

# Empowering your speed, scale, and supply

Continuing our commitment to providing a dependable  
supply of innovative cell culture solutions



Over recent years, there has been unprecedented demand for key bioproduction materials. This, combined with significant disruption to global supply chains, has left many biologic developers and manufacturers struggling to meet their scheduled timelines. As a result, it has never been clearer that establishing a robust supply chain for critical raw materials is essential.







One way that developers and manufacturers can improve supply security is by qualifying secondary and tertiary raw material suppliers. However, validating that the supplier can meet your individual requirements may take significant time. This can be compounded by the increased time required to manage a larger supply network. As such, it is vital to choose an experienced raw material supplier with established qualification protocols.

Since the foundation of the Grand Island Biological Company (GIBCO) in 1962, the Gibco™ brand has become synonymous with innovative cell culture products and in-depth technical support services. Additionally, throughout its history the Gibco

brand, now part of Thermo Fisher Scientific, has been supported by a history of redundant manufacturing capabilities and detailed raw material handling protocols across a global network.

At Thermo Fisher Scientific, we are committed to continuing this legacy, pursuing continual innovation to meet the bioprocessing challenges of tomorrow. We are also proactively investing in expanding our manufacturing capacity with the same high quality standards and site harmonization you have come to expect from us. Through this, we are striving to continue empowering biopharmaceutical developers and manufacturers around the world to achieve their bioprocessing goals.

# A global network to support your bioproduction needs

To provide an uninterrupted supply of bioprocessing solutions, we have established a comprehensive network of manufacturing facilities. This network enables us to offer robust supply assurance and consistent product quality to biopharmaceutical developers and manufacturers wherever they are in the world.



## North America


- Grand Island, New York**
  - Media, reagents, sera
  - Media and analytical services
  - Rapid prototyping labs
  - ISO 13485, 21 CFR 820, and MDSAP-certified
  - FDA-registered
- Miami, Florida**
  - Media, reagents, supplements, peptones
  - Animal origin-free facility
  - ISO 9001-certified
- Detroit, Michigan**
  - Peptones
  - ISO 13485-certified
- Baltimore, Maryland**
  - Media and analytical services
  - Rapid prototyping labs

## Europe

- Paisley, Scotland**
  - Media, reagents, sera, primers
  - ISO 13485 and 21 CFR 820-certified
  - FDA-registered
- Vilnius, Lithuania**
  - Supplying magnetic beads for cell therapy applications
- Oslo, Norway**
  - Dynabeads development
  - Dynabeads services
  - ISO 13485-certified

## Asia-Pacific

- Auckland, Christchurch, and Nelson, New Zealand**
  - Sera, animal proteins
  - ISO 9001 and 21 CFR 820-certified
  - FDA-registered
- Newcastle, Australia**
  - Sera
  - ISO 9001 and 21 CFR 820-certified
  - FDA-registered
- Shanghai, China**
  - Media development services
  - Rapid prototyping labs (coming soon)
- Singapore, Singapore**
  - Media development services
  - Media and analytical services
- Incheon, South Korea**
  - Distribution center



## Expanding our manufacturing capabilities, adding capacity, and shortening lead times

A key part of our commitment to supporting our customers is constantly evaluating our manufacturing network, and proactively investing in expanding our capacity to meet global demand.

To achieve this, we are making over \$650 million of capital investment to enhance our bioprocessing production capabilities. This will involve expanding capacity at several of our manufacturing facilities and within our distribution network.

This includes increasing production of all dry media formats, including our proprietary Gibco™ Advanced Granulation Technology (AGT™) format, at our Grand Island, New York and Paisley, Scotland sites. We are also adding additional dry powder

media manufacturing capacity at our Miami, Florida site and opening a new customer distribution center in Incheon, South Korea.

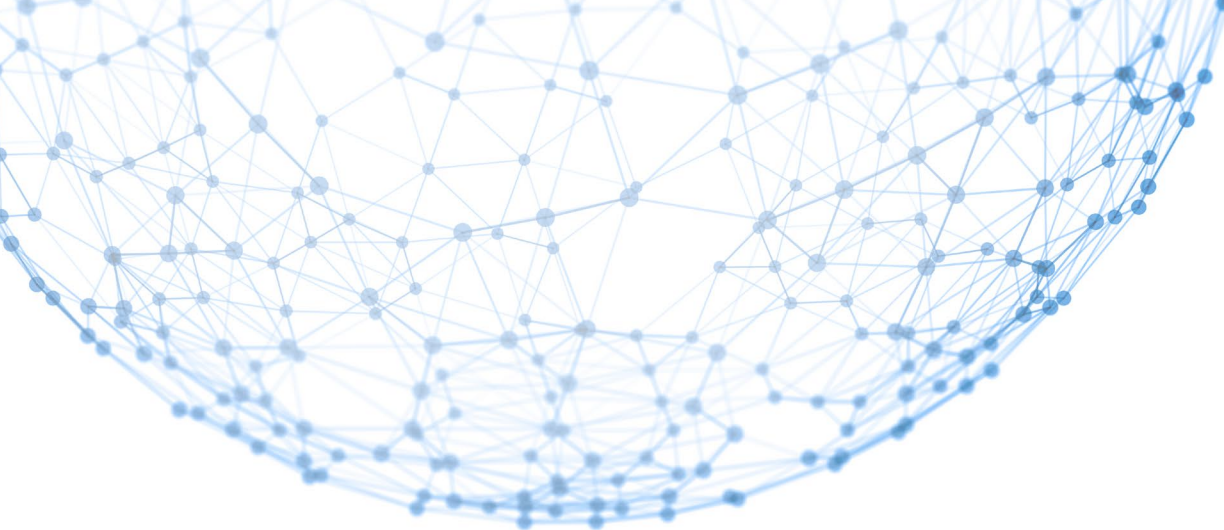
Together, these investments will enable us to improve global supply capacity, helping to reduce lead times and meet our commitments to our customers. Crucially, these investments are being implemented with the same high quality and process harmonization standards as our existing network, giving you confidence that consistent product quality will continue to be achieved at every site.

### Grand Island, Miami, and Paisley dry powder media manufacturing process comparison

Stage	Process	Grand Island	Miami	Paisley
<b>Dispensing</b>				
	POMS electronic weigh verification system	●	●	●
	Facility monitoring system: temp/RH	●	●	●
	Dedicated dust collection/HVAC	●	●	●
	.1% weigh tolerance	●	●	●
<b>Milling</b>				
	FitzMill™	●	●	●
	Pin mill	N/A	●	†
	Particle size analysis	●	●	●
<b>Blending</b>				
	Homogeneity criteria	●	●	●
	Facility monitoring system (temp/RH)	●	●	●
	Content uniformity	●	●	●
<b>Filling</b>				
	Tamper evident, fill tolerance and automated packaging	●	●	●

† Adding Pin mill capability at Paisley site





# Empowering bioprocessing around the world

To provide a dependable supply of innovative, end-to-end bioprocessing solutions on a global basis, we undertake careful strategic planning to meet the latest industry needs. This planning is made up of three core elements, encompassing both our products and services, as well as our manufacturing and supply network.

## Advanced bioprocessing solutions

Enabling our customers to achieve their bioprocessing goals is at the center of everything we do. To meet this commitment, we aim to provide a broad range of high-quality, scalable products

that can support all types of biologic manufacturing, including cutting-edge solutions for emerging therapeutic modalities.

## Our recent product releases include



### **Gibco™ Efficient-Pro™ Medium and Feed System**

A revolutionary medium and feed system for CHO workflows, optimized to elevate protein quality and improve process productivity



### **Gibco™ Bacto™ CD Supreme Fermentation Production Medium (FPM)**

The first chemically defined medium for microbial fermentation, developed to support high-density *E. coli* cultures



### Gibco™ Freedom™ ExpiCHO-S™ Kit

Our latest stable clone development kit, a beginning-to-end solution for the cloning and expression of recombinant proteins, supported by a simplified commercial licensing program



### Gibco™ High-Intensity Perfusion CHO Medium

An innovative, easy-to-use, chemically defined, and animal origin-free medium, designed for use at all perfusion cell culture workflow stages



### Gibco™ Viral Vector HEK Media Panel

A nutritionally diverse panel of media options suitable for a wide range of HEK293 cells, intended to accelerate AAV-based gene therapy process development



### Gibco™ CTS™ OpTmizer™ Pro Serum Free Medium (SFM)

A novel, serum-free medium, formulated to support the growth and expansion of human T lymphocytes used in allogeneic cell therapies

Alongside our comprehensive product range, we also offer extensive optimization services. Through our Gibco™ PD-Express™ Services, you can benefit from years of innovation in cell culture media optimization processes and dedicated technical experience for cell line, media, and process development. This includes access to our [advanced multi-omics analysis](#) and [rapid media prototyping capabilities](#), which can help accelerate media development and help you optimize process performance.

You can also benefit from our comprehensive raw material characterization and trace element analysis program. This can enable you to improve the predictability of your media formulations and reduce lot-to-lot variability.

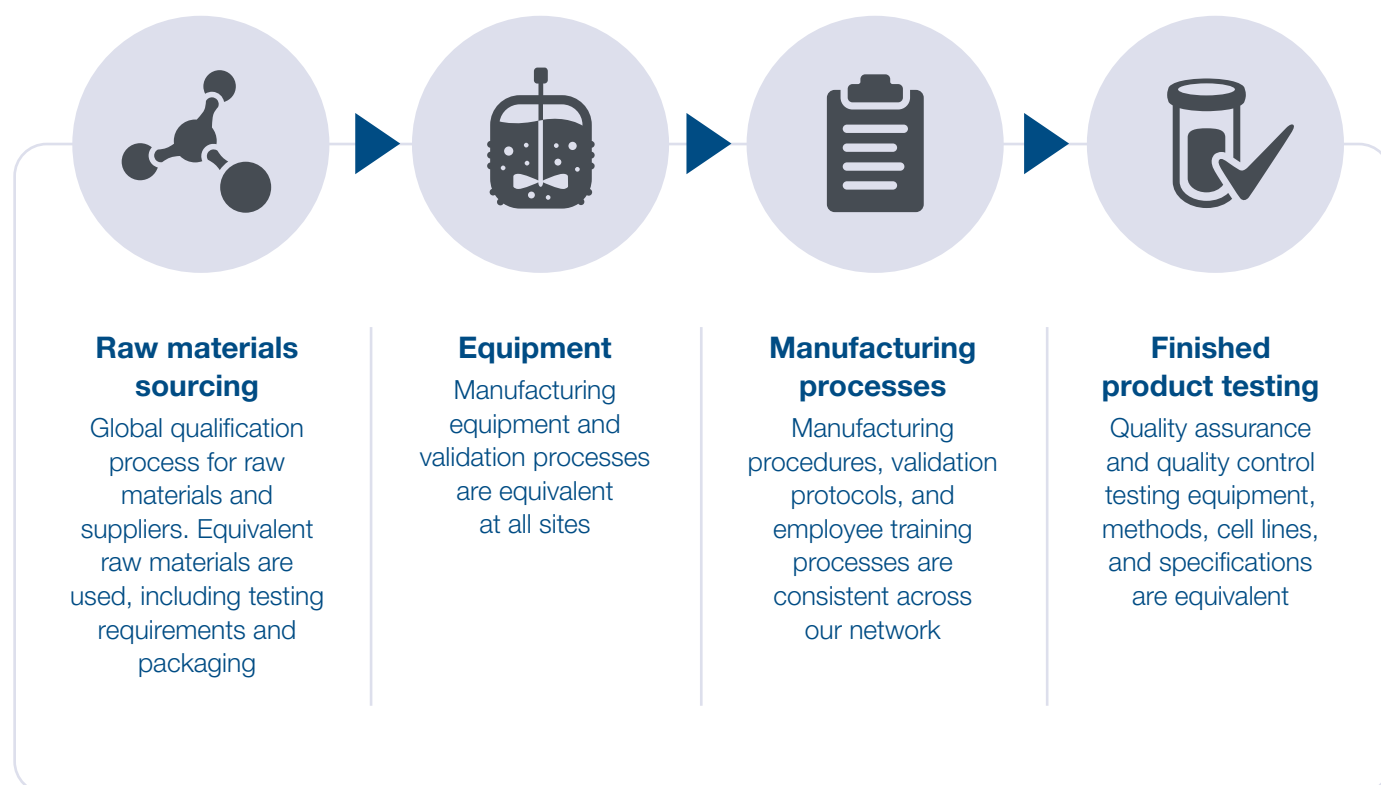
By combining our expertise, open and transparent approach to communication, and state-of-the-art products, we can provide complete workflow solutions that help you enhance your process and accelerate your product to market.


## Facilities harmonization

Within biopharmaceutical manufacturing, process and product consistency are both vital for success. Central to achieving this is utilizing high quality and consistent cell culture media, supplements, and other cell culture products, including buffers and reagents.

To maintain the consistency of Gibco products, we have established an in-depth global equivalency program which is implemented at all manufacturing sites within our network. This program includes harmonized capabilities across four key areas: raw materials sourcing, equipment, manufacturing processes, and finished product testing.

As a result of these efforts, you can rely on consistent quality products, regardless of the manufacturing site, supporting you to achieve optimal results within your process.



 To find out more about our facilities harmonization, and how we achieve equivalence at each of our sites, take a virtual facility tour: [www.thermofisher.com/gibcotours](https://www.thermofisher.com/gibcotours)





## Maintaining global redundancy

Avoiding critical raw material shortages is vital for biopharmaceutical developers and manufacturers at all stages of production. During the early phases, this is essential to allow process development to be completed on schedule. This is also key during the later manufacturing phases to prevent costly delays caused by production stoppages or, in the worst-case scenario, late-stage process amendment and revalidation.

Through careful planning and in-depth risk mitigation practices, our global manufacturing network has been strategically designed to maximize supply assurance and minimize delays. Our risk mitigation measures include:

- Proactive identification and qualification of new sources of key raw materials
- Continual investments in targeted areas of inventory to support growth

- Utilizing demand intelligence in forecasting to stay ahead of future supply chain disruptions
- Detailed customer notification programs for product specification changes
- Back-up power of our critical environment systems for up to seven days

Together with our in-depth equivalency approach, this enables us to offer dependable global manufacturing redundancy to our customers across the world, reducing the risk of supply disruption and delays. Overall, these measures are crucial to support our ability to manufacture products at the speed and scale you need, even during challenging times.





## Supporting your bioprocessing success from development to commercial manufacturing

We aim to provide the same level of support and expertise to customers regardless of their current workflow stage. Whether you begin working with us during early discovery or later during development, we endeavor to fulfil your unique project requirements.

One way that we can optimize the ability to meet your needs throughout your bioprocessing journey is by collaborating to discuss your future needs. Specifically, as you scale up, accurate forecasting of product and service requirements can help us to maintain consistent delivery. To streamline this process, we have dedicated sales, customer service, and program management teams who can work closely with you to support forecasting and understand your current and future needs.

Alongside our support teams, we also offer an easy-to-use online Bioproduction Customer Portal which enables you to track your orders, access documentation, and request additional support to help you manage your account. By providing these options, we can meet your preferred level of supplier involvement, while maintaining the highest level of supply assurance and helping you keep your timelines on track.





## Find out how we can support you

Backed by 60 years of bioprocessing knowledge and innovation, we are dedicated to supporting the biopharmaceutical industry by providing state-of-the-art Gibco products and trusted technical support services.

With our proven equivalency, innovative products, and teams of experienced bioprocessing professionals, you can rely on us to be a dependable cell culture solutions provider. No matter the size of your organization, your current workflow stage, or location,

we can work with you to meet your organization's requirements. To discover how we can help you achieve your project goals, [contact a local Thermo Fisher bioproduction representative.](#)



 Learn more about our global network and equivalency approach at [\*\*thermofisher.com/media-manufacturing\*\*](https://thermofisher.com/media-manufacturing)