



# Gibco Bulk Process Liquid and Buffer Capabilities

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# Global BioProduction Manufacturing Facilities



## Millersburg, PA

- BioProcess Containers
- Single-use technologies
- ISO 13485
- cGMP standards



## Logan, Utah

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



## Matamoros, Mexico

- BioProcess Containers
- Single-use technologies
- ISO 13485
- cGMP standards



## Bedford and Framingham, MA

- Chromatography resins
- ISO 13485



## Grand Island, NY

- Cell culture media, reagents
- Sera
- ISO 13485
- GMP 21 CFR 820



## Cramlington, UK

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



## Paisley, Scotland

- Cell culture media, reagents
- ISO 13485
- GMP 21 CFR 820



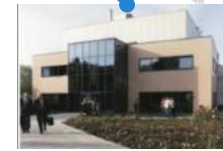
## Warrington, UK

- Analytics kits



## Lillestrom and Oslo, Norway

- Invitrogen™ Dynabeads™ Magnetic Beads
- ISO 9001– and ISO 13485–certified



## Naarden, the Netherlands

- Affinity ligands
- ISO 9001–certified



## Auckland and Christchurch, New Zealand; Newcastle, Australia

- Sera
- Protein products
- GMP 21 CFR 820



**US manufacturing**  
Grand Island, New York



**EMEA manufacturing**  
Paisley, Scotland

## Dry powder media



## AGT media



## 1X media/buffer



## Concentrated media/buffers



Serving over **110 commercial therapies** worldwide

# Benefits to Outsourcing Bioprocess Liquid Manufacturing

## Advantages

- Better product consistency
- Improved cell culture performance
- Suppliers of liquids are knowledgeable and experienced
- Fewer contamination risks
- Eliminate need for mixing tanks
- Time and labor-intensive steps eliminated:
  - QC of salts, liquid preparation, filtration, quarantine, finished good testing, documentation, procedures, validation
- Improved safety due to less handling
- Just-in-time logistics solutions
  - Doe & Ingalls™ cGMP warehousing (in US and Ireland)

## Customer benefit



**Decreased**  
capital and operating costs



**Improved**  
quality and compliance



**Increased**  
productivity

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



# Critical Attributes Help Ensure Product Integrity and Performance

Characteristics that determine whether a flexible container will **maintain product integrity** and perform as expected during specific bioprocess operations

- Biological compatibility
- Tensile properties
- Puncture resistance
- Glass transition temperature
- Transportability
- Clarity
- Permeability
- pH stability
- Extractable profile
- Cell culture growth performance
- Stability
- Standard & custom designs



Process Liquids Stability Data												
Product Description (Concentration)	Storage Conditions	Duration	Stability Testing CX5-14 BioProcess Containers Additional data points to include 36 and 48 months									
			Appearance	Conductivity	Endotoxin	Normality	Osmolality	pH	Sterility	Glucose	Glycine	Ultrate
			0 mo	3 mo	6 mo	12 mo	18 mo	24 mo	36 mo	48 mo	36 mo	48 mo
Sodium Hydroxide (3M)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
EDTA (0.5M)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Glucose (50%)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PBS (10X)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tris (20mM) NaCl (1.5M)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Glycine (100mM)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Process Liquids Stability Data												
Product Description (Concentration)	Storage Conditions	Duration	Stability Testing CX5-14 BioProcess Containers Additional data points to include 36 and 48 months									
			Appearance	Conductivity	Endotoxin	Normality	Osmolality	pH	Sterility	Glucose	Glycine	Ultrate
			0 mo	3 mo	6 mo	12 mo	18 mo	24 mo	36 mo	48 mo	36 mo	48 mo
WFI Quality Water	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MES (50mM) NaCl (200mM)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
HBSS (1X) w/ Ca, Mg, Phenol Red	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Acetic Acid (4M)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tween 80 (1%)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sodium Chloride (100mM), Phosphate (25mM), and Caprylic Acid (25mM)	15-30°C	0 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		3 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		6 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		12 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
		18 mo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

# Expanded Choice of Secondary Packaging



## 1, 5, 10, and 20 L bioprocess containers

- Corrugate cases
- Returnable plastic crates



## 50, 100, and 200 L bioprocess containers

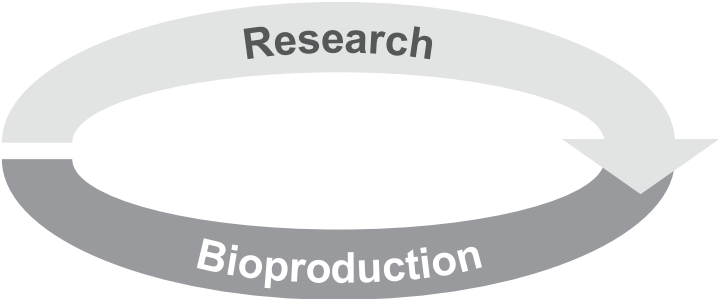
- Option to ship in different drum designs
- Bottom- or top-emptying
- Nestable
- Single-trip
- Hazardous material handling



## 100, 200, 500, and 1,000 L bioprocess containers

- ALLpaQ (Arca/Auer) plastic returnable systems
- Bottom- or top-emptying
- 100 and 200 L returnable containers available in EU

# Liquid Production Network



		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	(10–5,000 L )	✓	Under development
Alcohols (up to 20% v/v ethanol)	(400–2,500 L)	✓	Under development



# Grand Island Liquid Facility Investments

## Facility footprint

- 15,000 ft<sup>2</sup> manufacturing over two floors
- 12,400 ft<sup>2</sup> finished goods warehouse space
- Clean room, gowning, storage, formulation, staging

## Equipment deployed

- Multiple 10,000 liter tanks
- 5,000 liter tank
- 2,500 liter tank

## Support systems

- WFI still
- HVAC
- Clean steam generation
- Electronic batch records

**\$21.8M investment** to increase liquid manufacturing (5 million liters)



Additional capabilities added to include an **alcohol suite** to manage hazardous solutions

**Grand Island facility expansion for Annex 1 compliant Animal Origin-Free bulk liquids**



# Design Criteria and Quality Standards



To meet current and future customer requirements for insourcing bulk liquids, **our Grand Island manufacturing facility is built to and compliant with the following standards:**

Design criteria	Value	Rank
ISO 13485	Internationally recognized standard on the requirements for a quality management system for medical devices	Industry standard
21 CFR 820–compliant	FDA current Good Manufacturing Practice (cGMP) quality system regulation for medical devices	Industry standard
Annex 1 standard	cGMP guidelines to harmonize US/EU controls and procedures to manufacture sterile medicinal products	Differentiator
Animal origin–free (AOF)	All raw materials are free of animal-derived components; dedicated AOF equipment	Differentiator
Grade C and grade D controlled spaces	Monitored and controlled temperature, pressure, air change rate for formulation and filtration	Differentiator
Single material flow	One-way raw material flow with no return to inventory; dedicated AO/AOF raw materials for manufacturing	Differentiator
Proximity to raw material and finished goods warehouse	Segregated AO/AOF raw material sampling booths; close proximity to manufacturing and distribution	Differentiator
2nd floor formulation	Gravity transfer to fill and filtration for ergonomic workflow; separate formulation suites for each tank	Differentiator
Manifold filling	Semiautomated closed manifold system	Differentiator

# Examples of Customer Liquid Projects

## Total liquid volume in 2018

- 12.4M liters of catalog and custom liquid products
- 8.4M liters Grand Island, NY, USA
- 4.1M liters Inchinnan, Scotland



## Gibco BioProduction services

- Media / buffer / concentrate development
- Process development
- Scale-up / technology transfer

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 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 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 <b>HEPES:</b> [29,000L] 29 x 1,000 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

# Large Volume Powder Repacks

## Single Component Goods

Finished in GMP controlled dispensing suites

- Available in Securitainers ( $\leq 1\text{Kg}$ )
- Available in Ropak buckets (1 – 10Kg)
- Dose specific weights offered
- Chemicals may include:
  - Tris
  - Sodium bicarbonate
  - Glucose



## Multi-Component Buffers

Manufactured in GMP powder facility

- Available in Powdertainers (1 – 25Kg)
- Available in Securitainers ( $\leq 1\text{Kg}$ )
- Available in Ropak buckets (1 – 10Kg)
- Dose specific weights offered
- Includes custom formulations



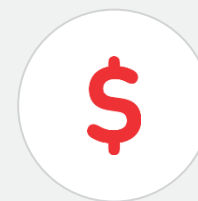
## Pre-Weighed Powders

- Eliminate labor intensive weighing steps with ready-to-use liquid or dry formats for catalog and custom formulations
- Custom packaging available to simplify connections at point-of-use
- Provide customers ease of shipping

# Outsourced Buffers Provide Cost and Time Savings

## Case Study: 0.1 M NaOH buffer cost analysis

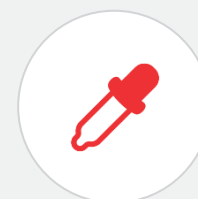
	In-house	ThermoFisher SCIENTIFIC
Batch size	2,000 L	10,000 L
Batches per year	20	4
QC releases	20	4
Prep time (2,000 L)	4 hours	1 hour
Annual prep time	10 days	2.5 days
Total batch cost	\$11,500	\$35,000
Per liter cost	\$5.75	\$3.50
Annual prep time	\$230,000	\$140,000



**\$90,000**  
annual savings



**75% reduction**  
in prep time



**80% reduction**  
in lot testing

# Buffer Economic Model

Buffer prep decisions require accurate economic cost models to evaluate options, including make vs. buy

Eric Langer, BioPlan Associates

- Interviewed 10 end-users to understand buffer prep costs
- Aggregated end-use supplied data ranges

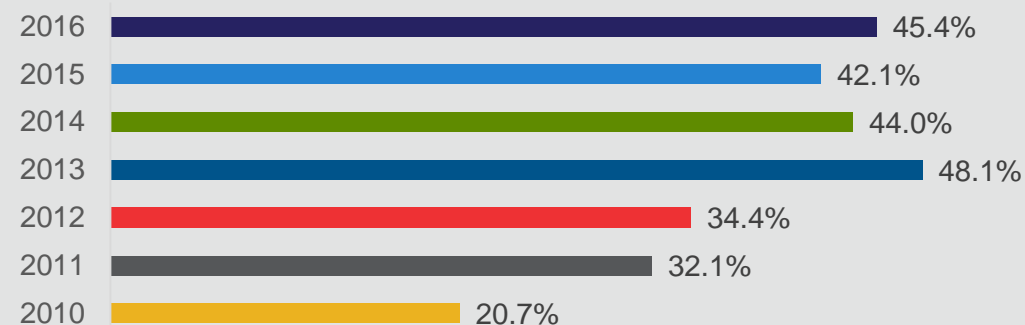
Buffer prep data entry guide

- Identify ranges for unknown costs
- Clarify cost definitions
- Ranges based on actual data collection

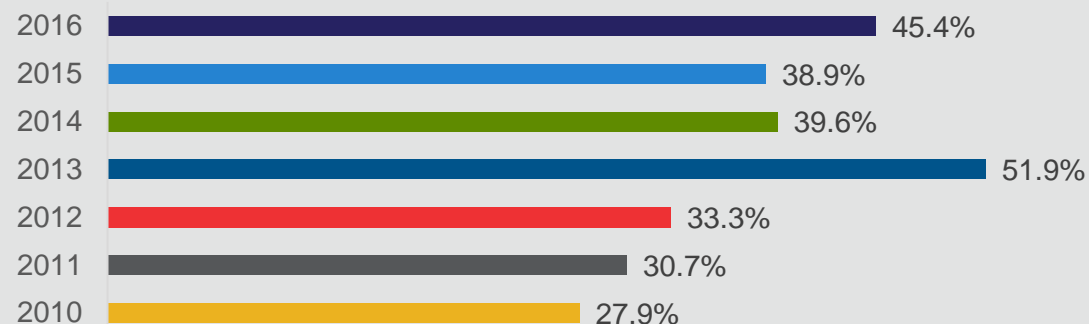
Additional information

- Contract pharma: Economics of in-house buffer preparation
- BioProcess International: Outsourcing of buffer preparation activity is increasing

## Trend in Outsourcing Upstream Production Operations



## Trend in Outsourcing Downstream Production Operations





# Cost Analysis Model

Input your facility's data here

Start here: Input your facility's annual liters buffer production

Your facility's size and type: Input here

250,000

Fixed expenses, buffer prep equipment	Calculated annual expenses	Your facility's cost: Input here
Capital facility expenses, (Buffer Prep Bldg-excl. Equip/HVAC)	\$184,936	Input your approx facility building cost (will calculate 10-Year amortization @ 4%) \$1,500,000
WFI (or RO) skid, tanks/piping (cost allocated to buffer prep-hardware)	\$42,679	Input cost for WFI, specifically installed for buffer prep => 5-Year amortization @ 4% \$190,000
Mixed buffer-only storage/holding tanks	\$17,970	Input your cost for storage, buffer prep => 5-Year amortization @ 4% \$80,000
Classified HVAC systems (allocated to buffers)	\$73,975	Input your approx facility building cost => 10-year amortization @4% \$600,000
Refrigerated storage unit (allocated to buffers)	\$86,304	Input your cost for storage, buffer prep => 10-Year amortization @ 4% \$700,000
Warehousing, facility operations, annual	\$10,000	Input warehousing cost--build (e.g., ~ \$20-\$70/ft2 or \$6-\$20/ ft2 rent) \$10,000
Utilities, electric, gas, used in buffer prep areas	\$80,000	Input annual utilities cost (est: e.g., ~ \$100k/1,000sf production space for buffers) \$80,000
Other buffer prep equipment	\$0	Input data recording, etc. Office areas, security, amenities, gowning=> \$0
Other facilities construction	\$0	Input expenses for pumps; housings; connectors; generators, etc => \$0
Automation of equipment for mixing	\$60,000	Input cost of inhouse secure electronics, data, related to buffer=> \$60,000
Filtration (equip. only, excl filter cost)	\$35,000	Input costs for, e.g., filtration-exclude filters ( filters-see variable/consumable costs) => \$35,000
Other equipment	\$0	Input any other equipment for buffer \$0
<b>Fixed costs subtotal</b>	<b>\$590,864</b>	
<b>Fixed costs per liter</b>	<b>\$2.36</b>	

Variable/staffing expenses, buffer prep	Calculated annual expenses	Your facility's cost: Input here
Validation/documentation, for buffers	\$200,000	Input your approx costs (e.g., estimate @ cost, or FTEs @\$150k (All-in Cost/FTE)) => \$200,000
Logistics, in-house	\$40,000	Input other logistics or support for inhouse buffer=> \$40,000
Quality control lab costs for buffers	\$150,000	Input buffer bioburden (LAL), quick, release; e.g., @cost, FTEs @ \$150k each => \$150,000
IT system setup and GMP, related to buffers	\$150,000	Input buffer-related IT/GMP costs FTEs @ \$150k each => \$150,000
Labor, annual, operations for buffer prep only	\$300,000	Input staff labor, annual, buffer prep only (Est @ cost; FTEs @ \$150k All-in Cost) => \$300,000
Regulatory, QA/documentation, related to buffer prep	\$75,000	Input QA cost /FTE related to buffers (Est @ cost; FTEs @ \$150k All-in Cost) => \$75,000
Repairs, labor buffer prep	\$25,000	Input typical cost of repair FTE, and related expenses \$25,000
Other G&A Labor	\$50,000	Input general and administrated staff expenses related to buffers \$50,000
<b>Variable/staffing subtotal</b>	<b>\$990,000</b>	
<b>Variable/staffing costs per liter</b>	<b>\$3.96</b>	

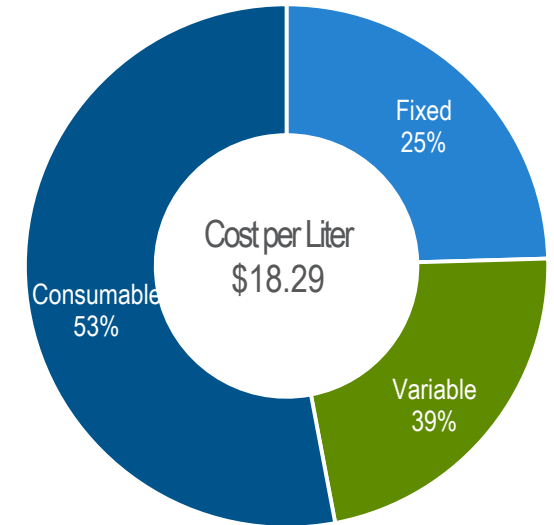
Consumable expenses, buffer preparation	Calculated annual expenses	Your facility's cost: Input here
Buffer ingredient costs	\$2,000,000	Input cost for primary buffer ingredients \$2,000,000
Other ingredients/powders	\$75,000	Input cost of other materials, buffers/reagents (per liter est)=> \$75,000
Filters and related consumables	\$500,000	Input cost for filtration and related consumables, e.g., 0.22 um filtration for buffers=> \$500,000
Single-use devices (bags, tubing, connectors, manifolds)	\$150,000	Input cost for buffer-related single-use (non-filter type) consumables, e.g., bags, tubing=> \$150,000
WFI costs, consumables, not elsewhere noted	\$0	Input other per liter WFI expenses=> \$0
Disposal expenses	\$50,000	Input disposal expense (e.g., buffers, waste, bags) => \$50,000
Other consumables, expenses	\$25,000	Input other variable costs (e.g., warehousing)=> \$25,000
<b>Consumables subtotal</b>	<b>\$2,800,000</b>	
<b>Consumables cost per liter</b>	<b>\$11.20</b>	
<b>Your total annual cost</b>	<b>\$4,380,864</b>	
<b>Your total cost per liter</b>	<b>\$17.52</b>	

Your current cost/liter for buffer production, including your all-in variable, fixed, and allocated costs

# Case Study: Cost Comparison from Economic Model and DSP Process Buffers

Cost to Outsource to Thermo Fisher Scientific				
DSP Buffer	Volume/ Batch	Unit Size (L)	Price/Unit	Price/L
Buffer 1	10950	200	\$725.52	\$3.63
Buffer 2	1300	200	\$1,203.98	\$6.02
Buffer 3	975	200	\$1,489.92	\$7.45
Buffer 4	500	200	\$1,677.65	\$8.39
Buffer 5	750	200	\$1,678.26	\$8.39
Buffer 6	200	200	\$2,499.60	\$12.50
Buffer 7	200	200	\$5,021.47	\$25.11
Buffer 8	600	200	\$1,685.18	\$8.43
Buffer 9	2400	200	\$1,008.58	\$5.04
Buffer 10	2400	200	\$4,116.65	\$20.58
Buffer 11	450	10	\$160.21	\$16.02
Buffer 12	1800	200	\$988.44	\$4.94
Buffer 13	500	200	\$3,410.10	\$17.05
Buffer 14	1600	10	\$245.10	\$24.51

Modeled Cost/L @ 500,000L annual volume*	
\$4.49	Modeled Fixed Cost
\$4.11	Modeled Variable Cost
\$9.69	Modeled Consumable Cost
\$18.29	Total Cost/L



\* Economic model developed by Eric Langer, BioPlan Associates

\*\* Assumes 20 batches/Yr

**\$** **\$5,000,000**  
potential annual savings

**Outsourcing downstream buffer manufacturing determined to be cost effective compared to modeled manufacturing costs**

# One Consistent Bioprocessing Supply Chain Partner

Free up your capacity and resources with a GMP extension of your supply chain



## Raw Materials

- Robust chemical supply chain for bio-manufacturing leveraging a breadth of suppliers and brands
- Emphasis on compliance, cost, and continuous supply



## Pre-Weighed Powders

- Eliminate labor intensive weighing steps with ready-to-use liquid or dry formats for catalog and custom formulations
- Custom packaging available to simplify connections at point-of-use



## Fully-Hydrated Bioprocessing Liquids

- Wide range of proven products, from buffers and bioprocessing liquids to time-tested Gibco™ media
- Designed to meet your specifications, including flexible BioProcess Containers (BPCs) in the size of your choice



## Warehouse and Supply Chain Management\*, including:

- Order and logistics management
- Supplier and quality management
- Custom inventory
- QC sampling
- Material handling
- ISO and GMP storage solutions

**End-to-end support from the supply and quality monitoring  
of critical raw materials to their inventory and logistics**

# Customer Success Stories with Outsourcing Large Volume Liquids

**Focused on delivering more control and choice to receive dependable, high-quality products that are designed to meet your exact bulk liquid and buffer requirements**

## Situation

- A large biotech company decided to technology transfer from one site to another and identified a need for bulk liquids

- Large biotech exceeding current capacity for downstream high-molarity NaCl and HEPES

## Our response

- Reviewed process steps and suggested the use of premade buffers to simplify the workflow

- Designed custom BPCs
- Local warehousing at a Doe & Ingalls facility

## Value delivered

- Custom bioprocess container to fit within workflow
- Custom batch size and specifications
- Delivery in 8 weeks

- Custom 1,000 L BPC design with attached tailgate samples—returnable containers
- Stability and leachable studies initiated to support outsourcing justification
- Specified raw material vendor and grade
- JIT delivery

# More Choice and Control Through Manufacturing Flexibility

The right liquid format, container, and manufacturing process for each product

## Liquid format

- Process liquids for upstream and downstream applications
- Gibco™ media and feeds for cell culture processes
- 1X and concentrates

## Container type

- Bottles from 10 mL to 1 L
- Flexible bioprocess containers from 1 to 1,000 L
- Custom designs and sizing available

## Film choice

- Industry-standard CX5-14 film for general applications
- Aegis™ 5-14 film for critical applications
- Industry-standard ASI 26/77 film for general applications

## Manufacturing speed

- Non-GMP Gibco™ Media Express™ (GME) services
- Full GMP for scale-up

Streamlined management of order, manufacturing, testing, storage, and delivery



Learn more at [thermofisher.com/bioprocessliquids](https://thermofisher.com/bioprocessliquids)





**Results matter.**

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The world leader in serving science

# EfficientFeed A+, B+, C+ Liquids

## Available in two formats

- AGT format – 1, 10, and 100 L
- Liquid format – available in 1 L boxy bottle and in 10 L bioprocess container with Aegis Film

## AGT format can be concentrated

## Liquid formats are concentrated

- EfficientFeed A+ 3X
- EfficientFeed B+ 3X
- EfficientFeed C+ 2X



# Liquid Manufacturing Process

Dispensary

Formulation

Filtration

Filling

Finishing

- POMS weigh verification system
- Raw material weighing (800+ raw materials)
- Facility monitoring system: pressure/temp/RH
- Dedicated dust collection/HVAC
- ISO cleanroom classified manufacturing rooms
- Segregation: dedicated weigh rooms/booths with  $\Delta P$



# Liquid Manufacturing Process

Dispensary

**Formulation**

Filtration

Filling

Finishing

- SS tank sizes of 200 L to 10,000 L, portable Nalgene tanks 10–400 L
- AOF 5,000 L and 10,000 L tanks and associated suites
- AOF 2,500 w/ alcohols, 5,000 and 10,000 L tanks in LVLM
- Facility monitoring system: pressure & temp monitoring
- ISO cleanroom classified manufacturing spaces
- Validated CIP/COP processes



## Water For Injection

- $\text{TOC} \leq 500 \text{ ppb}$
- $\text{Bioburden} \leq 10 \text{ CFU/100 mL}$
- $\text{Endotoxin} < 0.25 \text{ EU/mL}$
- $\text{Conductivity} \leq 1.2 \text{ uS/cm}$
- $\text{pH } 5.0\text{--}7.0$



# Liquid Manufacturing Process

Dispensary

Formulation

Filtration

Filling

Finishing



## Manual filling

- Aseptic fill into irradiated bottles and bags
- Dedicated HVAC
- Qualified ISO 7 annually
- Qualified ISO 5 annually
- Environmental monitoring program
- Media fill validation program
- Facility monitoring system: temp/pressure



## Autofillers

- Aseptic fill into irradiated bottles and bags
- Dedicated HVAC
- Qualified ISO 7 annually
- Qualified ISO 5 annually
- Environmental monitoring program
- Media fill validation program
- Facility monitoring system: temp/pressure



## Manifold Filling

- Aseptic fill into irradiated BioProcess Containers (BPC)
- Steam In Place final filters and BPC connections
- Pressure hold test, followed by positive pressure
- Filling room qualified Grade C per Annex 1
- Environmental monitoring program
- Media fill validation program
- Facility monitoring system: temp/pressure



# Liquid Manufacturing Process

Dispensary

Formulation

Filtration

Filling

Finishing

- Application of final bottle torque, bag seal, tamper-evident seal and labels
- Three automated packaging lines: 100 bottles/min
- Label verification and reconciliation

## Bottle features

- Wide mouth/no drip spout/flat sides for easy handling
- Ultra-clear PET/virtually unbreakable
- Industry standard heat inactivation (HI)–compliant
- 100 mL, 500 mL, and 1,000 mL



## Media bag features

- Easily customized (connections, in-line filtration, flow rates, tubing lengths, recirculation loops, etc.)
- 1 liter through 1000 liters

