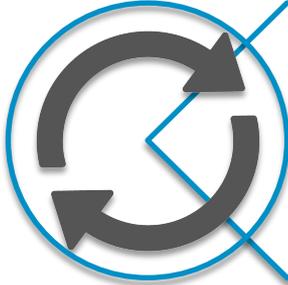


## **Large Volume Liquid Manufacturing Capabilities**

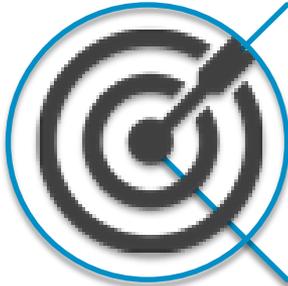
# Superior Liquids for Bioprocess Applications

*Greater choice and control over your bioprocesses through smart, simple and integrated solutions*



## **Product Continuity**

- Integrated global locations to help ensure security of supply
- Assurance of supply for films, resins and liquid raw materials
- Dedicated Project Management helps ensure customized support and process visibility



## **Consistency**

- Harmonized in-house liquid and bag manufacturing
- GMP, ISO 9001 and 13485 certified facilities
- AOF formulation, filling and filtration for liquids



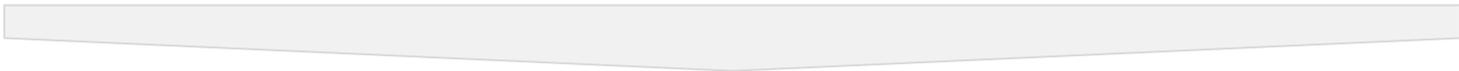
## **Standardization**

- Eliminate the need to use varying types of bioprocess containers throughout your process
- Eliminate the need to validate multiple types of bioprocess films throughout your process

# More Choice & Control Through Manufacturing Flexibility

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

<b>Liquid Format</b> <ul style="list-style-type: none"><li>•Process liquids for upstream and downstream applications</li><li>•Gibco® media and feeds for cell culture processes</li><li>•1x and concentrates</li></ul>	<b>Container Type</b> <ul style="list-style-type: none"><li>•Bottles from 10mL – 1L</li><li>•Bags from 1L – 1000L</li><li>•Custom designs and sizing available</li></ul>	<b>Film Choice</b> <ul style="list-style-type: none"><li>•Industry standard CX5-14 for general applications</li><li>•Aegis™ 5-14 for critical applications</li></ul>	<b>Manufacturing Speed</b> <ul style="list-style-type: none"><li>•Non-GMP Rapid Prototyping Service</li><li>•Full GMP for Scale Up</li></ul>
--	--	--	--



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



Learn more at: <http://thermofisher.com/bioprocessliquids>

# Integrated Global Locations Ensure Security of Supply

## Cramlington, UK

- 8000 ft<sup>2</sup> of class 10,000/ISO 7 clean room
- Film-to-finish capabilities
- Harmonized processes and systems



## Newport, UK

- ISO 9001:2008



## Paisley, Scotland

- cGMP Manufacturing-ISO 13485
- Liquid Area: Batches up to 10,000L
- Core Powder Area: Blending up to 5000Kg
- AOF Powder Area: Blending up to 1800Kg



## Logan, UT

- 2 facilities with 31,000 ft<sup>2</sup> of class 10,000/ISO 7 clean room
- 5 automated production lines with full film-to-finish capabilities

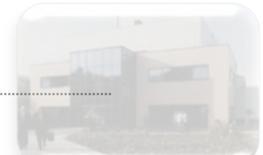


## Warrington, UK

- Analytics kits

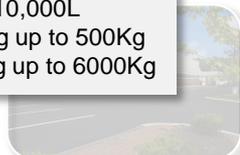
## Suzhou, China

- ISO 13485
- ISO 9001
- ISO 14001



## Grand Island, NY

- cGMP Manufacturing-ISO 13485
- Liquid Area: Batches up to 10,000L
- Core Powder Area: Blending up to 500Kg
- AOF Powder Area: Blending up to 6000Kg



## Rochester and Fairport

- ISO 9001:1994
- FDA Registered Facility



## Naarden, The Netherlands

- Affinity ligands

## Bedford, MA

- Chromatography resins
- ISO 13485

## Miami, OK

- ISO 9001:2008

## Auckland and Christchurch, New Zealand Newcastle, Australia

- Sera
- Protein products
- GMP 21 CFR 820

# Doe & Ingalls: Production Chemicals & Distribution

Extension of your supply chain management and finished good distribution



## Mitigate Risk

- Quality compliance & raw material traceability
- On-time delivery & back order management
- Change notice & corrective action management



## Increase Productivity

- Dedicated account management team
- Raw material handling services
- Supplier management
- Documentation management



## Reduce Costs

- cGMP chemical storage
- Inventory solutions
- Increased lots & consolidated shipments

# Current cGMP Liquid Manufacturing Capacity

		Grand Island, USA	Inchinnan, Scotland
Bottled liquids	(10ml – 2L)	✓	✓
Bagged liquids	(1L – 1,000L)	✓	✓
Batch sizes	(10L – 10,000L)	✓	✓ (Sept 2015)

	Grand Island, USA	Inchinnan, Scotland
Flexibility	<ul style="list-style-type: none"> <li>• 24 hours x 5 days bottled liquids</li> <li>• 24 hours x 5 days bagged liquids</li> </ul>	<ul style="list-style-type: none"> <li>• 12 hours x 5 days bottled media</li> <li>• 12 hours x 5 days bagged media</li> </ul>
Risk Mitigation	Can expand to work 24/7	

# Examples of Customer Liquid Projects



## Total Liquid Volume in 2014

- 7.4 M liters of catalog and custom liquids
- 1.8 M liters in bags
- 5.6 M liters in bottles

Liquid Type	Customer Product and Annual Volume Examples
Cell Culture Media	<b>GMEM:</b> [66,000L] 330 x 200L bag <b>Custom media formulation:</b> [462,500L] 925 x 500L bag <b>AIM V® T cell Medium:</b> 15,000 x 1L bag
Feeds and Additives	<b>10% Antifoam:</b> [13,000L] 2600 x 5L bag <b>CHO CDEfficientFeed™ A:</b> [3,800L] 760 x 5L bag <b>BME:</b> 8130 x 1L bottle
Process Liquids	<b>Sodium Citrate:</b> [90,000L] 450 x 200L bag <b>PBS:</b> [32,000L] 1600 x 20L bag <b>WFI:</b> [28,000L] 2800 x 10L bag
Concentrates	<b>CD CHO concentrate:</b> [296,400L] 1,800 x 150L bag + 1,320 x 20L bag <b>1000x CD Lipids:</b> [3,900L] 1950 x 2L bottle

# Expanded Choice in BPC Film for Liquids

## Film Choices for Liquids

- CX5-14 and Aegis BPCs are validated for liquid fills and shipments from Grand Island and Inchinnan
- Extractables and leachables data package available for each film
- Stability data in progress for liquids in CX5-14 and Aegis
- Continued supply of liquids in existing orders in 9101 and BF-1400 BPCs



CX5-14 Film



Chamber Inspection



Biocenter (Logan, UT)



Final Assembly

# Aspiration: Best in Class Large Volume Liquid MFG

Large Volume Liquids increase biopharmaceutical process efficiency and helps reduce risk by simplifying and standardizing workflows



## Why ?

- Outsource partnership / manufacturing extension
- Pronounced synergies with vertical integration
- Existing liquid / SUT expertise
- Enables cost reduction for customers

## What ?

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

2014

- Launch integrated custom LVL portfolio
- Grand Island expansion project scope

2015

- LVL new facility construction
- WFI launch (20 & 200L)

2016

- Facility / equipment implementation
- Validation

# Design Criteria & Quality Standards

To meet current and future customer requirements for insourcing Large Volume Liquids, our manufacturing facility will be built to the following standards:

- ISO 13485
- 210/211 CFR related to sterile filtration
- Annex 1 standard
- Animal Derived Component Free (ADCF)
- Controlled spaces
- Grade C & Grade D
- Single material flow
- Proximity to FG warehouse
- Proximity to RM warehouse
- 2nd Floor formulation

# Scope of Expansion

## Facility Footprint

15,000 ft<sup>2</sup>  
manufacturing over  
2 floors

12,400 ft<sup>2</sup> finished  
good warehouse  
space

Clean room,  
gowning, storage,  
formulation and  
staging

## Equipment Deployed

Multiple 10,000 liter  
tanks

5,000 liter tank(s)

2,500 liter tank(s)

## Support Systems

WFI still

HVAC

Clean steam  
generation

Compressed air

