

Simplifying custom media from development to GMP with an end-to-end approach

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Our approach to today's topic...

01 Custom media development service and workflow

02 Rapid media prototyping (Non-GMP)

03 GMP manufacturing capabilities

04 Lonza's value with real-world case studies of custom manufacturing

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Outsourcing media: Key considerations and risks

Scaling adds cost and time risk – plan early to stay on track



Delays in media optimization, process validation, and scale-up



Process development



Preclinical



Commercial

Media development



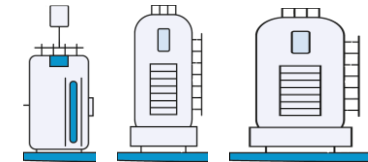
- > Advanced screening
- > Flexible engagement
- > Proprietary media and feed libraries
- > Cost-optimized formulation

Rapid media prototyping (Non-GMP)



- > Fast-turnaround delivery
- > Small-scale pilot production
- > Flexible packaging
- > End-to-end expertise

GMP manufacturing



- > Reliable and scalable manufacturing
- > Compliant processes
- > Traceable operations
- > Dual-site manufacturing

Custom media development service

Accelerate your media screening

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Media development lab and rapid prototyping services

APAC, Singapore

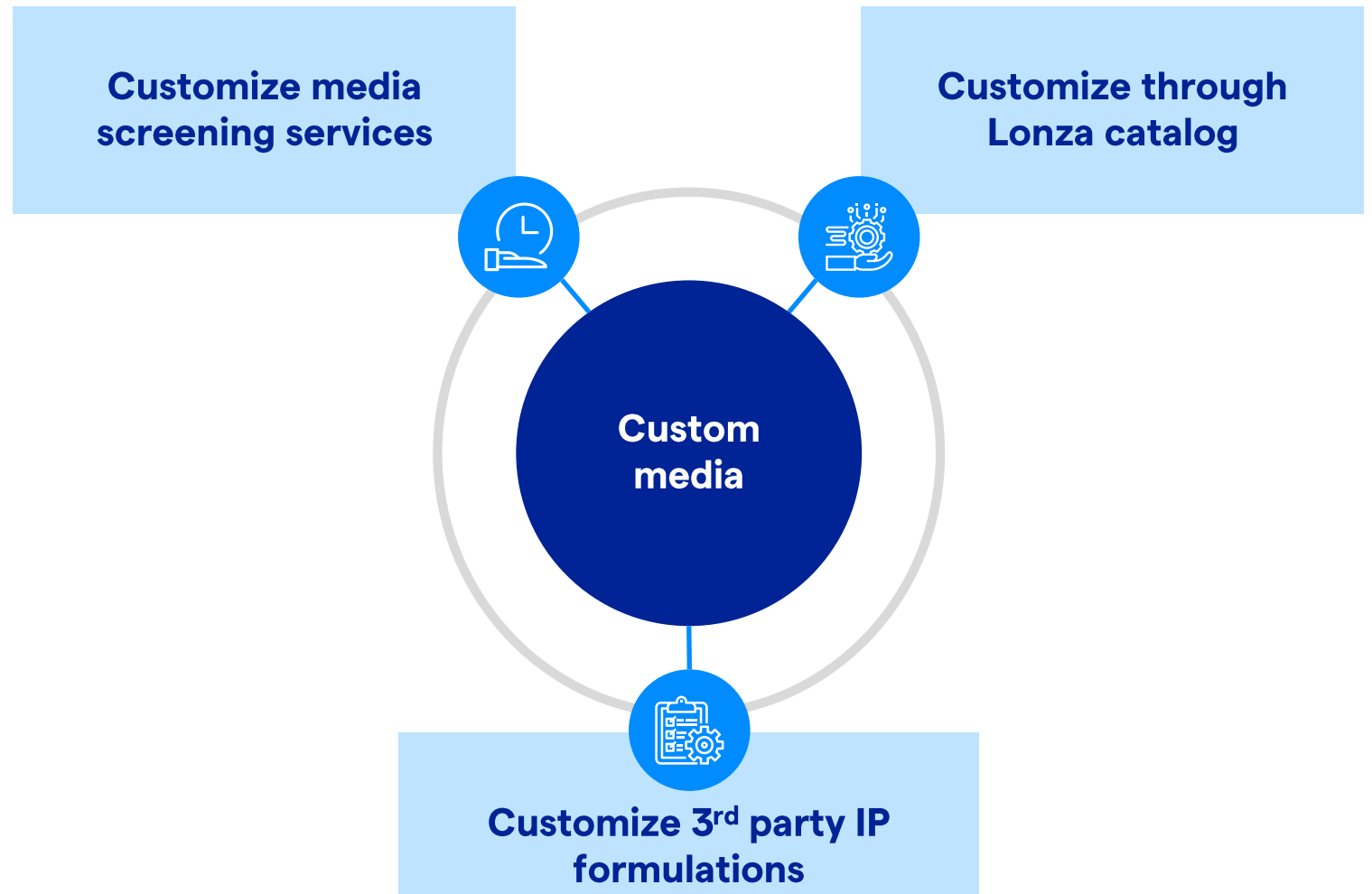
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Media development lab (MDL)

to offer comprehensive and accelerated CHO media screening capabilities, powered by Lonza's diverse collection of CHO media and feeds.



Media development lab | overview

Media screening services

	In-house development	Consultative model
 Description	Lonza performs full development using customer cell line and internal tools	Lonza guides optimization without cell line; customer performs experiments
 Workflow	CDA and Cell Line Transfer → Basal Media Screen → Feed & Supplement Screen → Product Quality Optimization → Bioreactor Run → (Prototype non GMP liquid media manufacturing (1-100L batches) → (Scale up to GMP media manufacturing)	CDA and Project Proposal → SOPs & DoE Design Provided → Reagents Shipped to Customer → Customer Executes DoE → Data Shared w/ Lonza → Lonza Analyzes & Recommends Formulation → (Prototype non GMP liquid media manufacturing (1-100L batches) → (Scale up to GMP media manufacturing)
 Service components	- Flexible Collaboration - Rapid Prototyping	- DoE Optimization - Screening - Bioreactor Validation - GMP Transition
 Format and scalability	Media: Liquid, small-scale, non-GMP (prototype stage) Batch Sizes: 1 L – 100 L Packaging Options: Bottles (0.5 and 1 L), Bags (5 L and 10 L) GMP Production Sites: Walkersville (US), Verviers (EU)	

Workflow: basal media and feed screening

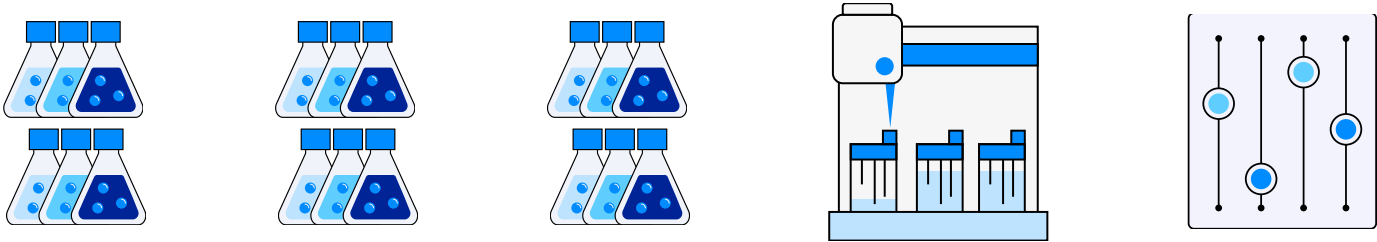
Diversity through simplicity

Diverse library

	Basal Media 1	Basal Media 2	Basal Media 3	Basal Media 4	Basal Media 5	Basal Media 6	Basal Media 7	Basal Media 8	Basal Media 9
Trace Metals Amount									
Trace Metals Variety									
Vitamins									
Fatty acids and Lipids									
Amino Acids									
Energy Sources									
Hydrolysate									
Nucleosides									

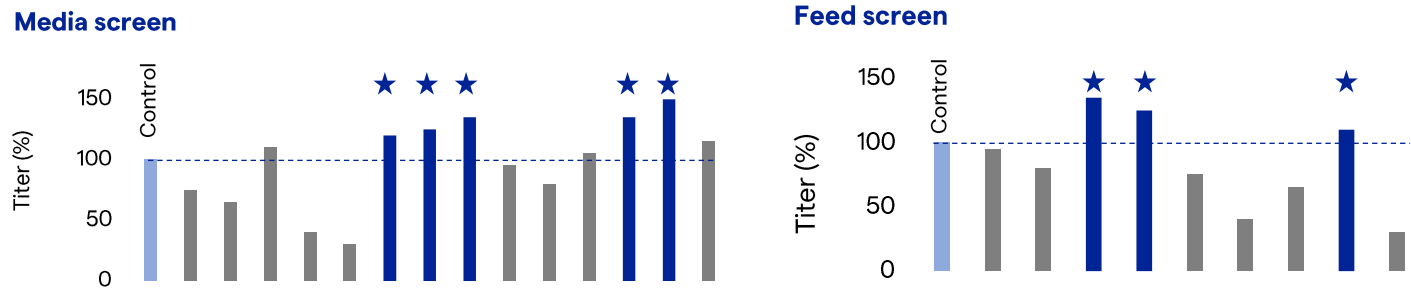
100+ media formulations developed using a rigorous, systematic approach

Advanced high-throughput screening



CHO K1, DG44, S, GS cells
Titer and PQA evaluation
Cell growth (VCC)
Spent Media Analysis

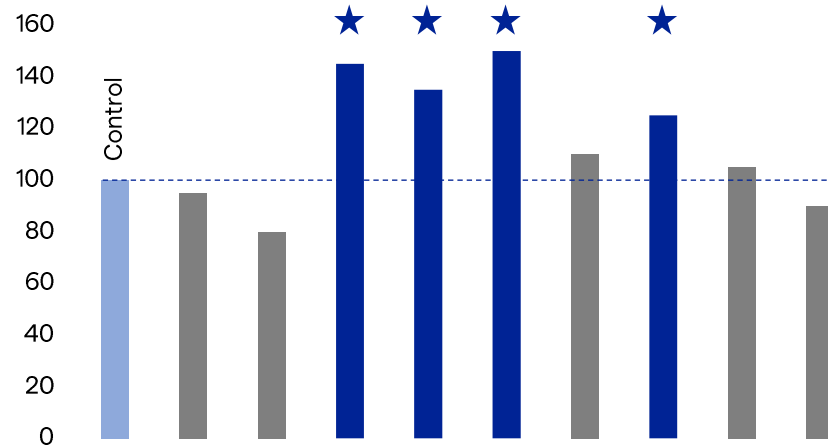
Identification of top performers
Proof of concept data



Shortlist top media candidates with titer increase

Workflow: optimization and confirmation

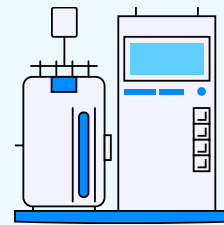
Confirmation, scalability, and manufacturability



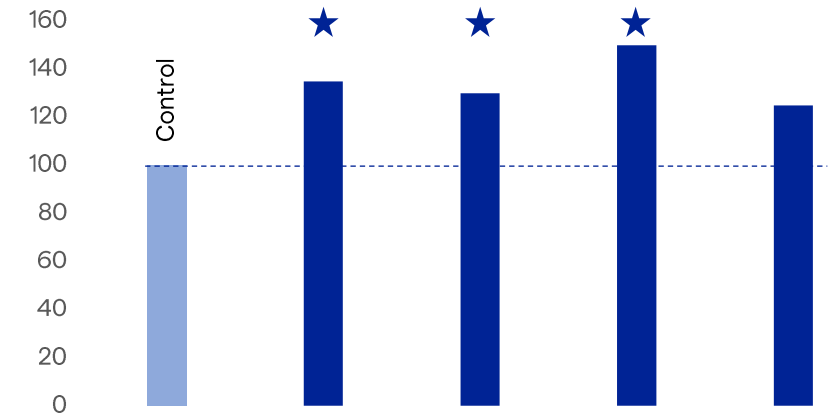
Optimization run

Proof of concept data

- > Small-scale screening in fed-batch mode
- > Controlled environments using mini bioreactors
- > Fortification of critical media components



Top 4 – 5 performing media



Scale-up and confirmation

Proof of concept data

- > Demonstrate > 600-fold scalability
- > Rapid media prototyping: Pilot batch delivery
- > Rapid media prototyping: Powder/liquid formats

Rapid media prototyping service (Non-GMP production)



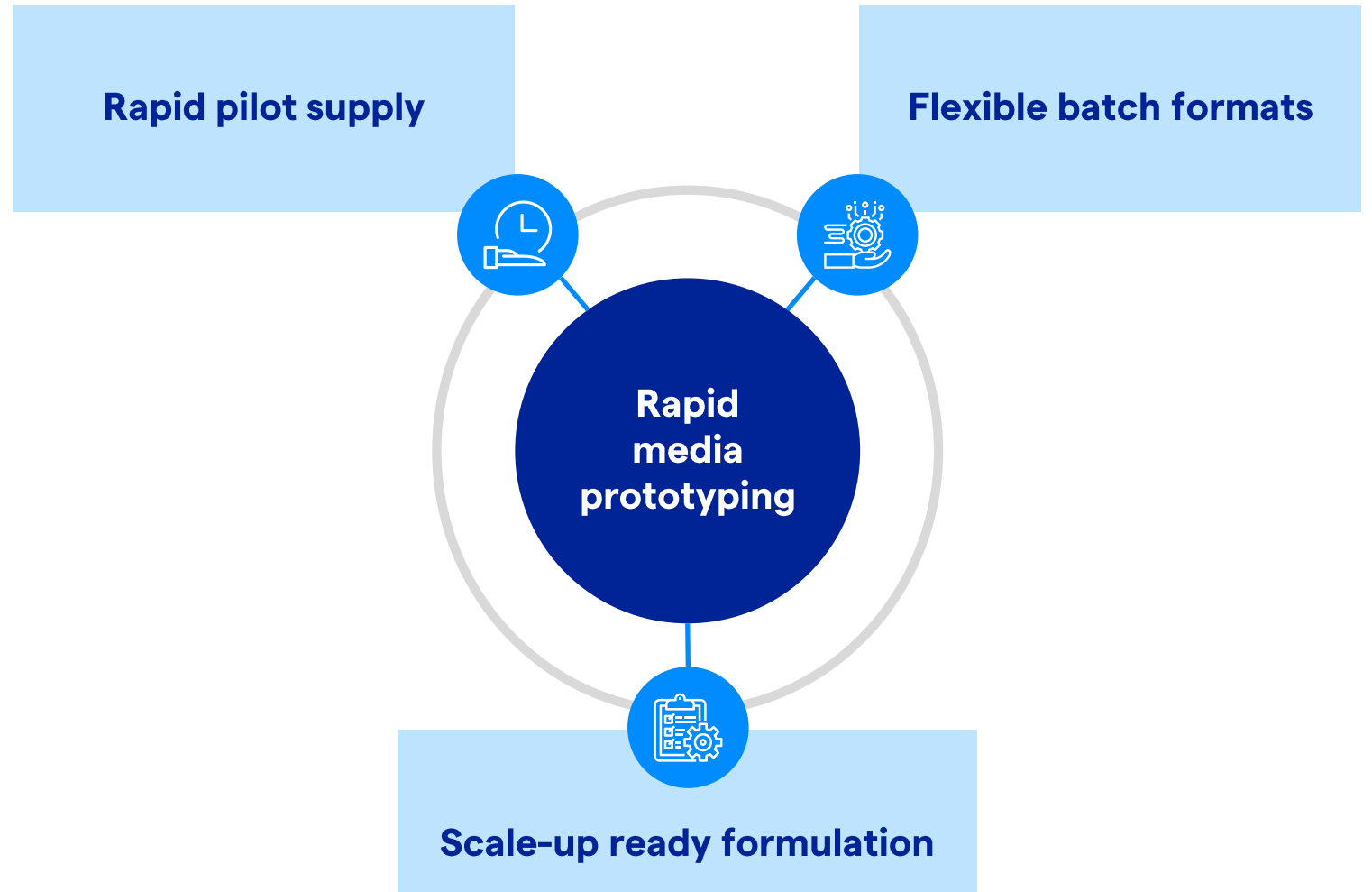
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Rapid media prototyping service

Walkersville, Singapore



Rapid media prototyping
to deliver high-quality,
non-GMP liquid and
powder manufacturing
services designed
to facilitate seamless
technology transfer to
GMP manufacturing.



Lonza custom media service

Non-GMP media

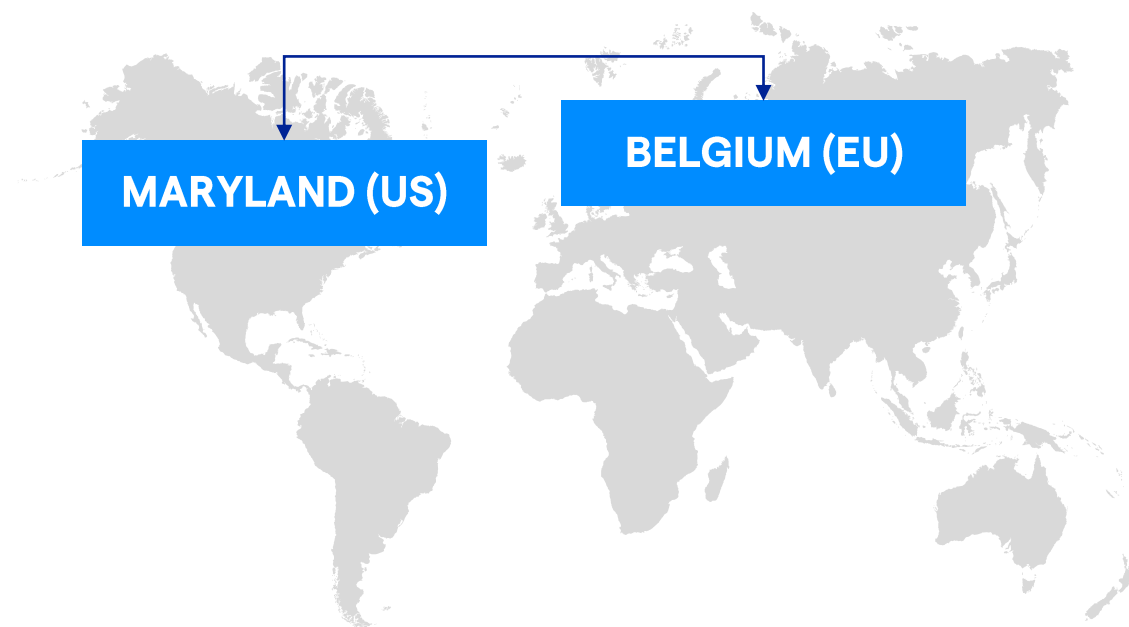
Purpose and application	Speed and flexibility	Scalability and quality	Testing and documentation	Packaging and labeling
- Development and early process screening - Rapid evaluation and optimization before transitioning to GMP production	- Up to 10 working days lead time - Small to mid-scale production - Ideal for prototyping and pilot runs	- GMP-grade or equivalent materials - WFI or Cell culture grade water	- Each batch is tested for appearance, pH, osmolality, and solubility for powders - Certificate of Testing (CoT) for each lot	- Standard packaging consistent with GMP formats - Marked “For Research Use Only”



Compliance	Formats	Assets	Sites	Batch Ssize	Features
Non – GMP	Liquid media	Bottles (0.5 L, 1 L) bags (5 L, 10 L)	Walkersville	1 L to 100 L	Tailored solutions for Biopharma
	Powder media	Bottles, buckets	Walkersville	1 kg to 10 kg	Tailored solutions for Biopharma

GMP manufacturing capabilities

Verviers, Belgium and Walkersville, MD, USA



Verviers, Belgium, EU

Capabilities



Lonza Verviers – Belgium, EU



Facility overview



- > 7671 m² – 200+ employees
- > Media liquids and powder manufacturing
- > **Liquid batches up to 10,000 L**
- > **Powder batches up to 1,500 kg***

Quality overview



- > ISO 9001:2015 & 13485:2016 Certified
- > 21 CFR 820 compliant



Belgium-based Lonza facility serving as the European Service Center for Lonza Bioscience since 1994.



Functions as a production and distribution hub for custom and research media, supporting products for cell therapy, and molecular biology.

Walkersville, US

Capabilities



Facility overview



- > 300,000 sq ft – 500+ employees
- > Global logistics and cold chain capabilities
- > Endotoxin testing and media manufacturing services
- > **Liquid batches up to 10,000 L.**
- > **Powder batches up to 7,000 kg**

Quality overview



- > ISO 9001:2015 & 13485:2016 Certified
- > 21 CFR 820 compliant



Established in **1947**, the Maryland facility began by producing tissue culture media.



For over **70 years**, it has supplied a diverse range of products to **customers worldwide.**

Lonza custom media service

GMP media



Purpose and application	Speed and flexibility	Quality and compliance	Testing and documentation	Packaging and labeling
- Commercial production with regulatory compliance - Custom formulations or catalog media revisions	- Standard 12-week lead time - Large-scale manufacturing	- GMP water loop systems - ISO 9001, ISO 13485, and 21 CFR 820	- Each batch QC tested for appearance, solubility, pH, and osmolality - Approved Batch Records - Certificate of Analysis (CoA) for every lot	- Approved containers consistent with GMP standards - Marked "For Further Manufacturing" to support downstream use

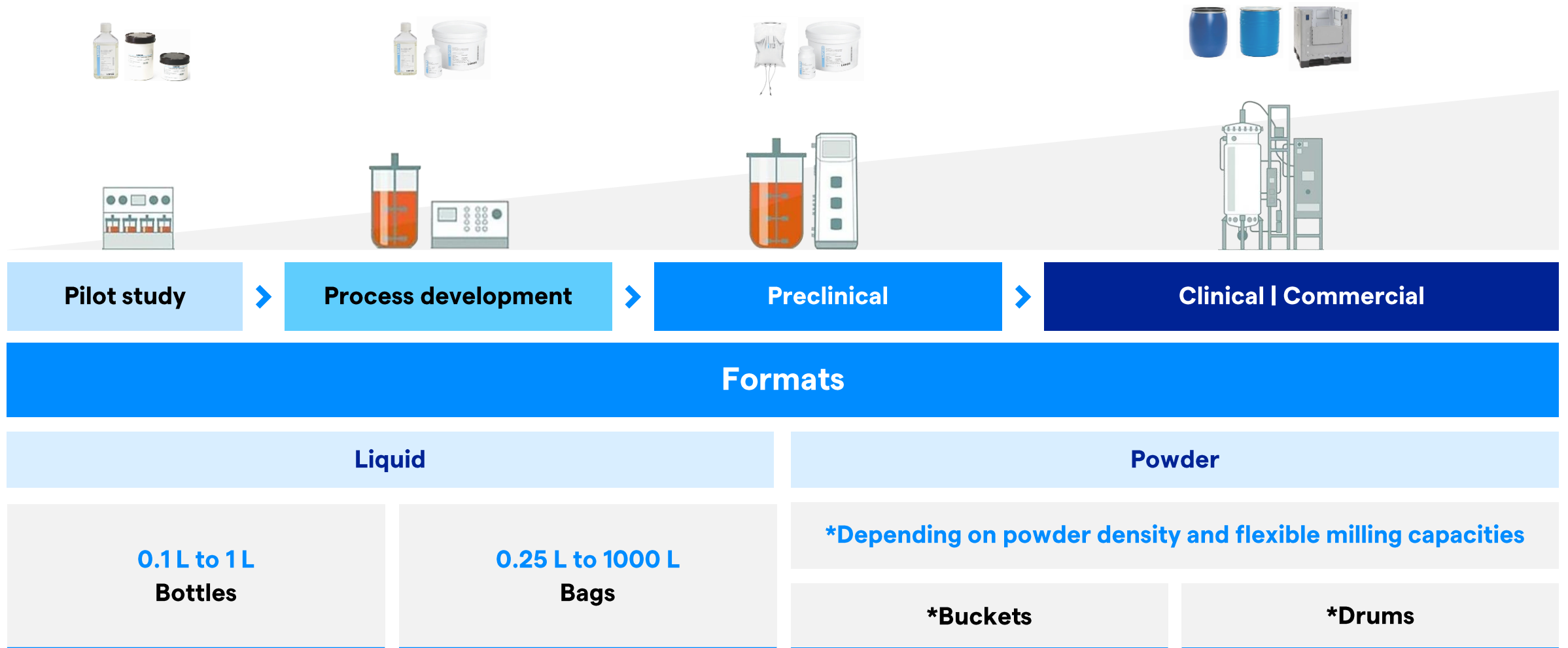


Compliance	Formats	Assets	Sites	Batch Size	Features
GMP	Liquid media	Bottles (≤ 1 L) Bags (≤ 20 L) Drums (50 L – 1000 L)	Verviers and Walkersville	Flexible up to 10,000 L	Customizable packaging, scalable
	Powder media	Buckets and drums	Verviers Walkersville	20 kg to 1,500 kg* 7 kg to 7,000 kg*	Flexible milling, precision blending

*Depending on powder density & Flexible milling capacities

Lonza | flexible packaging

Liquid and powder formats



Buffer capabilities

Catalog and custom formulations

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Protein production



Cell and gene therapy



Vaccine production



Bioprocessing buffers reagents



Custom cell culture media

Custom media

Upstream

- Custom media and feed production
- Powder and liquid formats
- Flexible batch sizes

Buffers

Upstream

- Media preparation
- Feed solutions
- Bioreactor pH control
- Cell washing/harvest

Downstream

- Cell lysis/clarification
- Chromatography
- Filtration
- Diafiltration
- Ultrafiltration
- Formulation and final fill

WFI

Upstream

- Cell culture media
- Cell processing and wash solutions
- Reconstitution of powdered reagents
- Glassware/container washing/ sanitization

Downstream

- Wash buffers
- Purification/elution buffers
- Analytical testing
- Downstream reagent preparation
- Critical final rinse water

Lonza buffers standards

Catalog and custom buffers



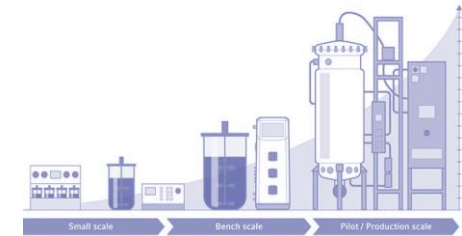
- > Catalogue/custom liquid and powder
- > Flexible bioprocessing containers and purification buffers
- > Global manufacturing capabilities
 - **Verviers, Belgium, Europe**
 - **Walkersville, Maryland, USA**
- > Scientific support for customization
- > Rigorous quality control for premium products and reproducible results

Description	Format	Volume
HEPES Buffer GMP (1M)	Liquid	100 mL
TheraPEAK® PBS	Liquid	1 L
PBS	Powder	50 L
		10 L
DPBS	Powder	50 L
		1000 L
HBSS (Hanks' Balanced Salt Solution)	Liquid	4 L

Process timeline

Streamlining simplicity

Dedicated team of experts will support you throughout the journey



Pilot ordering



Production



Technical transfer to GMP

- | | | |
|---|--|---|
| <ul style="list-style-type: none">> Simplified order form process | <ul style="list-style-type: none">> Delivery within 12 weeks* | <ul style="list-style-type: none">> The customer evaluated various sizes at the small scale. |
| <ul style="list-style-type: none">> Volume-Based Pricing | <ul style="list-style-type: none">> GMP-grade raw materials and processes | <ul style="list-style-type: none">> Small-scale evaluations define materials and specifications. |
| <ul style="list-style-type: none">> Project management and specification setup | <ul style="list-style-type: none">> GMP-equivalent batch records | <ul style="list-style-type: none">> Consistent GMP small-scale process |

Custom manufacturing case studies

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Case study #1: Assuring supply with expedited transparency

Building solutions to achieve long-term manufacturing success

A large U.S. pharma looking to switch its media manufacturer to Lonza for assurance of supply and a transparent concierge approach to partnership



	Speed 	Partnership 	Assured Supply 
Customer situation	 Large pharma needed to switch their manufacturing of custom media solution	 Looking for a direct relationship and collaborative partner in their process	 Risking up to 2 weeks down time in the transfer of their manufacturing process
Lonza response	 Quickly established a team and orient on their needs for secure supply	 A dedicated project team , mapped timeline, quality, and logistics to secure supply	 Executed test batches within 3 days for rapid qualification and scale
Value delivered	 Met all checklist needs to transfer manufacturing without any downtime	 Mitigated risks through dedicated support and transparency.	 Achieved the desired scale with ZERO downtime and no issues in manufacturing

Case study #2: Scaling manufacturing with success

Building solutions to achieve long-term manufacturing success

A global pharmaceutical company looking to scale for commercialization, optimizing their process quickly from pilot to commercial manufacturing



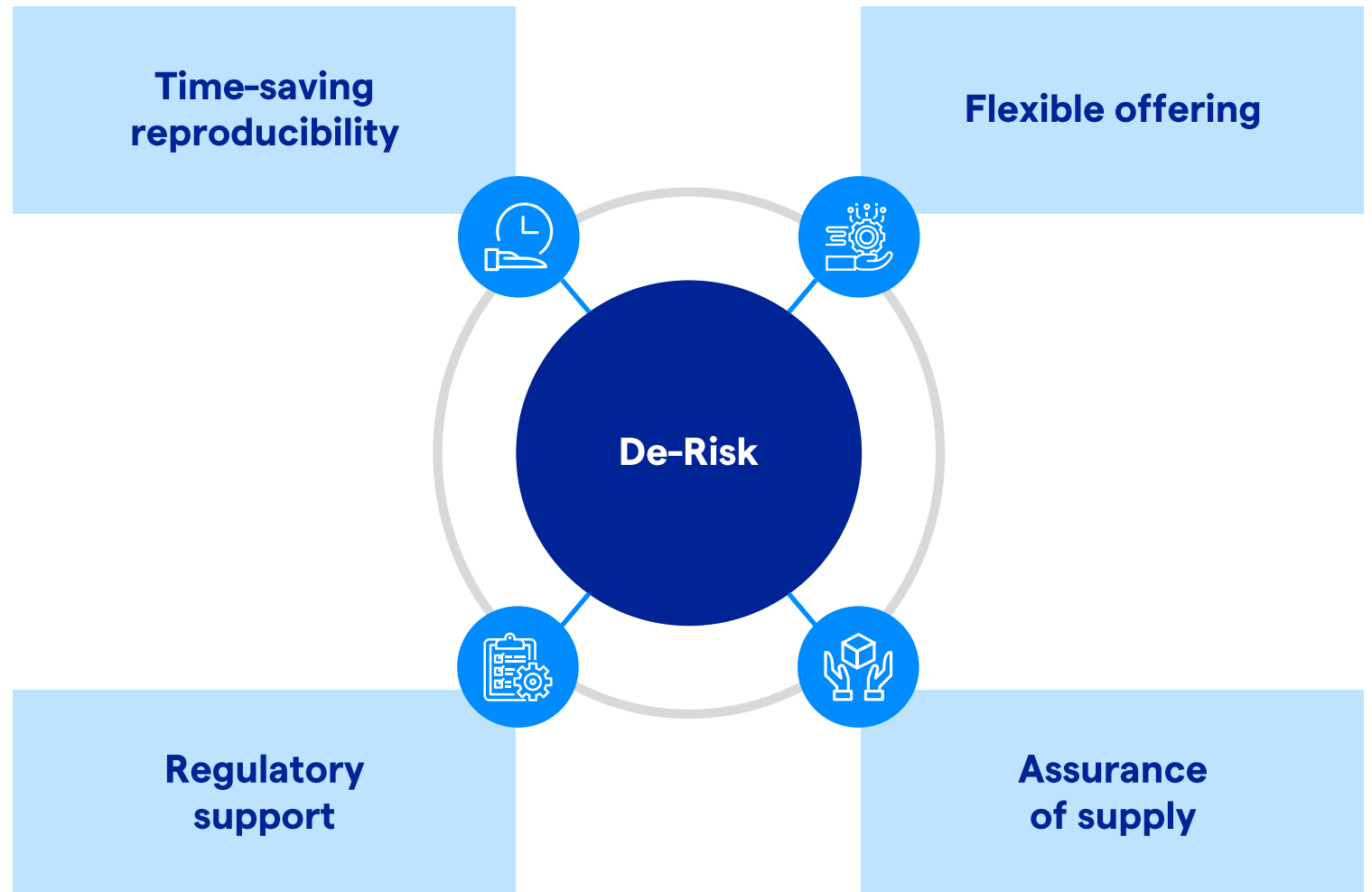
	Fast pilot to commercial scale 	Efficiency 	Partnership 
Customer situation	 Pharma company looking to scale their manufacture for the EMEA and APAC regions	 Starting with smaller batch sizes to optimize processes needed for unique formulation	 Looking for a partner to help them understand what is important as they scale and adapt the format of the media to powder
Lonza response	 Share media development expertise to support decision-making.	 Provided validation of raw materials for the desired final powdered format to de-risk when they were ready to scale	 Optimize processes through joint scale-up trials.
Value delivered	 Achieve seamless transfer from pilot to full-scale manufacturing.	 Save 2 – 3 engineering runs, reducing cost and timeline.	 Secure reliable supply and ongoing support in both regions.

Lonza capabilities

Value proposition



Our high-quality customized media manufacturing service ensures reliable performance for leading biopharmaceuticals, supporting seamless commercial production with assured supply and flexible packaging to meet diverse customer needs.



Thank you!

We look forward to working with you!!!



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