
- Cost and time savings
- Elimination of time- and labor-intensive steps



1. Langer ES. Outsourcing Media and Buffer Prep. Contract Pharma. 2014. [https://www.contractpharma.com/issues/2014-09-01/view\\_bio-news-amp-views/outsourcing-media-and-buffer-prep](https://www.contractpharma.com/issues/2014-09-01/view_bio-news-amp-views/outsourcing-media-and-buffer-prep) (Accessed January 2019)
2. Rader A, Langer E. Powders and Bulk Liquids. BioProcess International. 2014. <http://www.bioprocessintl.com/upstream-processing/biochemicals-raw-materials/powders-and-bulk-liquids-350510/4> (Accessed December 2017)

## Liquid products for upstream and downstream bioprocessing that meet your bulk liquid applications

Multiple buffers and solutions are needed throughout the workflow. We offer products to support every step.

### Upstream

- Hydration of media and feeds
- Dilution and neutralization
- Cell culture
- Cleaning and sanitization

### Downstream

- Equilibration and flush for various steps
- Diafiltration
- Cleaning and sanitization
- Storage
- Dilution and neutralization
- Packing and column qualification
- Precharge
- Intermediate and secondary washes
- Elution

### Case study: 0.1 M sodium hydroxide

#### Situation

- Their demand increased, so they looked at ways to optimize

#### Process

- Evaluated their personnel and activities
- Determined that 10–20% of time was used to make caustics, a non-core activity
- Stored more than needed in warehouse

#### Success

- Freed FTEs to work on core activities
- Saved space in warehouse for their formulations
- Reduced overall testing
- Realized a significant cost savings

### Cost comparison

	In-house	Thermo Fisher Scientific
Batch size	2,000 L	10,000 L
Batches per year	20	4
QC releases	20	4
Prep time (2,000 L)	4 hours	1 hour
Total batch cost	\$11,500	\$35,000
Cost per liter	\$5.75	\$3.50
Annual prep time	10 days	2.5 days
Labor costs per year	\$230,000	\$140,000

Achieve high quality, dependability, and cost savings by collaborating with the industry leader in large-volume bioprocessing liquids



**\$90,000**  
annual savings



**75% reduction**  
in prep time



**80% reduction**  
in lot testing

# Facilities

With facilities all over the world, Thermo Fisher Scientific helps to ensure a dependable supply of materials to our bioprocessing clients. We've built in redundancies in our manufacturing sites to mitigate the risk of supply disruption, helping to provide you with continuity you can depend on.

## Assurance of supply

- Redundant manufacturing facilities
- Persistent facility and capability investment
- Supply chain and supplier development
- Multilevel safety stock management
- Continuous investment in business continuity planning

## Quality

- Robust, defined, and proven quality management systems
- Dedicated animal origin-free manufacturing capabilities
- Highly specific analytical methods to help reduce risk of contamination
- Testing of raw materials, and in-process and finished goods
- Fully integrated serum sourcing and manufacturing in country of origin

## Process control and improvement

- Documented and controlled manufacturing procedures
- Process validation and statistical process control (SPC)
- High-functioning process and continuous improvement (PPI)
- Formalized system for customer interactions and priorities



### Logan, UT

- BPCs
- Single-use technologies
- ISO 7 (Class 10,000)-certified cleanroom



### Millersburg, PA

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

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

- Liquid manufacturing sites
  - Grand Island, NY
  - Paisley, Scotland
- Single-use manufacturing sites
  - Logan, UT
  - Millersburg, PA
  - Cramlington, UK
- Over 8 million liters of products manufactured per year to meet customer demand
- Ability to accurately forecast customer demand 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, New York was built to comply with EudraLex Volume 4, Annex 1, Manufacture of Sterile Medicinal Products guidelines



### Grand Island, NY

- Cell culture media, reagents
- Sera
- ISO 13485–certified
- FDA-registered
- Annex 1 environment



### Cramlington, UK

- BPCs
- ISO 7 (Class 10,000)–certified cleanroom



### Paisley, Scotland

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

# Capabilities

With our broad range of liquids and containers, we're prepared to give you exactly the product you need for your bioprocessing application. Even if your needs change, we're flexible enough to change with them. Our goal is to develop a long-term partnership with you based on mutual trust and success.

## Proven history

- Extensive liquid handling experience
- Over 20 years of experience customizing single-use assemblies
- Serving over 130 commercial therapies worldwide

## Optimization for custom products by

- Application
- Specific operating parameters
- Qualified components
- Time and cost requirements

## Bulk liquid sourcing

The Gibco™ liquid production network provides a global supply of cell culture media and components from multiple facilities, so customers can benefit from redundant supply and regional sourcing.

## Liquid production network

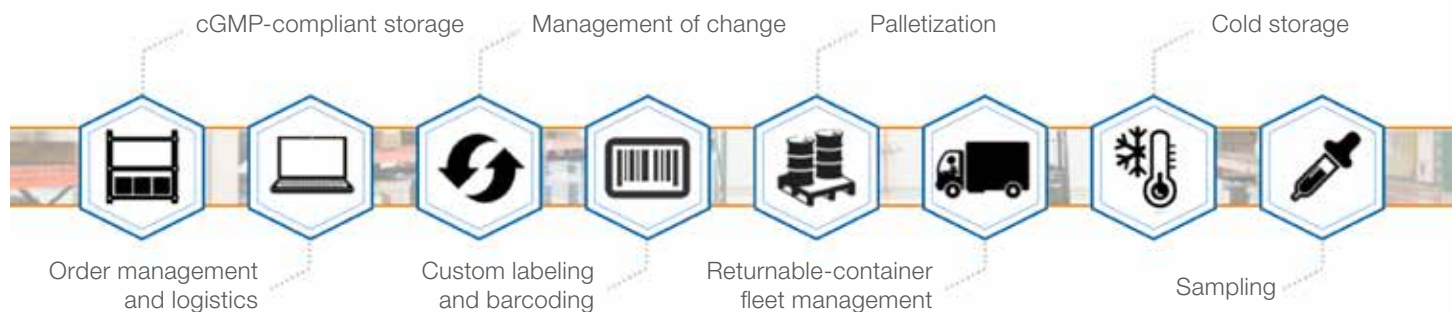
	Size	Grand Island, USA	Paisley, Scotland
Bottled liquids	10 mL–1 L	•	•
Bagged liquids	1–1,000 L	•	•
Batch sizes	10–10,000 L	•	•
Corrosive solutions	5,000 L polypropylene tank	•	
Alcohols (up to 20% v/v ethanol)	750–2,500 L	•	

## Supply chain excellence

If your organization does not have the infrastructure in place to manage the supply, storage, and logistics of your bulk liquids, we can help. Outsourcing these tasks to us can help you streamline your supply chain, thereby increasing productivity and reducing both long-term costs and the risk of supply interruption.

Let us become an extension of your supply chain:

- Mitigate risks
- Increase productivity
- Reduce costs





# Quality and stability

We're focused on meeting your current and future requirements for outsourcing bulk liquids with the utmost commitment to quality and compliance with cGMP standards.

## Quality you can rely on

Our quality department supports over 100 customer audits and technical visits per year between our Grand Island and Paisley locations. We encourage you to observe our high-quality systems and facilities in person, to give you the peace of mind that you are getting a superior product.

## Stringent vetting of suppliers

We have established a low-risk supply chain to meet the demands of our customers, 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. We also maintain supplier statements, which contain information on the species, tissue, and country of origin of any animal-derived substance, along with supplier information on purification or manufacturing steps that help reduce risk of adventitious animal-origin agents.

## Animal origin-free (AOF) products

We have made a significant investment by building an AOF manufacturing facility in Paisley, Scotland to create redundancy with our Grand Island location. This redundancy helps ensure that any disruption in supply that affects one of our locations can be mitigated by switching manufacturing to the other facility, thereby causing little to no disruption to customer deliveries and timelines.

## 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 stability data. We provide frequent and thorough product stability testing. Please see the table on pages 11–12 for details.

## Definitions

**Animal:** Includes eukaryotic organisms such as mammals (including humans), fish, birds, reptiles, amphibians, insects, mollusks, etc. Does not include eukaryotic organisms such as the higher plants, fungi, protozoa, and algae, or prokaryotic organisms such as bacteria or blue-green algae.

**Ruminant origin component:** Includes material derived from live, healthy animals of the suborder Ruminantia. Certificates of Suitability are required for qualification of supply.

**Animal origin component:** Includes material either directly derived from animal tissue, cells, body fluids, etc. (primary origin) or materials that employ animal-origin material in the manufacturing process (secondary origin). For a material to be considered of non-animal origin, it will not originate from or employ any materials in its manufacture that originate from animals described in the definition.

## Detailed documentation

### Certificate of Analysis (CoA)

We provide our customers with a CoA for all bulk liquids. The example shown here depicts information that may be found on your certificate. Requested customizations may alter the content. A sample of the CoA for a particular product and specification will be included with your quote as part of the documentation package. This sample will be representative of what you can expect to see once you have placed your order.

## Expert support, every step of the way

### Gibco™ BioProduction Services and field application specialists

Optimize your manufacturing workflow with professional 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.

**gibco** Certificate of Analysis

WFI for Cell Culture

Catalog Number: A12873  
Lot Number: 1900150  
Storage Temperature: 2 to 30C  
Expiration Date: 2020-02

Caution: For use as a raw material in further manufacturing applications.

TEST	SPECIFICATION	RESULT	UNITS
* Conductivity USP&P - Point of Fill	Passes Test	Passes Test	
* Endotoxin Testing	<=0.25	<0.03	EU/mL
* Nitrate	<=0.2	<0.2	PPM
* Osmolality	>=0.10 <=20	0	mOsm/kg
* pH	>=6.8 to <=7.5	5.8	
* Sterility Testing	Negative	Negative	
* Total Organic Carbon - Point of Fill	<=500	51	ppb

Notice: Effective 2016, the specification for this product has changed per ECR103244. Changes were made to identify Total Organic Carbon and Conductivity testing at point of fill, removal of JP (Japanese Pharmacopoeia) reference. If you have questions regarding this change, please contact Thermo Fisher Scientific Technical Support at 1-800-955-6288 in North America or [Techsupport@fisher.com](mailto:Techsupport@fisher.com) globally.

Read SDS.

Meets USP&P Monograph for Water for Injection in bulk at point of fill. "Point of fill" refers to sampling and testing for TOC and conductivity before the water is filtered and filled into final packaging.

Not intended for direct parenteral administration  
0.1 micron filtered.

Barbara J. Schuler  
Quality Systems Department Date: 08-Mar-2018

Page 1 of 2 Life Technologies Corporation  
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## Quality built into our newly expanded Grand Island facility

Design criterion	Value provided
ISO 13485	Internationally recognized standard on the requirements for a quality management system for medical devices
21 CFR Part 820 compliance	FDA cGMP quality system regulation for medical devices
Annex 1 standard	cGMP guidelines to harmonize US and EU controls and procedures to manufacture sterile medicinal products
Animal origin-free (AOF)	All raw materials are free of animal-derived components; dedicated AOF equipment
Grade C and grade D controlled spaces	Monitored and controlled temperature, pressure, and air change rate for formulation and filtration
Single material flow	One-way raw material flow with no return to inventory; dedicated animal origin (AO) and animal origin-free (AOF) raw materials for manufacturing
Proximity to raw material and finished-goods warehouse	Segregated AO and AOF raw material sampling booths; close proximity to manufacturing and distribution
Second-floor formulation	Gravity transfer to fill and filtration for ergonomic workflow; separate formulation suites for each tank
Manifold filling	Semi-automated, closed manifold system

## Frequency and parameters of stability testing and product output\*

Process liquid stability data														
Product description (concentration)	Storage conditions	Bioprocess container film	Duration	Stability tests										
				Appearance	Conductivity (mS/cm)	Endotoxin (EU/mL)	Normality (N)	Osmolality (mOsm/kg)	pH	Sterility	Amino acid (quantitative)	Nitrate (ppm)	Total organic carbon (ppb)	
Sodium hydroxide (3 M)	15–30°C	CX5-14	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
			12 mo	•	•	•	•	•	•	•	•	•		
			18 mo	•	•	•	•	•	•	•	•	•		
		24 mo	•	•	•	•	•	•	•	•	•			
		Aegis5-14	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
		ASI 26/77	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
EDTA (0.5 M)	15–30°C	CX5-14	0 mo	•	•	•	•	•	•	•	•			
			3 mo	•	•	•	•	•	•	•	•			
			6 mo	•	•	•	•	•	•	•	•	•		
			12 mo	•	•	•	•	•	•	•	•	•		
			18 mo	•	•	•	•	•	•	•	•	•		
		24 mo	•	•	•	•	•	•	•	•	•			
		Aegis5-14	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
		ASI 26/77	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
Glucose (50%)	15–30°C	CX5-14	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
			12 mo	•	•	•	•	•	•	•	•	•		
			18 mo	•	•	•	•	•	•	•	•	•		
		24 mo	•	•	•	•	•	•	•	•	•			
		Aegis5-14	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
		ASI 26/77	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
PBS (10X)	15–30°C	CX5-14	0 mo	•	•	•	•	•	•	•	•			
			3 mo	•	•	•	•	•	•	•	•			
			6 mo	•	•	•	•	•	•	•	•	•		
			12 mo	•	•	•	•	•	•	•	•	•		
			18 mo	•	•	•	•	•	•	•	•	•		
		24 mo	•	•	•	•	•	•	•	•	•			
		Aegis5-14	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
		ASI 26/77	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
Tris (20 mM) NaCl (1.5 M)	15–30°C	CX5-14	0 mo	•	•	•	•	•	•	•	•			
			3 mo	•	•	•	•	•	•	•	•			
			6 mo	•	•	•	•	•	•	•	•	•		
			12 mo	•	•	•	•	•	•	•	•	•		
			18 mo	•	•	•	•	•	•	•	•	•		
		24 mo	•	•	•	•	•	•	•	•	•			
		Aegis5-14	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
		ASI 26/77	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
Glycine (100 mM)	15–30°C	CX5-14	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
			12 mo	•	•	•	•	•	•	•	•	•		
			18 mo	•	•	•	•	•	•	•	•	•		
		24 mo	•	•	•	•	•	•	•	•	•			
		Aegis5-14	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
		ASI 26/77	0 mo	•	•	•	•	•	•	•	•	•		
			3 mo	•	•	•	•	•	•	•	•	•		
			6 mo	•	•	•	•	•	•	•	•	•		
WFI quality water	15–30°C	CX5-14	0 mo	•	•	•	•	•	•	•	•		•	•
			3 mo	•	•	•	•	•	•	•	•		•	•
			6 mo	•	•	•	•	•	•	•	•		•	•
			12 mo	•	•	•	•	•	•	•	•		•	•
			18 mo	•	•	•	•	•	•	•	•		•	•
		24 mo	•	•	•	•	•	•	•	•		•	•	
		Aegis5-14	0 mo	•	•	•	•	•	•	•	•		•	•
			3 mo	•	•	•	•	•	•	•	•		•	•
			6 mo	•	•	•	•	•	•	•	•		•	•
		ASI 26/77	0 mo	•	•	•	•	•	•	•	•		•	•
			3 mo	•	•	•	•	•	•	•	•		•	•
			6 mo	•	•	•	•	•	•	•	•		•	•

\* Subject to change. Real-time stability data is being collected by our team on an ongoing basis. Contact your sales representative for the most recent capabilities.



## Frequency and parameters of stability testing and product output\* (cont.)

Process liquid stability data														
Product description (concentration)	Storage conditions	Bioprocess container film	Duration	Stability tests										
				Appearance	Conductivity (mS/cm)	Endotoxin (EU/mL)	Normality (N)	Osmolality (mOsm/kg)	pH	Sterility	Amino acid (quantitative)	Nitrate (ppm)	Total organic carbon (ppb)	
MES (50 mM) NaCl (200 mM)	15–30°C	CX5-14	0 mo	•	•	•				•	•			
			3 mo	•	•	•				•	•			
			6 mo	•	•	•				•	•			
			12 mo	•	•	•				•	•			
			18 mo	•	•	•				•	•			
			24 mo	•	•	•				•	•			
		Aegis5-14	0 mo	•	•	•				•	•	•		
			3 mo	•	•	•				•	•	•		
			6 mo	•	•	•				•	•	•		
		ASI 26/77	0 mo	•	•	•				•	•	•		
			3 mo	•	•	•				•	•	•		
			6 mo	•	•	•				•	•	•		
HBSS (1X, with calcium, magnesium, phenol red)	15–30°C	CX5-14	0 mo	•		•			•	•	•			
			3 mo	•		•			•	•	•			
			6 mo	•		•			•	•	•			
			12 mo	•		•			•	•	•			
			18 mo	•		•			•	•	•			
			24 mo	•		•			•	•	•			
		Aegis5-14	0 mo	•		•				•	•	•		
			3 mo	•		•				•	•	•		
			6 mo	•		•				•	•	•		
		ASI 26/77	0 mo	•		•				•	•	•		
			3 mo	•		•				•	•	•		
			6 mo	•		•				•	•	•		
Acetic acid (4 M)	15–30°C	CX5-14	0 mo	•		•			•	•	•			
			3 mo	•		•			•	•	•			
			6 mo	•		•			•	•	•			
			12 mo	•		•			•	•	•			
			18 mo	•		•			•	•	•			
			24 mo	•		•			•	•	•			
		Aegis5-14	0 mo	•		•				•	•	•		
			3 mo	•		•				•	•	•		
			6 mo	•		•				•	•	•		
		ASI 26/77	0 mo	•		•				•	•	•		
			3 mo	•		•				•	•	•		
			6 mo	•		•				•	•	•		
Tween 80 (1%)	15–30°C	CX5-14	0 mo	•		•			•	•	•			
			3 mo	•		•			•	•	•			
			6 mo	•		•			•	•	•			
			12 mo	•		•			•	•	•			
			18 mo	•		•			•	•	•			
			24 mo	•		•			•	•	•			
Sodium chloride (100 mM), phosphate (25 mM), and caprylic acid (25 mM)	15–30°C	CX5-14	0 mo	•	•	•			•	•	•			
			3 mo	•	•	•			•	•	•			
			6 mo	•	•	•			•	•	•			
			12 mo	•	•	•			•	•	•			
			18 mo	•	•	•			•	•	•			
			24 mo	•	•	•			•	•	•			
		Aegis5-14	0 mo	•	•	•				•	•	•		
			3 mo	•	•	•				•	•	•		
			6 mo	•	•	•				•	•	•		
		ASI 26/77	0 mo	•	•	•				•	•	•		
			3 mo	•	•	•				•	•	•		
			6 mo	•	•	•				•	•	•		
DPBS (1X)	15–30°C	CX5-14	0 mo	•	•	•			•	•	•			
			3 mo	•	•	•			•	•	•			
			6 mo	•	•	•			•	•	•			
		ASI 26/77	0 mo	•	•	•				•	•	•		
			3 mo	•	•	•				•	•	•		
			6 mo	•	•	•				•	•	•		
NaCl (5 M)	15–30°C	Aegis5-14	0 mo	•	•	•			•	•	•			
			3 mo	•	•	•			•	•	•			
			6 mo	•	•	•			•	•	•			
		ASI 26/77	0 mo	•	•	•				•	•	•		
			3 mo	•	•	•				•	•	•		
			6 mo	•	•	•				•	•	•		
Acetate (20 mM sodium acetate, pH 5.0)	15–30°C	CX5-14	0 mo	•	•	•			•	•	•			
		Aegis5-14	0 mo	•	•	•			•	•	•			
		ASI 26/77	0 mo	•	•	•			•	•	•			
Histidine (10 mM histidine, pH 6.0)	15–30°C	CX5-14	0 mo	•	•	•			•	•	•	•		
		Aegis5-14	0 mo	•	•	•			•	•	•	•		
		ASI 26/77	0 mo	•	•	•			•	•	•	•		
Citrate (20 mM citrate, pH 3.0)	15–30°C	CX5-14	0 mo	•	•	•			•	•	•			
		Aegis5-14	0 mo	•	•	•			•	•	•			
		ASI 26/77	0 mo	•	•	•			•	•	•			
HEPES	15–30°C	CX5-14	0 mo	•	•	•			•	•	•			
			3 mo	•	•	•			•	•	•			
			6 mo	•	•	•			•	•	•			
			12 mo	•	•	•			•	•	•			
			18 mo	•	•	•			•	•	•			
			24 mo	•	•	•			•	•	•			
		Aegis5-14	0 mo	•	•	•				•	•	•		
			3 mo	•	•	•				•	•	•		
			6 mo	•	•	•				•	•	•		
		ASI 26/77	0 mo	•	•	•				•	•	•		
			3 mo	•	•	•				•	•	•		
			6 mo	•	•	•				•	•	•		

\* Subject to change. Real-time stability data is being collected by our team on an ongoing basis. Contact your sales representative for the most recent capabilities.

# Standard products

Get quality you can trust with our off-the shelf liquids and packaging, manufactured under stringent conditions to give you the results you want.

## Choose from our comprehensive Gibco™ catalog:

- Water for Injection (WFI) for Cell Culture
- Dynamis™ Medium
- CD OptiCHO™ Medium
- CD CHO Medium
- ExpiCHO™ Stable Production Medium
- EfficientFeed™ A+, B+, and C+ Supplement
- FunctionMAX™ TiterEnhancer additive
- Common and custom buffers

## Options for film and packaging

Thermo Scientific™ films are available with a variety of physical characteristics, engineered to meet the most demanding requirements of your bioproduction processes.

- BioProcess Containers (BPCs) with Thermo Scientific™ CX5-14, Aegis™ 5-14, and ASI™ 26/77 films are validated for liquid fills and shipments from Grand Island and Paisley
- Continuing to support legacy films

## Certificate of Analysis for Gibco WFI for Cell Culture

Parameter	Limit
Conductivity	≤5.0 μS/cm
Endotoxin	≤0.25 EU/mL
Nitrate	≤0.2 ppm
Osmolality	20 mOsm/kg
pH	4.0–7.5
Sterility	Negative
Total organic carbon	≤500 ppb

## Gibco WFI for Cell Culture

Gibco WFI for Cell Culture is pure, cell culture–grade water, produced to meet the most stringent quality control standards in accordance with the biopharmaceutical, pharmaceutical, and diagnostic industries. Every batch undergoes strict quality control testing.

- Multicompendial testing in accordance with Packaged Sterile Purified Water and Sterile Water for Injection Standards, and compliant with United States Pharmacopeia (USP) and European Pharmacopoeia (EP) specifications
- Produced in ISO-certified, cGMP, and FDA-registered facilities
- Membrane-filtered to 0.1 μm

Gibco WFI for Cell Culture is now available in 20 L and 200 L sizes. Get pure, high-quality water in a variety of custom sizes to suit your bioprocessing needs at [thermofisher.com/wfi](https://www.thermofisher.com/wfi).

## Media, feeds, and supplements

Gibco media, supplements, cells, and cell culture reagents are designed to deliver reproducibility and performance for results you can count on every day. These time-tested products help support the growth and maintenance of a variety of cells and cell lines. We have also developed an array of powdered and liquid formulations to fit your bioprocessing needs and budget.



# Custom products

When you are at the leading edge of your field, off-the-shelf bioproduction products may not be sufficient to meet your needs. In response, we offer a full suite of customizable materials and components, from buffers and liquids to containers and secondary packaging. Our extensive bioprocessing solutions help ensure that you can optimize your workflow and get the reliability you need.

## Boost your bioprocessing with custom capabilities

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

- **Custom BioProcess Container (BPC) engineering**—sizes, films, components library, and secondary packaging
- **Formulation**—catalog or custom specification
- **Manufacturing**
  - Non-GMP: Gibco™ Media Express (GME) is for formulation prototyping to enable suitability prior to scale-up to GMP
  - cGMP products
- **Gibco BioProduction Services**—technical consultation
- Custom labeling and documentation
- Custom solutions for storage and global distribution
- Multicompendial raw material library

## One supplier, countless solutions

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

Partnering with us gives you the peace of mind that you're working with a manufacturer with stringent quality control practices and a high level of technical expertise. We have processes in place that enable us to identify and fulfill your requirements, providing outstanding customer service every step of the way.



# Bulk process liquid options

Bulk liquids are an essential component of bioprocessing. Our many years of experience make us the go-to partner for custom formulations. Whether your workflows require caustic chemicals, standard buffers, or made-to-order sizes of our trusted products, we stand ready to serve you.

## Options for bioprocess liquids include:

- Catalog or custom
- Various buffer formulations
- 1X and concentrates
- Raw material grade
- Custom labeling

## Example of the broad array of liquids provided for one of our customers

Liquid type	Gibco™ product and annual volume examples
Cell culture media	<b>GMEM:</b> 66,000 L (330 x 200 L bag) <b>Custom media formulation:</b> 462,500 L (925 x 500 L bag) <b>AIM V T Cell Medium:</b> 15,000 L (15,000 x 1 L bag)
Feeds and additives	<b>10% antifoam:</b> 13,000 L (2,600 x 5 L bag) <b>CHO CD EfficientFeed A supplement:</b> 3,800 L (760 x 5 L bag) <b>BME:</b> (8,130 L) 8,130 x 1 L bottle
Bioprocess liquids	<b>Sodium citrate:</b> 90,000 L (450 x 200 L bag) <b>PBS:</b> 32,000 L (1,600 x 20 L bag) <b>WFI:</b> 28,000 L (2,800 x 10 L bag)
Concentrates	<b>CD CHO concentrate:</b> 296,400 L (1,800 x 150 L bag + 1,320 x 20 L bag) <b>1,000X CD lipids:</b> 3,900 L (1,950 x 2 L bottle)



# Container and packaging selections

There are a number of containers or secondary packaging options to ship your bulk process liquid. Depending upon your requirements, the choice of containers may be very simple: just determine the right liquid format, container, and manufacturing requirements for each product. We'll walk you through the process.

All containers have two aspects: the bioprocess container and the outer container. Select the appropriate volume to fit your workflow and then choose an outer container to meet your needs (Table 1).

## Select an outer container

**Table 1. Outer container types by pack size.**

Volume—pack size	1, 5, 10, and 20 L	50 L	100 and 200 L	500 and 1,000 L
Corrugate cases	X			
Returnable plastic nesting totes	X			
Drums—top and bottom drain		X	X	
ALLpaQ returnable systems		X*	X*	X

\* 50, 100, and 200 L ALLpaQ containers are only available in the UK.

### Corrugate cases and returnable plastic crates

- Fiber-corrugate and plastic-corrugate shipping boxes are available as the outer shipping containers for small-volume, end-ported liquid BPCs
- HDPE plastic nesting totes with attached lids are available as the outer shipping containers for small-volume end-ported BPCs



### Drums—top and bottom drain

- Available as the outer shipping containers for intermediate-volume 3D liquid BPCs
- Options available include top- or bottom-drain, straight-sided, nestable, or UN-certified for hazardous products
- Single-shipment use only



### ALLpaQ plastic returnable systems

- Available as the outer shipping containers for intermediate- to large-volume 3D BPCs
- Top- or bottom-drain options
- These containers are used on a returnable basis



# Shipping container options

Choose the container that fits your liquid of choice and your sustainability goals.

## Go green with ALLpaQ containers

We are committed to finding ways to deliver our products with the environment in mind—it's part of how we enable our customers to make the world healthier, cleaner, and safer. To minimize the adverse environmental impact of packaging our bioprocessing liquids, buffers, culture media, and bulk drug precursors in single-use drums, we invested in the ALLpaQ™ returnable packaging system. This system may potentially reduce, over 3 years, your carbon footprint by 51% or more and eliminate waste by 90% or more from manufacturing and shipping, compared to single-use drums (Table 1).

**Table 1. Total carbon footprint and waste based on equivalency within 3 years.** Calculations included: carbon footprint for sourcing and from truck shipments; drum replacement for 12 shipments; and an ALLpaQ system that can be reused up to 12 times with a typical lifespan of 3 years.

	Drum	ALLpaQ	Value
	<b>Carbon footprint (CO<sub>2</sub>e kg)</b>		
100 L	408	199	51% reduction
200 L	513	226	56% reduction
100 L drum/ 500 L ALLpaQ	2,040	870	57% reduction
	<b>Total waste generated (kg)</b>		
100 L	212	22	90% reduction
200 L	267	25	91% reduction
100 L drum/ 500 L ALLpaQ	1,061	96	91% reduction

# Standard BPC options

Standard BioProcess Container (BPC) designs are a great way to get started, with a variety to choose from in both two-dimensional (2D) and three-dimensional (3D) formats.

## 2D Labtainer BPC systems

### Key features

- Thermo Scientific™ 2D Labtainer™ systems are 2-panel, pillow-style BPCs
- Chambers are constructed from CX5-14, Aegis5-14, and ASI 26/77 films
- Labtainer systems have 2–3 edge ports along one end with a handle on the opposing end
- Two-port Labtainer BPCs are available in sizes from 1 L to 20 L
- Three-port Labtainer BPCs are available in sizes from 5 L to 20 L
- BPCs can be customized for easy integration with existing process operations and equipment

## 3D Productainer BPC systems

### Key features

- Use this system to eliminate post-use cleaning steps required with reusable containers, and to reduce cross-contamination risks
- All Thermo Scientific™ 3D Productainer™ BPCs are constructed in an ISO 7–certified cleanroom under cGMP conditions
- All 3D Productainer BPCs are designed to fit the full range of support containers, both square and cylindrical, from 50 L to 1,000 L



# Standard BPC options cont.

2D standard 1 L BPC design

(CX5-14, Aegis5-14, ASI 26/77)

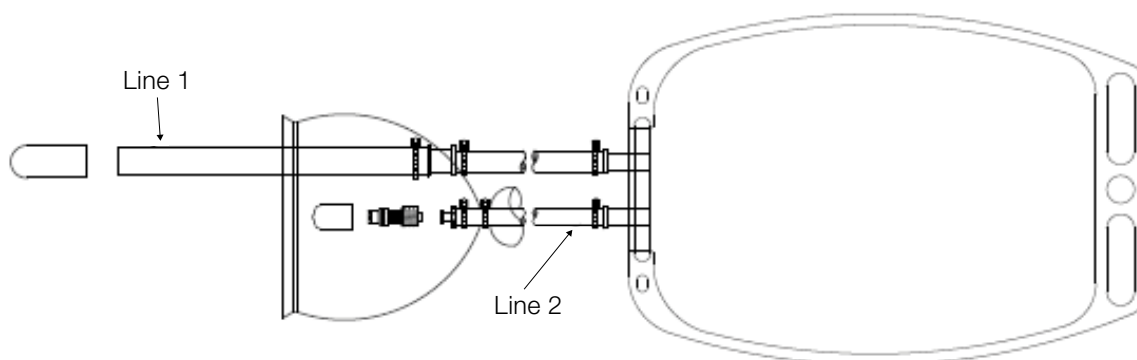


Table 2. Materials used in 2D standard 1 L BPCs.

Line	Tubing (ID x OD x wall, total length)	Connector(s)
Line 1	Thermo Fisher Scientific fill line	Sealed after filling
Line 2	C-Flex 082 tubing 1/4 x 3/8 x 1/16 in., total length 4 in. (6.4 x 9.5 x 1.6 mm, total length 10.2 cm)	Female luer lock and SmartSite™ needle-free valve port

# Standard BPC options cont.

2D standard 5, 10, and 20 L BPC design

(CX5-14, Aegis5-14, ASI 26/77)

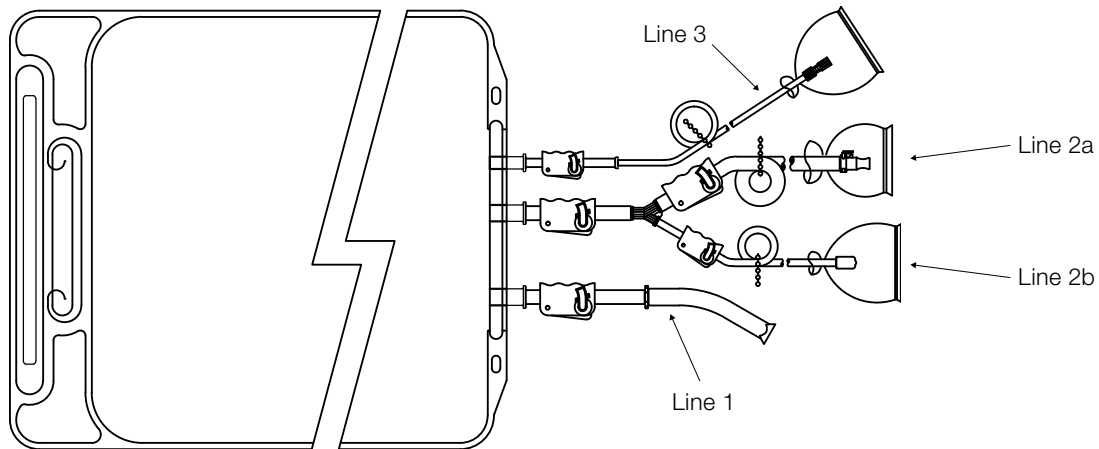


Table 3. Materials used in 2D standard 5, 10, and 20 L BPCs.

Line	Tubing (ID x OD x wall, total length)	Connector(s)
Line 1	Thermo Fisher Scientific fill line	Sealed after filling
Line 2a	<b>C-Flex 082 tubing</b> 3/8 x 5/8 x 1/8 in., total length 42 in. (9.5 x 15.9 x 3.2 mm, total length 106 cm)	Polycarbonate 3/8 in. MPC series quick-connect insert (male)
Line 2b	<b>C-Flex 082 tubing</b> 1/4 x 3/8 x 1/16 in., total length 42 in. (6.4 x 9.5 x 1.6 mm, total length 106 cm)	Polypropylene male luer lock
Line 3	<b>C-Flex 082 tubing</b> 1/8 x 1/4 x 1/16 in., total length 36 in. (3.2 x 6.4 x 1.6 mm, total length 91 cm)	SmartSite needle-free valve port, female luer connector

# Standard BPC options cont.

3D standard top-drain 50, 100, and 200 L BPC design

(CX5-14, Aegis5-14, ASI 26/77)

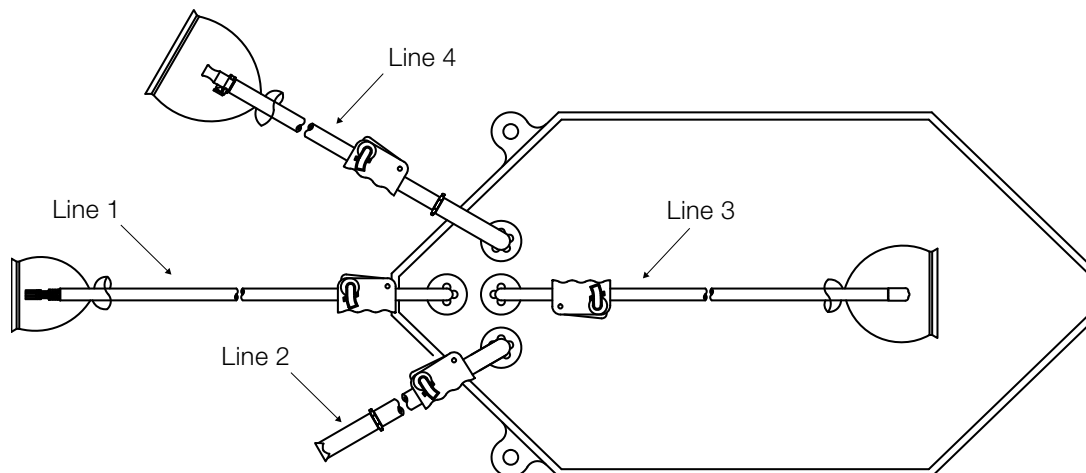


Table 4. Materials used in 3D standard top-drain 50, 100, and 200 L BPCs.

Description	Tubing (ID x OD x wall, and length)	Connector(s)
Line 1	<b>C-Flex 082 tubing</b> 1/4 x 1/2 x 1/8 in., total length 48 in. (6.4 x 12.7 x 3.2 mm, total length 122 cm)	SmartSite needle-free valve port, female luer connector
Line 2	<b>Thermo Fisher Scientific fill line</b>	<b>Sealed after filling</b>
Line 3	<b>C-Flex 082 tubing</b> 1/4 x 1/2 x 1/8 in., total length 48 in. (6.4 x 12.7 x 3.2 mm, total length 122 cm)	Polypropylene male luer lock
Line 4	<b>C-Flex 082 tubing</b> 3/8 x 5/8 x 1/8 in., total length 36 in. (9.5 x 15.9 x 3.2 mm, total length 91 cm)	Polycarbonate 3/8 in. MPC series quick-connect insert (male)



# Standard BPC options cont.

3D standard bottom-drain 50, 100, and 200 L BPC design

(CX5-14, Aegis5-14, ASI 26/77)

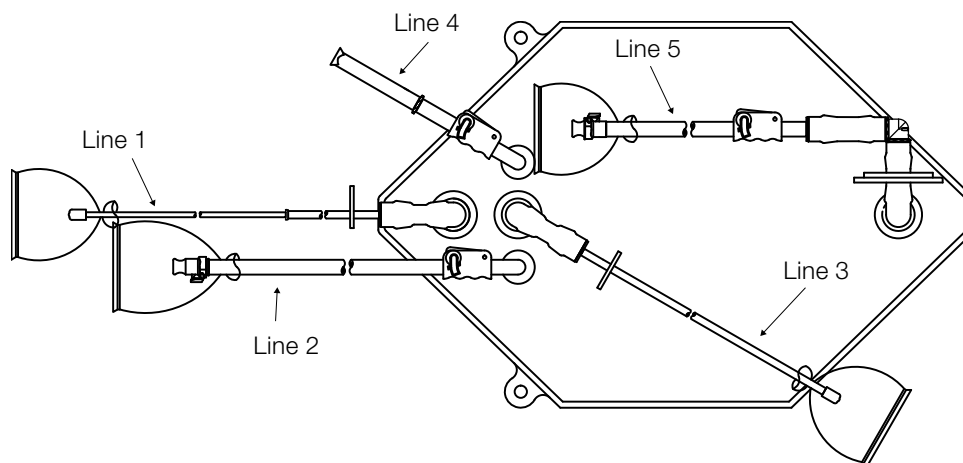


Table 5. Materials used in 3D standard bottom-drain 50, 100, and 200 L BPCs.

Description	Tubing (ID x OD x wall, and length)	Connector(s)
Line 1	<b>C-Flex 082 tubing</b> 1/4 x 3/8 x 1/16 in., total length 48 in. (6.4 x 9.5 x 1.6 mm, total length 122 cm)	Polypropylene male luer lock
Line 2	<b>C-Flex 082 tubing</b> 1/2 x 3/4 x 1/8 in., total length 48 in. (12.7 x 19.1 x 3.2 mm, total length 122 cm)	Polycarbonate 1/2 in. MPX series quick-connect insert (male)
Line 3	<b>C-Flex 082 tubing</b> 1/4 x 3/8 x 1/16 in., total length 48 in. (6.4 x 9.5 x 1.6 mm, total length 122 cm)	SmartSite needle-free valve port, female luer connector
Line 4	<b>Thermo Fisher Scientific fill line</b>	<b>Sealed after filling</b>
Line 5	<b>C-Flex 082 tubing</b> 1/8 x 1/4 x 1/16 in., total length 40 in. (3.2 x 6.4 x 1.6 mm, total length 101 cm)	Polycarbonate 1/2 in. MPX series quick-connect body (female)

# Standard BPC options cont.

Standard 500 and 1,000 L BPC design

(CX5-14, Aegis5-14, ASI 26/77)

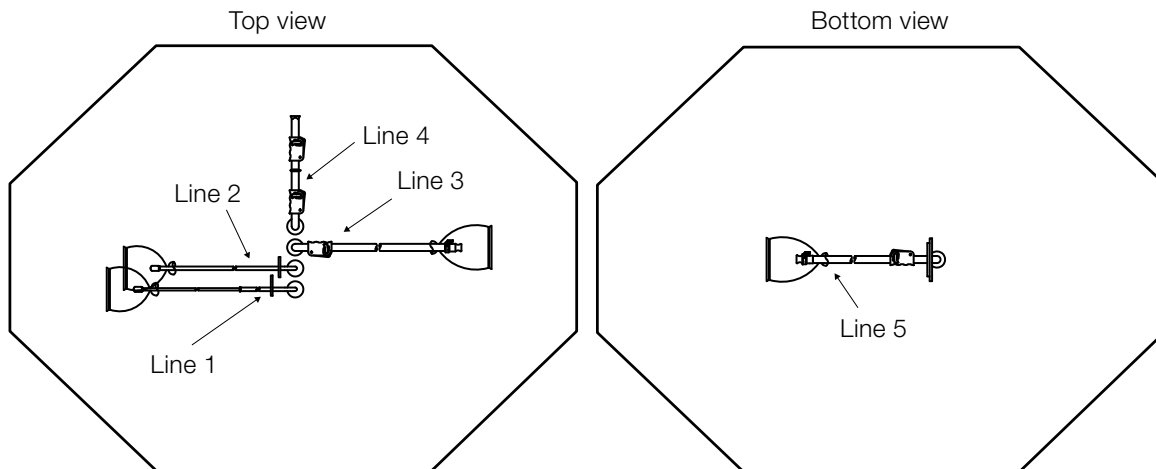


Table 6. Materials used in standard 500 and 1,000 L BPCs.

Description	Tubing (ID x OD x wall, and length)	Connector(s)
Line 1	<b>C-Flex 082 tubing</b> 1/8 x 1/4 x 1/16 in., total length 42 in. (3.2 x 6.4 x 1.6 mm, total length 106 cm)	Polypropylene male luer lock
Line 2	<b>C-Flex 082 tubing</b> 1/4 x 3/8 x 1/16 in., total length 48 in. (6.4 x 9.5 x 1.6 mm, total length 122 cm)	Polypropylene female luer lock
Line 3	<b>C-Flex 082 tubing</b> 1/2 x 3/4 x 1/8 in., total length 48 in. (12.7 x 19.1 x 3.2 mm, total length 122 cm)	Polycarbonate 1/2 in. MPX series quick-connect insert (male)
Line 4	<b>Thermo Fisher Scientific fill line</b>	<b>Sealed after filling</b>
Line 5	<b>C-Flex 082 tubing</b> 1/2 x 3/4 x 1/8 in., total length 60 in. (12.7 x 19.1 x 3.2 mm, total length 152 cm)	Polycarbonate 1/2 in. MPX series quick-connect body (female)

# Custom BPC design

Custom BPCs are specifically tailored to meet your process needs. These containers consist of a combination of film, tubing, fittings, and connectors, which may or may not include a filter. Each choice can be customized for you from the ground up.

If you're thinking about customization, we recommend a few ways to get started.

- 1. Use a standard BPC as your base**
  - Customize the lengths of tubing
  - Change a connector
- 2. Design a separate tubing assembly to connect to a standard BPC**
- 3. Customize every part of your BPC; choose your:**
  - Film (type and size of chamber)
  - Tubing (type and lengths)
  - Connectors (types)
  - Filters (membrane and size)

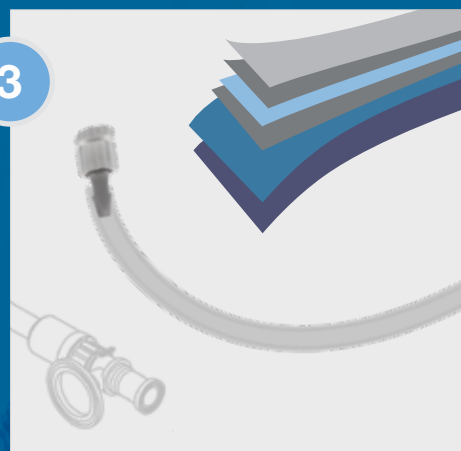
1



2



3



# Custom BPC design cont.

## Film options

Our BPCs are constructed with various film types to meet your single-use bioprocessing needs, whether upstream for cell culture and fermentation, or downstream for sophisticated applications, or simply as holding and transfer systems in your cGMP bioprocessing facilities.

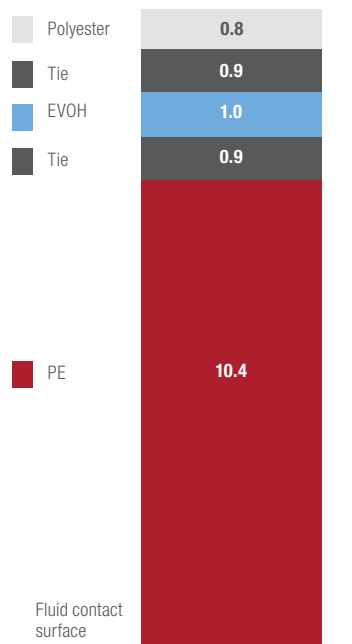
### Films for the most demanding applications

Thermo Scientific films are engineered to meet the most challenging requirements of your bioproduction processes.

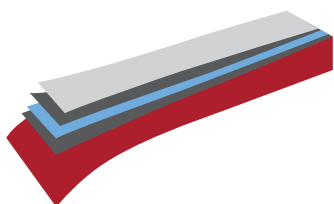
**Aegis5-14 film** is our highest-quality polyethylene (PE) film, and is produced in a cGMP facility; the outer layer of this single-web, 5-layer film is a polyester elastomer coextruded with an EVOH barrier layer and a low-density polyethylene product contact layer.

**CX5-14 film** has the same construction as Aegis5-14 film and is one of the most widely used PE films in the industry, proven over 10 years.

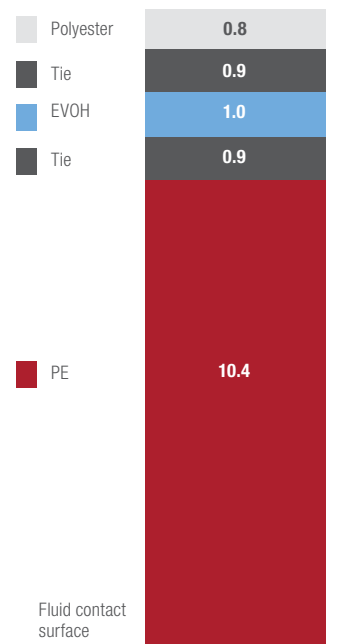
**ASI 26/77 film** polyethylene (PE) film is a dual-web, multilayer film that is produced in a cGMP facility and used for general applications.



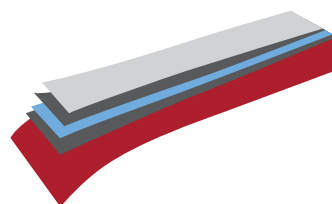
Schematic cross-section



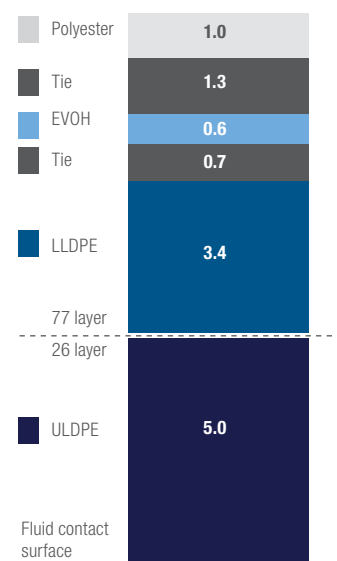
Schematic 3D view



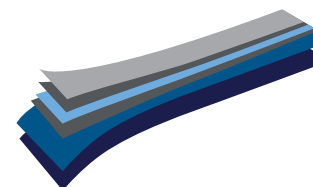
Schematic cross-section



Schematic 3D view



Schematic cross-section



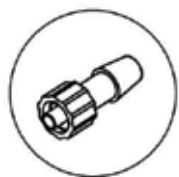
Schematic 3D view

# Custom BPC design cont.

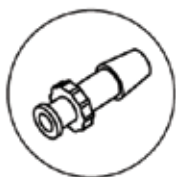
## Connector options

We take pride in offering one of the largest catalog component libraries in the industry, which allows us to integrate connectors, tubing, and sensors to design a custom BPC or tubing assembly to fit your specific needs. Our services organization will assist you with drawings, implementation, and technical support to help ensure optimum production performance.

### Luer connectors



Luer lock insert connection



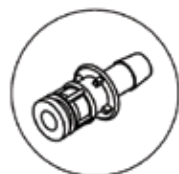
Luer lock body connection

- **Method of connection**—push insert and body connectors together and twist to secure
- **Options**—luer connectors are available in different materials and barb sizes
- **Advantages**—simple to use
- **Limitations**—limited to 6.4 mm (1/4 in.) barb sizes
- **Uses**—use when small-volume aseptic connections are required; can be made in an ISO 5 clean area

Type	Material	Hose barb size available
Luer lock	Kynar™ PVDF	3.2 mm (1/8 in.), 6.4 mm (1/4 in.)
Luer lock	Polypropylene	3.2 mm (1/8 in.), 6.4 mm (1/4 in.)

### CPC quick-connects

Method of connection—push



Male (insert)



Female (body)

- **Method of connection**—male (insert) and female (body) connectors together until they click
- **Options**—available in different materials and sizes; includes HFC series with integral shutoff valve
- **Advantages**—quick, easy, and secure to use
- **Limitations**—ISO 5 clean area or better required for an aseptic connection
- **Uses**—use when secure aseptic connections are required; can be made in an ISO 5 clean area

Type	Material	Hose barb size available
MPC series	Polycarbonate	9.5 mm (3/8 in.), 12.7 mm (1/2 in.)
MPX series	Polysulfone	12.7 mm (1/2 in.)
MPU series	Polysulfone	19.1 mm (3/4 in.)
HFC39	Polysulfone	6.4 mm (1/4 in.), 9.5 mm (3/8 in.)

### Sample ports



SmartSite connection

- **Method of connection**—inset syringe into port to remove sample
- **Options**—similar devices are available: SmartSite and Clave™ connectors
- **Advantages**—no needle required
- **Limitations**—flow rate
- **Uses**—use when samples of ≤50 mL are required

Type	Material	Hose barb size available
	Acrylic, polyurethane, and/or silicone	NA
Clave	NA	NA



# Custom BPC design cont.

## Connector options

### Tri-clamps



SterilEnz fitting



Mini tri-clamp

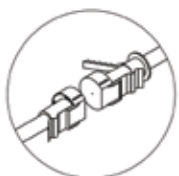


Tri-clamp

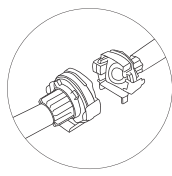
- **Method of connection**—place flanges together with gasket between them; secure using a clamp
- **Options**—available in 12.7 mm (1/2 in.) and 19.1 mm (3/4 in.) (also known as mini tri-clamps) tri-clamp (TC) flange sizes in a range of different materials; SterilEnz™ fittings have the advantage that the tri-clamp connection is protected by an integral bag
- **Advantages**—largest barb size of all available connectors on BPCs; very secure connection
- **Limitations**—not suitable for making aseptic connections
- **Uses**—use when the BPC has to be connected to a vessel with a tri-clamp port and sterility is not required; normally used in downstream applications

Type	Material	Hose barb size available
SterilEnz mini TC	Polyethylene	12.7 mm (1/2 in.)
SterilEnz TC	Polyethylene	12.7 mm (1/2 in.), 19.1 mm (3/4 in.)
Mini TC	Polypropylene	3.2 mm (1/8 in.), 6.4 mm (1/4 in.), 9.5 mm (3/8 in.), 12.7 mm (1/2 in.)
Mini TC	Kynar	3.2 mm (1/8 in.), 6.4 mm (1/4 in.), 9.5 mm (3/8 in.), 12.7 mm (1/2 in.)
TC	Polypropylene	3.2 mm (1/8 in.), 6.4 mm (1/4 in.), 9.5 mm (3/8 in.), 12.7 mm (1/2 in.), 25.4 mm (1 in.)
TC	Kynar	3.2 mm (1/8 in.), 6.4 mm (1/4 in.), 9.5 mm (3/8 in.), 12.7 mm (1/2 in.), 25.4 mm (1 in.)

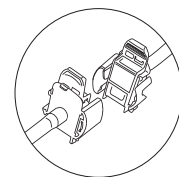
### Aseptic connection devices (ACD)



Pall Kleenpak connection



CPC AseptiQuik connection (X)



CPC AseptiQuik connection (S)

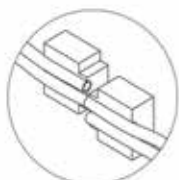
- **Method of connection**—similar to tri-clamp; connection faces vary by model
- **Options**—Pall™ Kleenpak™, GE™ ReadyMate™ Disposable Aseptic Connector (DAC) and Colder Products Company™ (CPC) AseptiQuik™ connectors
- **Advantages**—allow aseptic connections to be made anywhere without dependence on an instrument
- **Limitations**—not the most economical option
- **Uses**—use when aseptic connections are required and an ISO 5 clean area is not available

Type	Material	Hose barb size available
Pall Kleenpak	Polycarbonate and/or silicone	6.4 mm (1/4 in.), 9.5 mm (3/8 in.), 12.7 mm (1/2 in.)
ReadyMate DAC	Polycarbonate and/or silicone	6.4 mm (1/4 in.), 9.5 mm (3/8 in.), 12.7 mm (1/2 in.), 19.1 mm (3/4 in.)
CPC AseptiQuik	Polycarbonate and/or silicone	3.2 mm (1/8 in.), 6.4 mm (1/4 in.), 12.7 mm (1/2 in.), 9.5 mm (3/8 in.), 19.1 mm (3/4 in.)

# Custom BPC design cont.

## Connector options, cont.

### Tubing welder



Tubing in welder jaws



End plug

- **Method of connection**—automatic instrument cuts and joins two tubes aseptically
- **Options**—requires either C-Flex or PharMed™ tubing attached to the BPC; since a terminal connector is not required, the normal end treatment is an end plug
- **Advantages**—flexibility
- **Limitations**—requires an instrument to make the connection
- **Uses**—use when aseptic connections are required and an ISO 5 clean area is not available

Type	Material	Hose barb size available
End plug	Polypropylene	3.2 mm (1/8 in.), 6.4 mm (1/4 in.), 9.5 mm (3/8 in.), 12.7 mm (1/2 in.), 19.1 mm (3/4 in.)
End plug	Kynar	3.2 mm (1/8 in.), 6.4 mm (1/4 in.), 9.5 mm (3/8 in.), 12.7 mm (1/2 in.)

### Steam in place



CPC Steam-Thru connection

- **Method of connection**—same as tri-clamps where the mating flange will be part of the steam-in-place supply assembly
- **Options**—other options may be available upon request
- **Advantages**—validated aseptic connection is possible
- **Limitations**—flow rate
- **Uses**—use when an aseptic connection of a BPC to a stainless steel vessel with a tri-clamp port is required

Type	Material	Hose barb size available
Unitized mini TC	Silicone	9.5 mm (3/8 in.), 12.7 mm (1/2 in.)
Unitized TC	Silicone	9.5 mm (3/8 in.), 12.7 mm (1/2 in.), 19.1 mm (3/4 in.)
CPC Steam-Thru (TC and mini TC)	Polysulfone	9.5 mm (3/8 in.), 12.7 mm (1/2 in.)
CPC Steam-Thru II	Polysulfone	9.5 mm (3/8 in.), 12.7 mm (1/2 in.)
Millipore Lynx ST connectors (TC and mini TC)	Polyetherimide and/or silicone	6.4 mm (1/4 in.), 12.7 mm (1/2 in.)

# Custom BPC design cont.

## Filter options

Filtration is an important step in bioprocessing, and a variety of filters are available through the Thermo Scientific™ catalog component library to meet your needs. Our open-architecture approach enables us to provide customers with a broad choice of both filters and manufacturers, including opportunities for dual sourcing.

### Some major characteristics relevant to filter selection:

- **Membrane material**—the major types of filter material used in bioprocessing today are polyethersulfone (PES) and polyvinylidene fluoride (PVDF)
- **Membrane size**—required filter pore size will be influenced by the size of the materials being filtered, as well as the level of filtration the process necessitates
- **Affinity to water**—the presence of aqueous solution impacts the type of filter that may be most advantageous to your process
- **Application**—the sequence within your process where filtration takes place and the type of material being filtered have implications for filter selection

Table 7. A sample of the filters available through our comprehensive catalog component library.

Supplier	Type	Material	Final filter pore sizes (µm)
Domnick Hunter	PROPOR SG, DEMICAP capsule	PES	0.1, 0.2
	PROPOR SG, MURUS capsule	PES	0.1, 0.2
Mei L ssner	SteriLUX, UltraCap capsule	PVDF	0.1, 0.2
	SteriLUX capsule	PVDF	0.2
	STyLUX, UltraCap capsule	PES	0.1, 0.2
	STyLUX, capsule	PES	0.1, 0.2
Pall	Fluorodyne II DJL, Kleenpak capsule	PVDF	0.1
	Fluorodyne II DFL, Kleenpak capsule	PVDF	0.2
	Supor EKV, Kleenpak capsule	PES	0.2
Millipore	Millipak filter unit	PVDF	0.1, 0.2
	Opticap XL capsule	PVDF	0.1, 0.2
	Opticap XL capsule	PES	0.1, 0.2
Sartorius	Sartopore 2 capsule	PES	0.1, 0.2

A variety of factors unique to your process may influence your choice of filter, in addition to those considerations listed. Contact your Thermo Fisher Scientific bioproduction sales representative to address any questions or for assistance with identifying the best filter for your process needs.

# Manufacturing needs

## Prototyping designed to help you scale up

Fast, non-cGMP media and process liquid production at pilot scale is available for accelerated testing and scale-up. Our Gibco™ Media Express service offers high-quality custom media, buffers, and process liquids to rapidly finalize your formulations before cGMP scale-up. With our responsive customer service and experienced production team, your custom formulation can be shipped as quickly as 10 days after ordering.

- cGMP-qualified raw materials and processes enable a seamless transition to larger cGMP volumes
- Prototyping for bulk process liquids and buffers in single-use BPCs
- Conversion of liquid and powder media to Advanced Granulation Technology™ (AGT™) format

## Gibco Media Express standard capacity and packaging

We can rapidly deliver your media in a variety of formats. Please work with your bioproduction account manager for custom inquiries.

## Spotlight on bulk processing liquids

In addition to media prototyping, Gibco Media Express also enables pilot testing of bulk processing liquids in your BPC of choice.

Buffer prototyping is the first step toward gaining the benefits of outsourcing your large-scale cGMP liquids.

**Table 8. Processes and materials mirror cGMP production, helping to accelerate technology transfer during customer scale-up.**

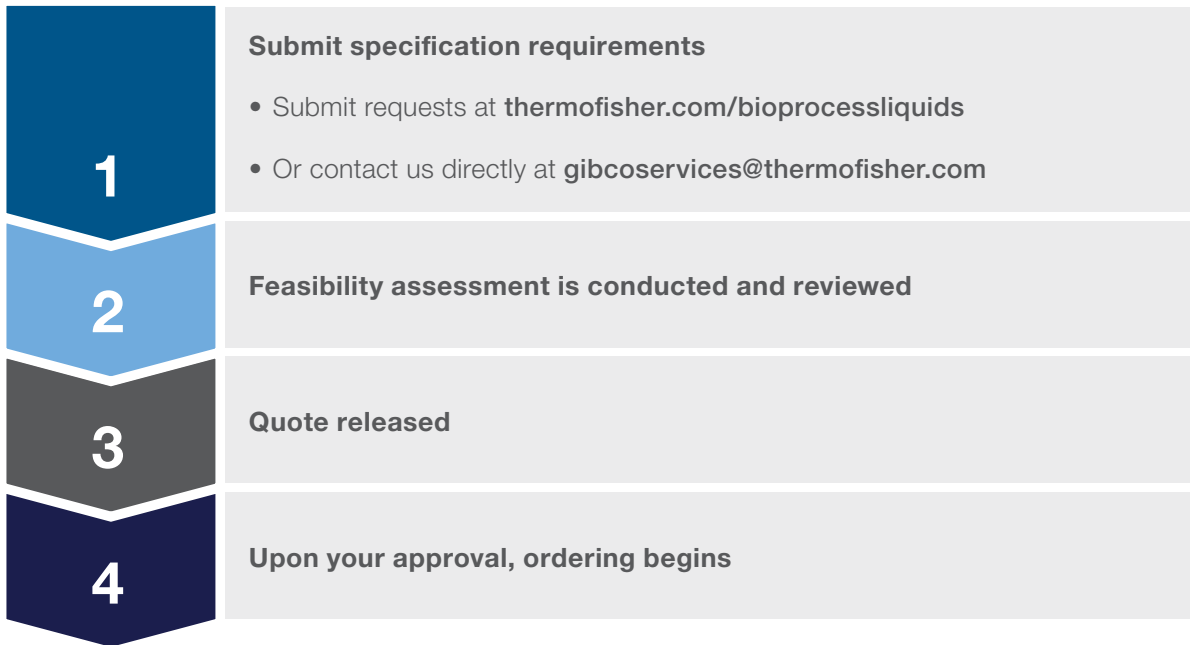
Gibco Media Express: Test and finalize formulation		cGMP: Clinical- to commercial-scale production	
Feasibility	Gibco Media Express team conducts review of product feasibility and design for manufacturing	Technology transfer	Feasibility review team conducts full cGMP feasibility study on custom orders
Raw materials	cGMP-qualified raw materials; novel raw materials by request		cGMP-qualified raw materials
Batch records	Full batch record created		Full batch record created
Equipment	POMS manufacturing execution system (MES) dispensing Lab-scale FitzMill™ equipment, tumble blenders Lab-scale AGT granulator		POMS manufacturing execution system (MES) dispensing cGMP FitzMill equipment, tumble and ribbon blenders Commercial-scale AGT granulator
Capacity	Liquid: 1–200 L Dry powdered medium (DPM): 1–10 kg AGT medium: 1–8 kg		Liquid: 10–10,000 L Dry powdered medium (DPM): 20–7,500 kg AGT medium: 50–1,500 kg
QC, analytical	Some tests available for an additional fee include pH, osmolality, sterility, endotoxin, and bioburden		Standard and custom testing available
Packaging	Standard packaging; custom packaging by exception		Standard and custom packaging options available
Delivery	Liquid, DPM: 2 weeks AGT medium: 4 weeks (on standard orders)		Liquid, DPM, AGT: 8 weeks New product ready for market: 10 weeks

**Table 9. Maximum GME batch sizes by standard packaging for liquid media and buffers.**

Container	Size	Maximum batch size
Bottle	100 mL	20 L
	500 mL	100 L
	1,000 mL	200 L
Aegis5-14 BPC	1 L	100 L
	5 L	100 L
	10 L	200 L
	20 L	200 L
	50 L	200 L
	100 L	200 L
CX5-14 BPC	1 L	100 L
	5 L	100 L
	10 L	200 L
	20 L	200 L
	200 L	200 L

# How to get started

In the complex world of biopharmaceuticals 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. After determining which options are best for you, contact your local bioproduction sales representative. From here, our team will walk you through the next steps.





# Appendix

## Part numbers for standard bulk liquid BPCs

Table 10. Part numbers for the standard 1, 5, 10, and 20 L BPCs, based on film, size, and location.

	Chamber size	Grand Island Core	Grand Island LVL	Paisley
CX5-14 film	1 L	100030008	100044636	100030008
	5 L	100030268	100044519	100030268
	10 L	100030270	100044532	100030270
	20 L	100030272	100044633	100030272
Aegis5-14 film	1 L	100030009	100078812	100030009
	5 L	100031922	100076127	100031922
	10 L	100031923	100076128	100031922
	20 L	100031924	100076129	100031924
ASI 26/77 film	1 L	100045059	100062106	100045059
	5 L	100046712	100046715	100046712
	10 L	100046713	100046716	100046713
	20 L	100046714	100046717	100046714

Table 11. Part numbers for the large-volume, top-drain standard 50, 100, and 200 L BPCs, based on film, size, and location.

	Chamber size	Grand Island Core	Grand Island LVL	Paisley
CX5-14 film	50 L	100030273	100040733	100030273
	100 L	100030275	100031935	100031935
	200 L	100030277	100038215	100030276
Aegis5-14 film	50 L	100031929	100076131	100031929
	100 L	100031931	100076133	100031936
	200 L	100031933	100076135	100031933
ASI 26/77 film	50 L	100046709	100046729	100046709
	100 L	100046710	100046731	100046710
	200 L	100046711	100046733	100046711

Table 12. Part numbers for the large-volume, bottom-drain standard 50, 100, and 200 L BPCs, based on film, size, and location.

	Chamber size	Grand Island Core	Grand Island LVL	Paisley
CX5-14 film	50 L	100034763	100040734	100030274
	100 L	100030275	100031935	100040735
	200 L	100034765	100040737	100030278
Aegis5-14 film	50 L	100034766	100076132	100031930
	100 L	100034767	100076134	100031932
	200 L	100034768	100076136	100031934
ASI 26/77 film	50 L	100046722	100046730	100046738
	100 L	100046724	100046732	100046739
	200 L	100046726	100046734	100046740

Table 13. Part numbers for the standard 500 and 1,000 L BPCs, based on film, size, and location.

	Chamber size	Grand Island Core	Grand Island LVL	Paisley
CX5-14 film	500 L	100031938	100041680	100031937
	1,000 L	100031940	100041682	100031939
Aegis5-14 film	500 L	100031943	100076137	100031942
	1,000 L	100031945	100076138	100031944
ASI 26/77 film	500 L	100046727	100046735	100046741
	1,000 L	100046728	100046736	100046742

### More locations to serve your needs

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

#### Grand Island, New York

USA  
800-955-6288  
[custommedia@thermofisher.com](mailto:custommedia@thermofisher.com)

#### Millersburg, Pennsylvania

USA  
717-692-2104  
[usmbg.customerservice@thermofisher.com](mailto:usmbg.customerservice@thermofisher.com)

#### Paisley, Scotland

UK  
+44 141 8146100  
[eucustommedia@thermofisher.com](mailto:eucustommedia@thermofisher.com)

#### Logan, Utah

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435-792-8500  
[info.bioprocessing@thermofisher.com](mailto:info.bioprocessing@thermofisher.com)

#### Cramlington, England

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+44 167 0734093  
[eucustommedia@thermofisher.com](mailto:eucustommedia@thermofisher.com)



For a free technical consultation or a complimentary product sample, call 800-955-6288 or email us at [gjbcoservices@thermofisher.com](mailto:gjbcoservices@thermofisher.com)

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