



ThermoFisher
S C I E N T I F I C

Gibco Chemicals Overview

Name

Title

Date

Global Challenges Facing Customers



Cost pressures



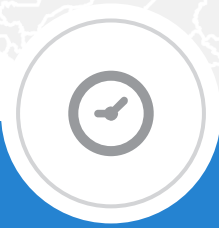
Single-source constraints



Unique manufacturing requirements



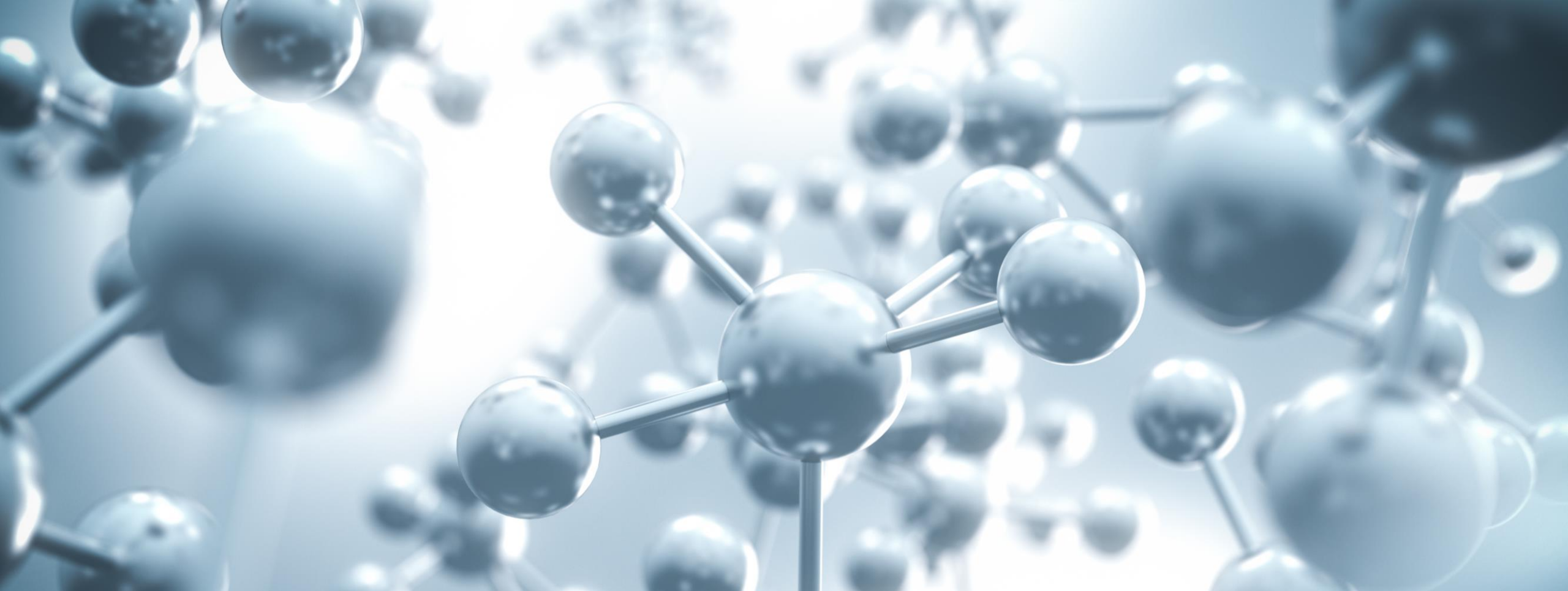
Regional limitations



Extended lead times



Visibility to supply chain



Introducing Gibco Chemicals

A High-Quality, Customizable Solution



Gibco™ Chemicals

A focus on quality, transparency, and custom needs

- Fulfills pharmaceutical and biopharmaceutical requirements
- Transparency of supply chain
- Emphasis on multi-compendium offering
- Customizable for unique customer requirements

Leverages strengths of Thermo Fisher Scientific

- Expansion of the Gibco™ product portfolio
- ISO-certified and cGMP-compliant quality systems
- Vast and diverse supplier portfolio managed on behalf of customer

A Process Focused on Compliance

Gibco Chemicals are manufactured in cGMP-compliant facilities



ISO 13485 certified to meet medical device standards



cGMP compliant, with robust quality systems



Produced in animal origin-free environment



Photo: Thermo Fisher Scientific manufacturing facility in Grand Island, NY. ISO 13845 certified, cGMP compliant.

Transparency from raw material sourcing to on-site delivery



Base manufacturer

- Raw material origin
- Focus on larger chemical market

Thermo Fisher Scientific

- Quality management
- Supplier management
- QC release
- Regulatory information
- Inventory management (lot control, safety stock, etc.)
- Just-in-time delivery
- Advanced supply chain services offering

Customer

Visibility
to

Quality documentation

Technical Information guides focused on customer experience

- All quality records collected in one document
- Easy management for record and regulatory purposes

Statements included:

- Product specifications
- Site-of-manufacturing information
- Packaging information
- Regulatory statements
 - BSE/TSE
 - Melamine
 - residual solvents, etc.

* Certificates of Analysis & SDS also available upon request

gibco

TECHNICAL INFORMATION GUIDE

L-Arginine Hydrochloride, USP/EP/JP

Catalog Numbers A37688

Pub. No. MAN0017863 Rev. 1.0

WARNING! Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from thermofisher.com/support.

Contents and storage

Product	Catalog Number	Packaging description	Storage (1)
L-Arginine Hydrochloride, USP/EP/JP	A37688	Double-bagged poly liner and rigid outer poly container	15°C to 30°C

(1) Please reference the certificate of analysis for manufacture and expiration date of this material.

Manufacturing and supply information

Gibco™ Chemical products are produced in cGMP-compliant facilities registered with the FDA as manufacturers of medical devices, which are also certified to the ISO 13485 standard. Chemicals are qualified to ensure they meet compendia standards or are equivalent materials of high purity. The packaging process is performed in temperature and humidity controlled suites in our animal origin free facility. The suites are maintained per controlled procedure and cleaning methods that are validated.

Information	Details
Manufacturing site	Life Technologies Corporation 3175 Staley Road Grand Island, NY 14072
Manufacturing Site ISO Certifications	thermofisher.com/us/en/home/technical-resources/manufacturing-site-iso-certifications.html
Supply information	Additional supply information will be disclosed upon the signing of a confidential disclosure agreement.
Country of origin	Japan

Packaging

Packaging materials are subjected to acceptance inspection in the package-testing laboratory. The materials are selected at Grand Island according to special criteria with regard to suitability for the application. In addition, the materials are inspected for physical condition upon receipt for cleanliness but not sterility.

Physical chemical information

Information	Details
CAS	1119-34-2
Synonyms	L-2-Amino-5-guanidinopentanoic acid hydrochloride, H-Arg-OH.HCl
Linear formula	C ₆ H ₁₃ N ₄ O ₂ .HCl
Manufacturing process	Fermentation
Manufacturing process flow	Fermentation ► Purification ► Filtration ► Crystallization ► Drying ► Filling/Packaging
Raw material origin	Bacterial

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

ThermoFisher
SCIENTIFIC

Global Reach of Product and cGMP Supply Chain Services

We focus on the supply chain so customers can focus on their core competencies

Simplifying the supply chain

- Dual-site manufacturing in the US and UK
- Built-in logistic services that can span the globe
- cGMP advanced services

Successful risk mitigation strategies



Global supply redundancies



Localized inventory solutions



Change management

Bioproduction manufacturing and cGMP service centers



● Thermo Fisher Scientific manufacturing sites

● cGMP Supply Chain Service Centers

* All sites are ISO certified and cGMP compliant

Applying enterprise-solution service models across the entire raw material supply chain

Americas Manufacturing and Distribution Centers

From manufacturing to distribution,
we support customers:



Throughout the drug development phase and commercial manufacturing



At any location in the Americas with products manufactured at our New York facility and distributed to your choice of supply chain service centers



* All sites are ISO certified and cGMP compliant

European Manufacturing and Distribution Centers

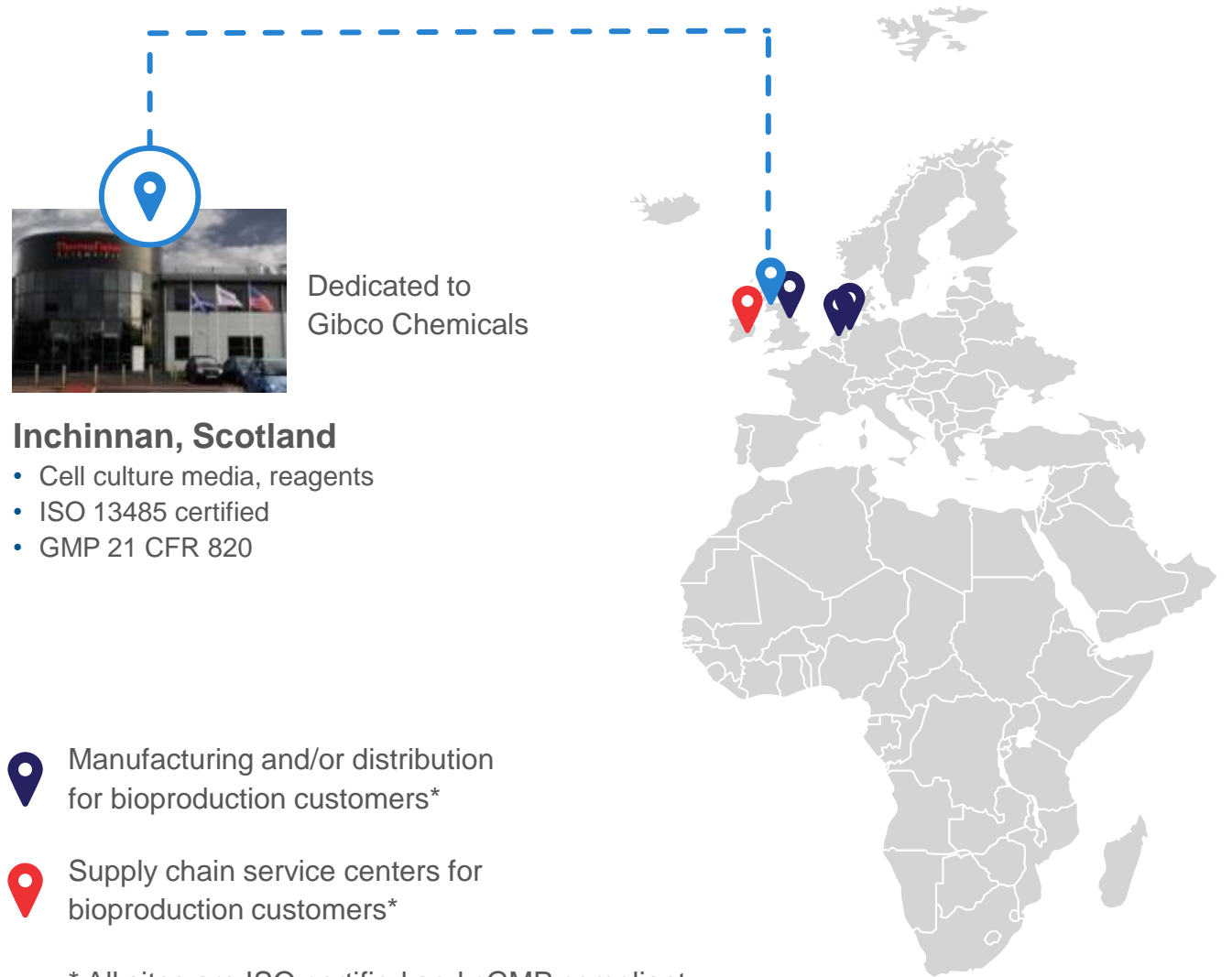
From manufacturing to distribution,
we support customers:



Throughout the drug development phase and commercial manufacturing



At any location in Europe, the Middle East, and Africa



* All sites are ISO certified and cGMP compliant

Asia Pacific Manufacturing and Distribution Centers

Dual-site manufacturing in our North American and European facilities, coupled with locally based distribution, supports our customers in the Asia Pacific region.



Supply Chain Services

Focused on customer experience at each level of service



Project consultation

- Material planning
- Supply chain risk assessment
- Product customization management



Procurement and vendor management

- Order and logistics management
- Supply and quality agreements
- Product documentation consolidation
- Complaint process handling
- Change management



Local inventory management

- ISO-certified, cGMP-compliant service centers
- Ambient and cold temperature storage conditions
- Validated ERP/WMS systems (lot and expiry tracking)
- Inventory programs: safety stocking, JIT delivery, and emergency delivery



Advanced supply chain services

- Custom labeling/barcoding
- Poly-pallet exchange
- Production-ready repacking and kitting services
- Lot management
- Cold-chain management
- QC sampling in certified clean room



Gibco Chemicals

Launching Amino Acids

Amino acid market

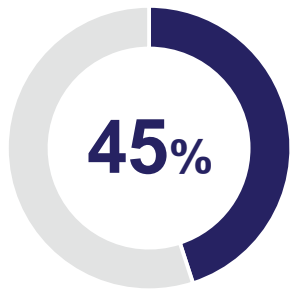
**~\$1.5
billion**

The amino acid market generates
~\$1.5 billion in annual revenue.

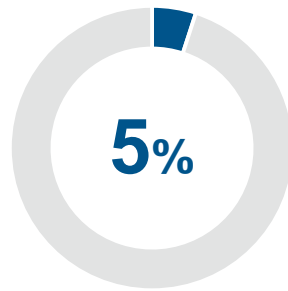
0.01%

Life sciences usage only makes
up 0.01% of the total amino acid
market. Therefore, it is often
looked at as a specialty usage.

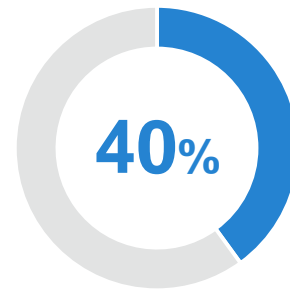
Amino acids are used in many applications



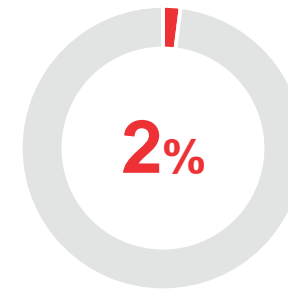
Food additives



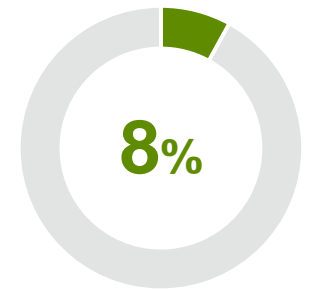
Cosmetics



Animal feed



Specialty



Industrial

Introducing Gibco Chemicals Amino Acids

First product family to launch: amino acids



For use as a raw material in further manufacturing applications



Compendial testing: USP/EP/JP



Current pack size options:

500 g, 1 kg, 12 kg

Custom sizes available upon request



3-lot samples available



Validation guides
(documentation compilation)



cGMP-compliant and ISO-certified manufacturing and supply chain



- Glycine
- L-Alanine
- L-Arginine Hydrochloride
- L-Arginine
- L-Aspartic Acid
- L-Cysteine Hydrochloride Monohydrate

- L-Glutamic Acid
- L-Glutamine*
- L-Histidine Monohydrochloride Monohydrate**
- L-Histidine
- L-Isoleucine

- L-Leucine
- L-Lysine Hydrochloride
- L-Methionine
- L-Phenylalanine
- L-Proline
- L-Serine

- L-Threonine
- L-Tryptophan
- L-Valine

Amino acids are available compendial tested for USP, EP, and JP unless otherwise specified.

* EP and JP only.

** USP and JP only.



Gibco Chemicals

A focus on quality, productivity, and customization

Standard features

- ✓ cGMP manufacturing
- ✓ Supplier quality management
- ✓ Site auditability
- ✓ Dedicated source
- ✓ Documentation support



Quality

Utilizing our quality systems and cGMP-compliant facilities to provide:

- Transparency of the process
- Redundant global footprint
- Focus on the customer's requirements



Productivity

Helps save time and control costs:

- Supply chain management allows us to meet just-in-time needs
- Scale-up from early clinical to commercial manufacturing with ease
- Utilize global footprint and reduce risk to raw material supply chains



Customization

Flexibility you value:

- Control specifications that are outside of the compendia
- Optimize products for your unique manufacturing space requirements
- Reduce bottlenecks by implementing our tailgate sample process

Gibco Chemicals provides high-quality products



**cGMP-compliant
manufacturing
ISO-certified facilities**



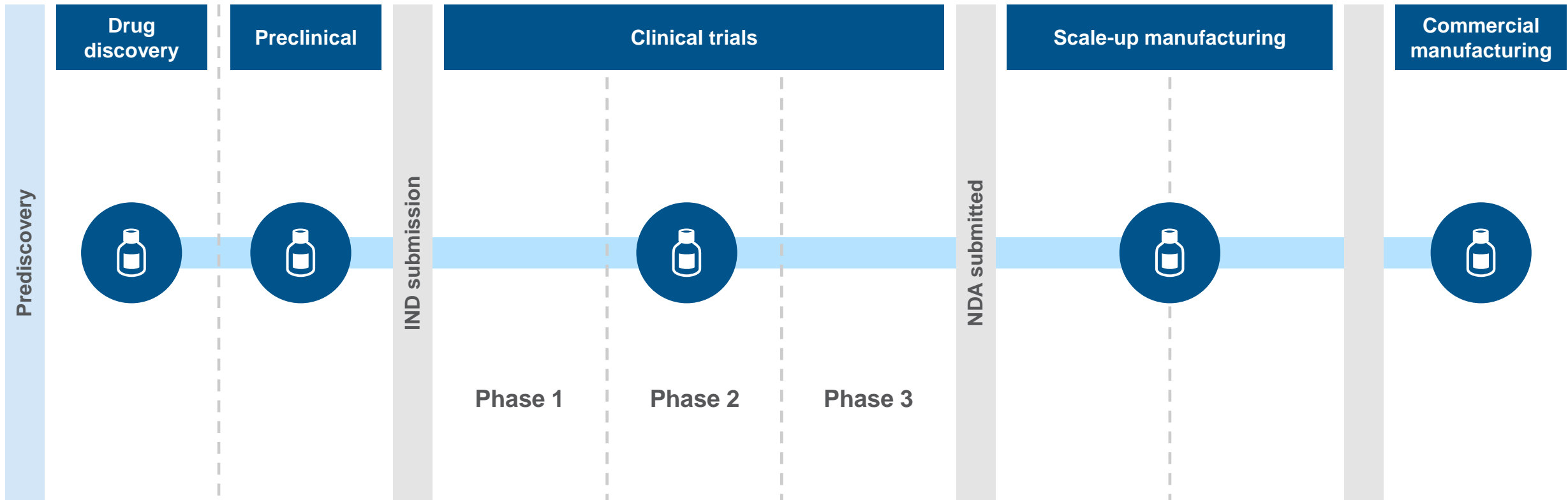
**Multi-compendium focus
for global manufacturing**



**cGMP supply
chain logistics**

Broad Usage Areas for Gibco Chemicals

Gibco Chemicals supports the entire drug development timeline from R&D to commercial manufacturing



Circumvent revalidation of raw materials throughout your process

Customer-defined specifications

Manufacturing product to unique, customer-defined specifications

Tailgate samples

Optimizing quality assurance process by providing side samples taken during packaging process

Custom package types and volumes

Customizing packaging type and volume

cGMP supply chain services

Outsourcing unique in-house testing, inventory management, and other supply chain services



Customer Challenges That Gibco Chemicals Can Answer



Cost pressures

Gibco Chemicals ...

focuses on reducing the total cost of ownership to further control rising costs in this highly regulated industry



Single-source constraints

Gibco Chemicals ...

enables access to basic manufacturers while maintaining focus on providing quality products



Unique manufacturing requirements

Gibco Chemicals ...

offers multiple packaging options and is flexible to accommodate customization

Challenges Facing Customers, and the Answer in Gibco Chemicals



Regional limitations

Gibco Chemicals ...

focuses on multi-compendium testing and multi-site manufacturing to meet global needs



Extended lead times

Gibco Chemicals ...

has built-in partnership with our premier services to address customer-defined safety stock



Visibility to supply chain

Gibco Chemicals ...

provides documentation and cGMP advanced services to meet customer's quality and regulatory needs



Questions



Thank you

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The world leader in serving science