Secure your custom media supply with manufacturing capacity and quality you can trust.

As demand increases and supply chains become more complex, having a reliable, quality-focused media supplier isn't just an advantage—it's a necessity. Discover how Gibco™ manufacturing capabilities and secondary supply solutions can help strengthen supply continuity and support your biopharmaceutical operations from development through commercial production.

Build resilience into your bioproduction network.
Learn how at **thermofisher.com/media-manufacturing**

gibco

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This brochure walks you through how Thermo Fisher Scientific helps biopharmaceutical manufacturers operate with confidence at every stage of growth. From the challenges of global supply volatility and regulatory pressure, to proven solutions, world-class manufacturing capabilities, and a resilient multi-site supply network — explore how Gibco can serve as your trusted primary or secondary media supplier, and see real-world case studies that demonstrate the impact of that partnership.

Click the arrows below to navigate to the page/section you require.

Manufacturing excellence matters more than ever

Today, biopharmaceutical manufacturers operate in an environment defined by:

Global supply volatility

Geopolitical instability, raw-material constraints, and transport risks threaten media continuity

Ambitious growth

New facilities, higher titers, and global expansion require a scalable, dependable supply network

Tight regulatory oversight

Any supplier or material change demands validation, documentation, and time-intensive risk assessments

Margin pressure

Rising input costs meet pricing constraints, pushing teams to balance reliability and efficiency

Pressure to deliver consistently

Process variability translates to yield loss, product quality deviations, and costly rework

Every batch counts—a single upstream disruption may ripple through a manufacturing network, cost millions, and delay therapies to patients

The pain behind the process—operational burden

What are the key operational challenges facing biopharma manufacturers?

- Supply interruptions cause production downtime and delayed delivery commitments
- Lot variability can require requalification needs, potential yield loss
- Documentation and change-control burdens may extend release timelines
- Limited scalability adds constraints during scale-up or commercial launch
- Margin compression and operational inefficiencies can add cost pressures

What is needed?

- Resilient, dual-source media supply to help ensure business continuity
- Consistent, validated performance to maintain process reliability
- Robust, regulatory-ready documentation to support efficient qualification and audit readiness
- Scalable production capacity that aligns with clinical and commercial growth
- A collaborative, solutions-oriented engagement that functions as an extension of your team

Working together to achieve your outcomes

A trusted collaborator focuses on enabling your operational goals through:

- Multi-site manufacturing for continuity
- Stringent quality systems help ensure reproducibility
- Full change-control and traceability documentation
- Flexible scaling from development to commercial
- Transparent, responsive collaboration

Batch confidence is gained with:

- Stable, predictable supply across facilities
- Decreased production delays and documentation headaches
- Simplified qualification and compliance
- Scalable capacity for growth
- Reduced total cost of risk

Our manufacturing capabilities and secondary supply enable reliability at scale — so you can focus on science, not supply.

Understanding media manufacturing for bioproduction

We can work with you to optimize your own proprietary formulation — from small-scale to large-scale current good manufacturing practice (cGMP) supply — and offer choices in format options.

- Focus on your core competencies
- Improve process performance
- Enhance manufacturability of your medium
- Improve quality with consistent raw materials

We can help troubleshoot your processes or provide your formulation in any of the following formats:

- Liquid
- Liquid concentrates
- Dry powder media (DPM)
- Gibco™ Advanced Granulation Technology™ (AGT™) media

Overview of our cGMP manufacturing services

Our biomanufacturing services offer competitive turnaround times and batch sizes to meet a global commercial output—consistent, reliable, and scalable solutions.

- Large-scale media manufacturing for clinical or commercial biomanufacturing applications.
- 8- to 10-week turnaround target.
- Batch, fed-batch, or perfusion.
- Mammalian or microbial platforms.
- Multiple formats available (liquid, liquid concentrates, DPM, and AGT format).
- Both pin mill and FitzMill™ technology capabilities.
- Innovative add-mix capability that uses liquid media concentrates (LMC) to produce 30,000 L batches of liquid mediaMedia format.

Media format	Batch sizes**
Gibco™ liquid media	10 L to 10,000 L
Gibco™ dry powder media (DPM)*	1 kg to ~5,000 kg
Gibco™ Advanced Granulation Technology™ (AGT™) media format*	50 kg to 1,000 kg

*** Based on bulk density/production suite.**
**** Sizes can be customized to meet your needs.**

Focus on your core competencies	Improve process performance	Enhance manufacturability of your medium	Improve quality with consistent raw materials

The value of a secondary supplier in biologics manufacturing

Mitigating risks and ensuring supply continuity

- **Mitigating supply chain disruptions:** Secondary suppliers help maintain production continuity during disruptions caused by natural disasters, geopolitical instability, or supplier failures.
- **Risk management:** Reduces dependency on a single supplier, thereby minimizing risks associated with supply shortages and quality issues.

Enhancing operational flexibility and capacity

- **Increased capacity:** Dual sourcing allows for scaling up production capacity to meet increased demand without compromising quality.
- **Vendor independence:** Enables flexibility and independence from primary suppliers, supporting a more robust supply chain.

The value of a secondary supplier in biologics manufacturing

Regulatory compliance

Supporting regulatory guidance

Regulatory agencies recommend contingency plans for critical raw materials to facilitate continuous supply. Secondary suppliers help meet these recommendations, also supporting continuous supply.

- Risk reduction and redundancy
- Contingency planning for your supply chain
- cGMP and raw-material risk management

Cost and quality management

Enabling efficiencies

Having multiple suppliers can lead to better negotiation leverage, supporting cost savings and mitigating supply chain risks from price fluctuations.

Quality assurance and supplier qualification

Enables comparison of material quality from different suppliers, maintaining high standards and compliance with GMP, which involves robust supplier qualification systems and raw material testing strategies.

Our global supply network

Harmonization of quality standards and practices at our global facilities helps to provide consistent quality and supply worldwide.

North America

Grand Island, New York
Media, reagents, sera · Media and analytical services · Gibco™ Rapid Prototyping Service lab · Multi-site ISO 13485, 21 CFR 820, MDSAP-certified · FDA-registered

Miami, Florida
Media, reagents · Animal origin–free facility · ISO 9001

Detroit, Michigan
Peptones · Multi-site ISO 13485

Baltimore, Maryland
Media and analytical services · Gibco Rapid Prototyping Service lab

Europe

Paisley, Scotland
Media, reagents, sera · Multi-site ISO 13485, 21 CFR 820 · FDA-registered

Vilnius, Lithuania
Magnetic beads

Asia-Pacific

Oceania (New Zealand & Australia)
Sera, animal proteins · ISO 13485, 21 CFR 820 · FDA-registered

Shanghai, China
Media development services

Suzhou, China
Gibco Rapid Prototyping Service lab

8 **Global facilities** across 3 continents

3 **Harmonized** manufacturing sites

3 **Rapid Prototyping** Service labs

118 **Countries** served

Manufacturing capacity across our global network

A global footprint and redundancy in key capabilities at our facilities support an uninterrupted worldwide supply with a broad range of network capacities.

1. Large-capacity, purpose-built, and segmented (animal origin and animal origin–free) manufacturing facilities
2. Facilities are strategically located to help ensure ultimate redundancy, capacity, and continuity

Blender size by site

Site	Tbl	30 ft³	50 ft³	1500 kg	75 ft³	4500 kg	200 ft³	300 ft³
Grand Island	2	1			3		1	1
Paisley	3			1*	2	1*		
Miami			1**				1	

Media format	Grand Island	Paisley, Scotland	Miami	Detroit
AGT format	297,000 kg	225,000 kg	-	-
AOF	610,000 kg FitzMill technology	50,000 kg FitzMill & Pin mill technology	750,000 kg FitzMill & Pin mill	-
AO (powder)	670,000 kg FitzMill technology	400,000 kg FitzMill technology	-	-
AO peptones	-	-	-	610,000 kg FitzMill technology (milled in Baltimore)
Liquids (core)	9.6 million L	4 million L	625,000 L	-
Level (BPCs)	3.5 million L	3 million L	-	-

FitzMill is a trademark of IDEX MPT, Inc.

Packaging solutions

We can produce your media with packaging and labels customized to the needs of your project, helping to reduce risk and improve operational efficiency in your workflow.

1. Custom sizes
2. Exceptional Thermo Scientific™ films
3. Single-use technology
4. Extensive components library
5. Rigid containment product portfolios
6. Easy integration — support with drawings, implementation, and tech transfer

Media format	Packaging	Manufacturing option	
		cGMP	Gibco rapid prototyping service
Liquid	Vials	1.8, 5, 10, and 20mL	
	PET bottle	1.8, 5, 10, and 20mL	
	BPCs	1.8, 5, 10, and 20mL	
	Custom BPC options	1 L to 1,000 L	
DPM and AGT format	Drum bags, top ports	100, 200, 500, 1,000 L	-
	PP container	42, 180, 327, 1,155 mL	
	HDPE buckets	1, 2.1, 3.7, 5, 6 gal	1 and 2.1 gal
	HDPE drums	20, 30 and 55 gal	-

Supply resiliency

Our four pillars of equivalency

Site equivalency and harmonized processes help us produce the same quality product at each site

Raw materials supplier

Inventory specifications and review process

Equivalent manufacturing

Processes, validation steps, and staff training

Core equipment

Offers product homogeneity, validated at the same standards

Test equipment

QC release testing, cell lines used, and specifications are identical

Harmonized sites: Grand Island, NY / Miami, FL / Paisley, Scotland

Raw materials

1 Dual sourcing

- Dual sourcing established for 630+ raw materials
- Enhances material availability and reduces supply interruptions

2 Inventory management

- Safety stock programs and strategic pre-buys help maintain continuous supply
- Offers production stability during fluctuating demand

3 Increased allocations

- Strong supplier partnerships help secure priority access to key materials
- Reduces risk of shortages for critical components

4 Quality agreements

- Expanded quality agreements with key suppliers strengthen quality oversight
- Ongoing review of change notifications helps ensure transparent communication

5 Strategic relationships

- Long term supplier collaborations reinforce reliability across the supply chain
- Shared focus on consistent performance and supply continuity

Integrated approach designed to help support reliable, on-time material supply

Process requirements and QMS equivalency

Aligned manufacturing processes and quality management systems produce resiliency across our network.

Manufacturing process requirements

- Raw material supply and management
- Raw material testing and release criteria
- Electronic weighing verification
- Cell culture water (WFI or MiliQ water)
- Manufacturing environment control (temperature, relative humidity)
- Liquid in-process testing (solubility, pH, osmo)
- Mixing dynamics

Quality management systems

- Quality management systems
- Finished good release testing
- Raw material testing and release criteria
- SKU setup and management
- Complaint management (Trackwise)
- Raw material trace element impurity testing
- Equipment validation/qualification
- Packaging materials
- Training and learning management systems
- Batch record review process tracking
- Equipment calibrations

Core equipment

Our equipment, validation steps, and staff training are harmonized across the Miami, Grand Island, and Paisley sites, which offers product homogeneity.

Dry powder media (DPM)

- FitzMill
- Pin Mill
- V-Blenders
- Cone blenders
- Drum blenders
- Ribbon blenders
- Homogeneity criteria

Based on internal Thermo Fisher studies, Pin and FitzMill are comparable:

- Pin Mill offers smaller particle size, lower bulk density, and slightly greater turbidity than FitzMill.
- Potential impact of particle size and bulky density difference is blending and packaging.
- Potential impact of greater turbidity is dissolution rate.
- FitzMill and Pin Mill offer comparable dissolution, pH, osmolality, and powder appearance (color).
- Raw material recovery (amino acid, vitamins, polyamines, and trace metals) is comparable using both technologies as demonstrated by analytical test results.

Core equipment

Liquid media

- Stainless steel tanks
- Thermo Scientific™ Nalgene™ tanks and liners
- Mixing design (overhead)
- Dispensary materials
- Filter pore size

Quality

Our world-class facilities receive over 200 customer audits a year to confirm compliance.

- Quality testing is harmonized across the network
- Approximately 90% of our raw materials come from established markets
- Raw material audit program
- Detailed certificate of analysis (CoA) provided for quality assurance
- Ongoing risk management using a scoring matrix, regularly rescored to monitor changes
- Raw material impurity testing*

Strict raw materials supplier qualification

Technical questionnaire → **Audit** → **Technical questionnaire** → **Supplier (approved / not approved)**

- Multiple lot testing
- Certification
- Audit
- Vendor scoreboard
- Ongoing audit/testing

*** Available as a custom service.**

Technology transfer and protection of intellectual property

We offer a streamlined technology transfer while maintaining confidentiality and protection of customer intellectual property (IP). You can rely on our deep experience and uncomplicated communications to accelerate your projects.

Confidential information management
Handled according to established confidentiality practices — R&D will never have access to your formulation

Employee confidentiality
Proprietary files exchanged through restricted, password-protected systems

Controlled data access
R&D and manufacturing functions operate separately to manage information flow

Collaborative transfer process
Program and technical teams coordinate to support accurate information exchange

Secure information sharing
Proprietary files exchanged through restricted, password-protected systems

Gibco VeriCert Exchange Services
Securely facilitates the transmission of quality control release data for custom cell culture media and raw material components

Key points

- Your intellectual property is protected through strict confidentiality systems
- Access to advanced technologies helps accelerate your work
- Clear, uncomplicated communication supports a smooth tech transfer process
- Our teams meet your strategic, technical, and quality needs with a customer-centric approach
- Extensive experience in quality systems, manufacturing, engineering, and process science enables reliable guidance
- Dedicated support teams are available whenever you need experienced answers and solutions

Formats offered and comparisons

Liquid media	Dry powder media (DPM)	Advanced Granulation Technology (AGT) media
		
• Ready-to-use solutions • High shipping and storage costs • Require cold storage facilities	• Reduced shipping and storage requirements • Complex hydration process: Hydrate, Dissolve, Adjust pH and osmolality, Sterile-filter	• Fast reconstitution — 50% fewer steps than DPM • Reduced shipping, storage costs • Comparable pH, osmolality, cell growth/viability, titers, and N-glycan profiles to DPM • 95% less dust generation*

* Dust investigations were conducted by Delft Solids Solutions (Netherlands) using a Heubach dust meter according to the DIN 55992-1 standard. Method not necessarily representative of the amount of dust generated during normal bioprocessing procedures.

Ready-to-use formulations offer ease of use

Liquid formats prepared by Thermo Fisher are ready for immediate use upon receipt, enhancing efficiency.

- Ready-to-use solutions, less labor-intensive media preparation
- Available in bottles and closed-system bioprocessing containers (BPCs)
- Easy transitions from R&D to process development to manufacturing

Format benefits, cont.

Gibco dry powder media (DPM)

Gibco™ media are used to manufacture many leading blockbuster drugs, most of which rely on the DPM format. DPM is a leading format for large-scale production in biomanufacturing

- Highly consistent blend compatible with single-use technologies
- Long shelf life and easily scalable
- Established track record of production and performance
- Supported assurance of supply through harmonized facilities
  - 1 kg to ~5,000 kg batch sizes

Advanced Granulation Technology (AGT) media

Our most advanced media format available for cell culture. We have the experience to help develop your media through our proprietary AGT media format, fortifying your process to support manufacturing efficiency.

- Auto pH — just add water
- Fast dissolution and mixing time
- Designed to reduce dust generation
- Minimal filtration pressure buildup
  - 50 kg to 1,000 kg batch sizes

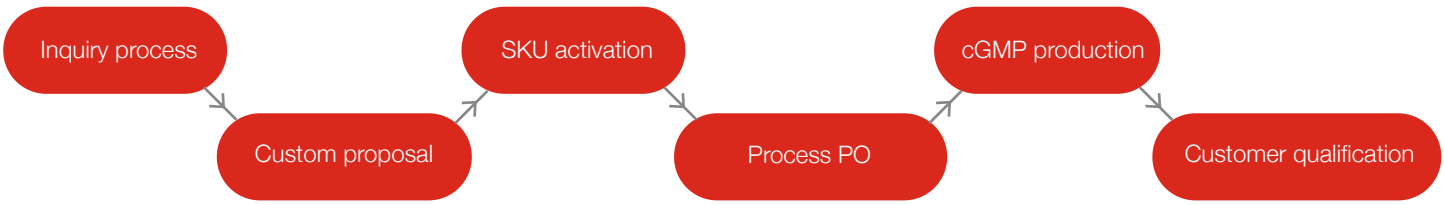
Launch your process development with the Gibco Rapid Prototyping Service

Use the Gibco Rapid Prototyping Service to rapidly kickstart and advance your projects with easy transfer to cGMP. It can also be used to test media format compatibility when scaling.

Rapid prototyping service for non-GMP pilot-scale prototyping of your media	
Batches up to 600 L or 30 kg	Mammalian or microbial platforms
Offering both pin mill and FitzMill technology	Rapid lead times — orders typically shipped within 10–15 working days
Conversion between formats (DPM and AGT media)	

cGMP Project overview example

Customer owned formulation (COF) projects are triaged by a large, cross-functional team led by a single point of contact.



Timelines depend on (but not limited to):

- Procurement of new raw materials
- Price negotiations
- Project complexities needing non-GMP validation batches
- Customer qualification process

Qualifying Thermo Fisher Scientific as your secondary media supplier

Step	Major activities
Quick assessment	• Share formulation, specifications, and process needs under confidentiality • Align on quality targets and performance goals
Easy qualification	• Raw-material documentation and supply continuity (multi-site options) • Run side-by-side tests to confirm performance and quality • Regulatory compliance information
Qualifying Thermo Fisher as a secondary supplier is fast, low-effort, and well supported	

Our experience by the numbers

80
COF commercial molecules

>400
Analytical projects*

>6,700
Customer samples analyzed*

49
Scale up formulations to GMP**

83
Tech transfers between our global manufacturing sites

118
Countries served

Media shipped*
Powder - **1,477,170 kg**
Liquid - **2,025,779 L**

* In the past five years. ** January–November 2025

Case studies

Case study 1 - Enabling successful advancement toward GMP

Optimizing custom media and feed solutions: offering speed, quality, and value.

Client

A global biopharmaceutical company developing recombinant proteins and antibodies, seeking support for their customer-owned formulations (COF) used in pilot and production-scale processes.

Challenge

Despite working with another COF supplier, the customer faced tightening product specifications — especially trace element controls — along with the need for assured supply and faster PO-to-delivery timelines.

Solution

Thermo Fisher implemented a one-team, collaborative approach to help deliver a tailored COF strategy. We optimized internal processes, provided transparent pricing, qualified new suppliers to meet strict trace element requirements, and supported both pilot and GMP activities.

Results

Preferred supplier: Earned the customer's trust through consistent quality, transparency, and strong technical and commercial support. Operational agility: Cut GRP leadtimes to four weeks. Business impact: Delivered cost savings, scalable solutions, and reliable supply.

Operational agility · Technical support · Collaborative partnership · Enhanced efficiency

Case study 2 - Early collaboration supports multi-million-dollar cGMP success

Enabling commercial-scale biologics manufacturing for a global CDMO

Client

A U.S.-based global CDMO providing end-to-end development and manufacturing for protein biologics, cell and gene therapies, and mRNA — from process development through clinical and commercial cGMP production.

Challenge

The CDMO needed fast validation of customer-owned formulations (COF) to onboard new molecules. They required scalable, consistent validation batches and a supplier who could help ensure speed, operational efficiency, stable pricing, and long-term supply reliability.

Solution

Thermo Fisher used the Gibco Rapid Prototyping Service lab to help deliver quick-turn validation materials using the same raw materials and processes as GMP manufacturing, streamlining scalability.

Results

Rapidly validated and enrolled multiple molecules using COF media. Accelerated transition from validation to GMP production. Completed three stability studies supporting GMP readiness and long-term reliability.

Rapid prototyping to cGMP collaboration · Reliable supply · Proven quality

Case study 3 - Global manufacturing redundancy avoids tariff disruption

Strengthening global supply continuity through multi-site manufacturing redundancy

Client

A global CDMO with a portfolio spanning oncology, nephrology, and autoimmune disease therapeutics. Their commercial programs include multiple molecules using Gibco™ customer owned formulation (COF) media and Gibco™ catalog media.

Challenge

The customer needed to transfer several product SKUs to the Paisley, UK site to avoid tariffs and improve supply resilience. This minor-to-moderate process change required evaluation, and with key molecules nearing NDA stage, the Paisley site also needed qualification for future commercial supply and surcharge exemption.

Solution

Thermo Fisher implemented a multi-site manufacturing strategy to help ensure uninterrupted supply and global flexibility:

- Transferred required product SKUs from the US to the Paisley site
- Provided equivalent supporting documents and validation documentation to support regulatory and technical assessments
- Supplied three lots of Paisley site cGMP media for customer verification

Results

Enabled expedited validation at the Paisley site, allowing the customer to continue placing orders with minimal operational disruption. Secured consistent quality and strengthened supply continuity for downstream manufacturing. Reinforced Thermo Fisher as a trusted and preferred media supplier for long-term commercial success.

Navigating tariffs through rapid tech transfer · Reliable supply · Proven quality

Common thread across all three case studies

Whether the challenge is trace-element control, fast COF validation, or rapid tariff response, Thermo Fisher's combination of harmonized global sites, dedicated rapid prototyping labs, and a collaborative one-team approach translates into measurable operational, financial, and regulatory wins for biopharmaceutical manufacturers.

See our capabilities in action

Gibco™ media manufacturing services: collaborating for operational success

Watch how our global facilities, harmonized processes, and collaborative teams enable reliable supply at every scale.

Continue exploring

- **Manufacturing capabilities overview** - visit webpage
- **Rapid Prototyping Service** - visit webpage

Ready to talk?

Speak with our team to discuss your manufacturing needs and how Gibco can serve as your trusted primary or secondary media supplier.

Reduce risk. Improve continuity. Scale with confidence.
See how at **thermofisher.com/media-manufacturing**