

2026 ISPE **ANNUAL MEETING** & EXPO

18-21 October | Washington, D.C., USA





IS YOUR COLD STORAGE READY FOR PHARMA 4.0?

COLD STORAGE INFRASTRUCTURE
IN THE ERA OF PHARMA 4.0.

LOWENCO

2026 **ISPE ANNUAL MEETING** & EXPO



LOWENCO

COLD STORAGE THROUGH PHARMA 4.0 LENS

TODAY WE WILL COVER:

- **MARKET CONDITIONS HAVE CHANGED:**
What should we expect from Pharma 4.0-ready cold storage?
- **COMPARISON:**
How do different cold storage strategies perform through the lens of pharma 4.0?
- **CASE: FROM PRINCIPLE TO IMPLEMENTATION**
What happens when pharma 4.0 cold storage expectations meet operational reality?
- **LIFECYCLE PERSPECTIVE:**
How does different cold storage approaches perform over 25 years?
- **READY FOR THE NEXT 25 YEARS?**
Considerations before your next cold storage decision

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YOUR SPEAKERS TODAY

Ryan Pridgen

Area Sales Director, North America
LOWENCO A/S

Ryan.pridgen@lowenco.com

- +20 years of experience in quality control, strategic manufacturing, sales and stakeholder engagement
- Deep understanding of pharmaceutical process systems and facility operations
- Proven track record in complex CapEx projects across the pharmaceutical industry
- Has supported leading pharma companies in scaling infrastructure
- Experienced in aligning engineering solutions with both end-users and client needs



Jon Parfrey

Area Sales Director, North America
LOWENCO A/S

Jon.parfrey@lowenco.com

- +10 years facilitating excellence in time and temperature-sensitive pharmaceutical distribution
- Strong background in pharma, energy and cold storage solutions
- Specialty is in the design, development and delivery of world class temperature-controlled products storage and distribution operations with an extensive background in cGMP facility design; refrigerated and frozen storage environment validation; and cold chain network strategy implementation



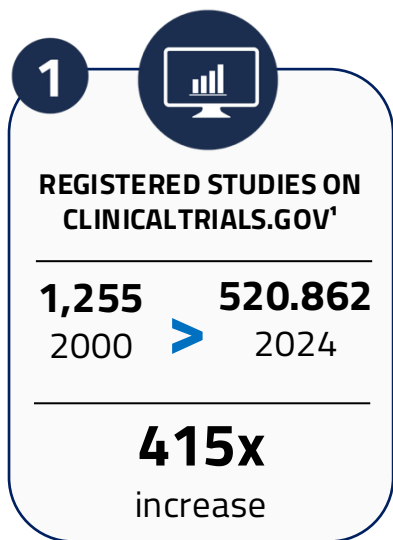
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THE PAST TEACH US ABOUT FUTURE EXPECTATIONS

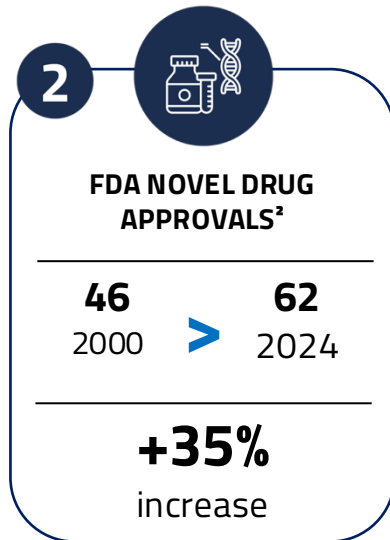
THE 25-YEAR LOOK BACK

MORE RESEARCH



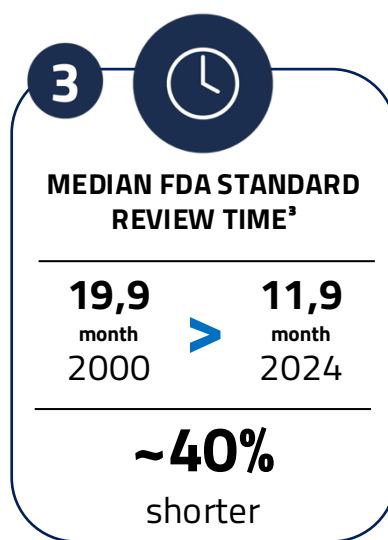
1 Source: ClinicalTrials.gov – Trends and Charts on Registered Studies (May 2025). ClinicalTrials.gov launched on February 29, 2000 with 1,255 studies; 520,862 studies were registered by the end of 2024.

MORE COMPLEX PRODUCTS



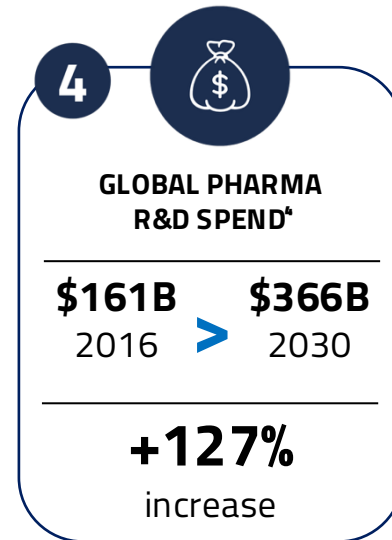
2 Source: Our World in Data (2025) – New drugs approved in the United States. Annual number of new drugs approved by the U.S. Food and Drug Administration (FDA). View data: ourworldindata.org.

FASTER



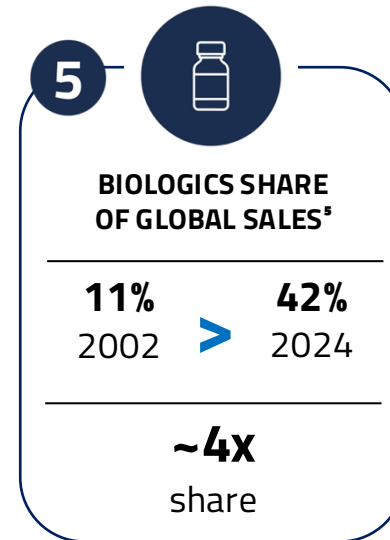
3 Source: FDA – CDER Approval Times for Priority and Standard NMEs/New BLAs; FDA PDUFA FY2025 Performance Report. Median total approval time for standard NMEs/new BLAs (CY); estimated median time to first approval for standard NDAs/BLAs (FY).

MORE INVESTMENT



4 Source: Evaluate Pharma® (May 2024), World Preview 2024: Pharma's Growth Boost. Figure 12: Worldwide Total Pharmaceutical R&D Spend in 2016–2030.

MORE PRODUCTS TO MARKET



5 Source: Lindsley, C.W. (2017). New 2016 Data and Statistics for Global Pharmaceutical Products and Projections through 2017. ACS Chemical Neuroscience, 8(8), 1635–1636. (QuintilesIMS/IMS Health data). Biologics accounted for 11% (\$46B) of global sales in 2002; IQVIA – Global Use of Medicines 2024. Biologics represented 42% of the global Rx pharmaceutical market in 2024.

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PHARMA 4.0

A shift towards digital & automated operations...

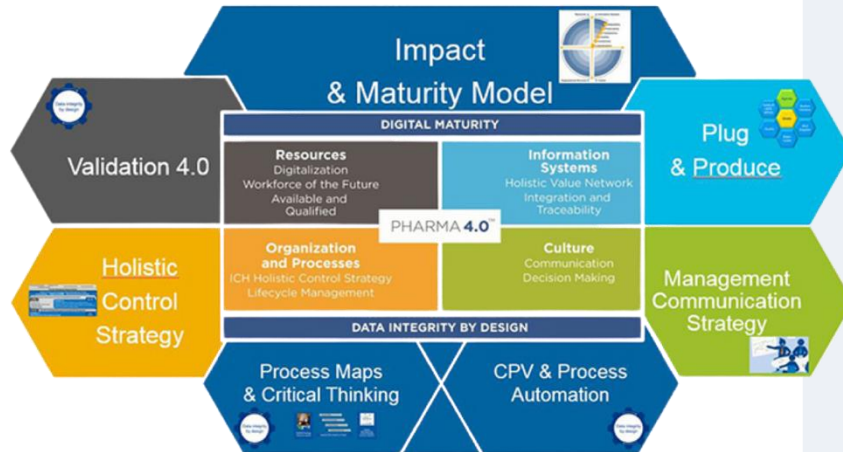
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OBJECTIVE OF PHARMA 4.0™

Leverage the full potential of digitalization to provide faster therapeutic innovations and improved production processes.

Source: ISPE Pharma 4.0™



TRANSLATION OF PHARMA 4.0 INTO COLD STORAGE

Source: LOWENCO A/S

RESOURCE EFFECTIVE

More output and capacity must be achieved with smarter use of space, energy and resources.

HUMAN -CENTRIC

Technology strengthens how people work.

CONNECTED & INTEGRATED

Systems, manufacturing, equipment and data that work seamlessly together.

ACCESSIBLE DATA ACROSS TOUCHPOINTS

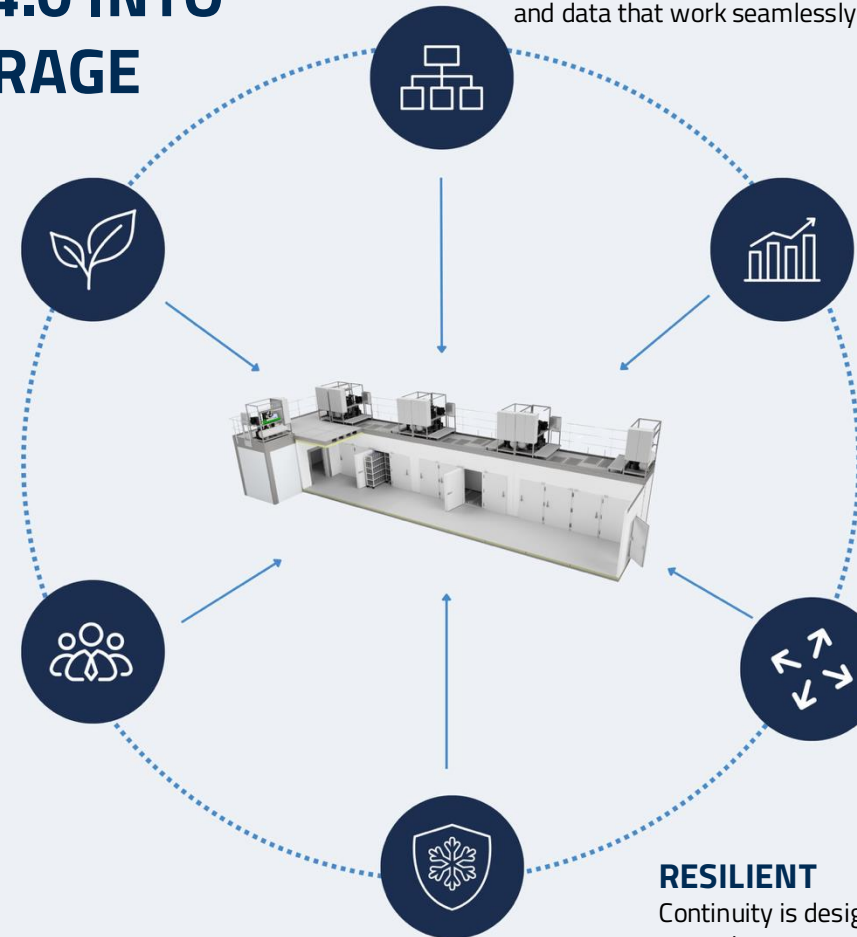
Decisions are informed by trusted and accessible data.

FLEXIBLE & ADAPTIVE

Operations respond to changing requirements.

RESILIENT

Continuity is designed into operations.



THE COLD STORAGE COMPARISON

-THREE APPROACHES

-SAME EXPECTATIONS

**VIEWED THROUGH
A PHARMA 4.0 LENS**



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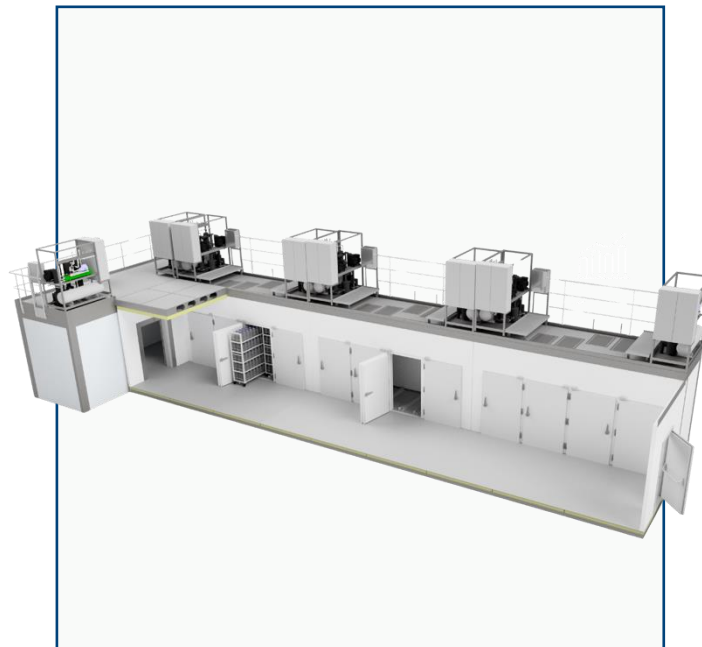


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WAYS TO BUILD COLD STORAGE CAPACITY



FREEZER FARM



**LARGE-SCALE
INTEGRATED**

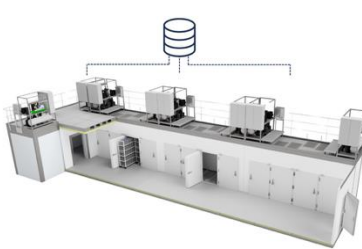


GMP COLD ROOM

CAN IT CONNECT & TURN DATA INTO INSIGHTS?

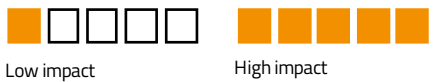
CONNECTED & DATA DRIVEN

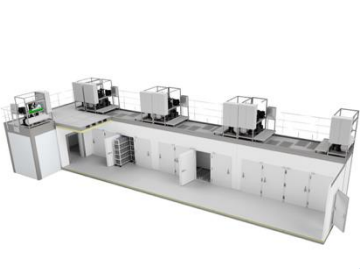


CONNECTED & DATA-DRIVEN IMPACT		 FREEZER FARM	 LARGE-SCALE INTEGRATED	 GMP COLD ROOM
 Connection with data ecosystem (ease of integration)				
 Consolidated number of data sources				
 Reduced monitoring burden				
 Reduced alarm-management burden				
 Predictive Maintenance Potential				

CAN IT ADAPT & PROTECT?

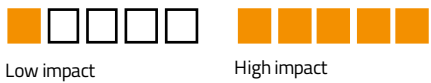
ADAPTIVE | RESILIENCE

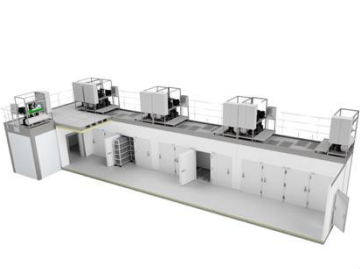


ADAPTIVE & RESILIENCE IMPACT						
	FREEZER FARM		LARGE-SCALE INTEGRATED		GMP COLD ROOM	
 Ease of capacity expansion						
 Flexibility of set points/zones						
 Product-temperature uniformity						
 Build-in redundancy (if a unit falls)						
 Temperature Recover						
 Ability to accommodate future requirements						

CAN IT SCALE WITHOUT ADDING COMPLEXITY?

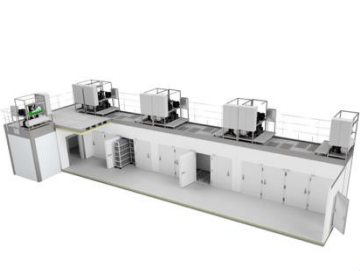
HUMAN-CENTRIC & RESOURCE EFFECTIVE



OPERATIONAL & RESOURCE IMPACT	  		
	FREEZER FARM	LARGE-SCALE INTEGRATED	GMP COLD ROOM
 Minimize floor space required			
 Minimize energy consumption			
 Minimize heat rejection			
 Minimize CO ₂ emissions			
 Minimize monitoring burden			
 Minimize maintenance burden			
 Minimize validation burden			
 Products be accessed without personnel entering ULT environment			

SO, HOW PHARMA READY ARE THE THREE APPROACHES?



PHARMA 4.0 PRINCIPLES				
		FREEZER FARM	LARGE-SCALE INTEGRATED	GMP COLD ROOM
	CONNECTED Can it connect storage with facility data eco-system to simplify overview?			
	DATA-DRIVEN Can it enable data-driven decisions?			
	ADAPTIVE Can it adapt to changing needs and conditions?			
	RESILIENT Can it maintain temperature during normal operation.			
	HUMAN-CENTRIC Can it reduce the operational burden on people?			
	RESOURCE-EFFECTIVE Can it minimize space, energy and infrastructure requirements?			

CASE STUDY

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PROJECT REQUIREMENTS

-  – 40 °C to – 80 °C setpoint
-  Temperature sensitive
-  Flexibility in temperature setpoint
-  8 Cold rooms VS 24 large-scale units
-  Facility design (footprint)
-  ESG initiatives

LOWENCO WAS CHOOSEN BECAUSE:

-  Modular design offered flexibility in temperature setpoints between LSSU units and adjustments for future SKUs
-  Tighter temperature control in the forced air configuration of the high density LSSU units
-  24 LSSU units saved ~2,500 ft²
-  Implementation of the LSSU Module allowed the client to avoid heat tracing and stick built facility connections
-  The efficiency of the LSSU chambers allows the compressors to cool only the dense storage chambers and not an entire cold room including unutilized space. Thus saving energy and reducing overall TCO for a positive ESG impact

LIFECYCLE PERSPECTIVE

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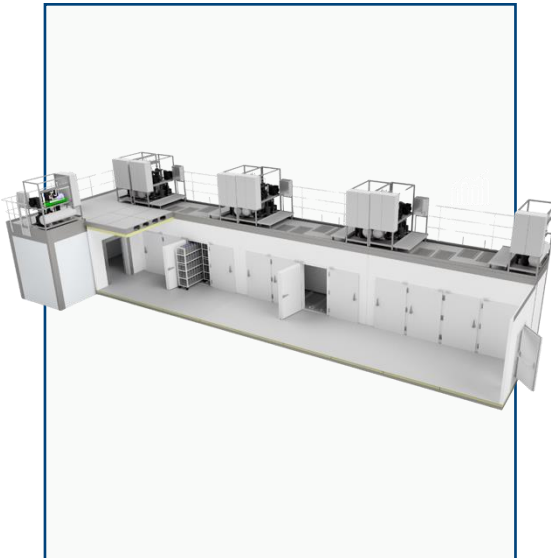


FINANCIAL LIFECYCLE IMPACT

Different cold-storage architectures create fundamentally different lifecycle cost structures



FREEZER FARM



**LARGE-SCALE
INTEGRATED**



GMP COLD ROOM



CONTEXT:

- -80°C setpoint
- 25.900 L storage volumen
- 10L bottles
- 25 years lifecycle

218 UPRIGHTS

VS

6 MODULAR UNITS

incl. corridor, ante-room
& dedicated tech-space

VS

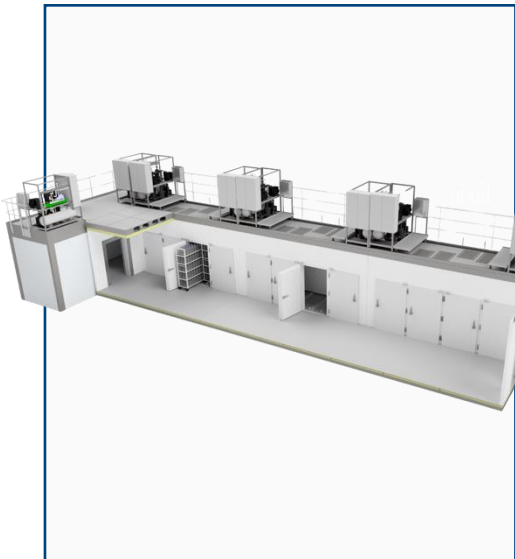
1 COLD ROOM

incl. ante-room

THE TRUE COSTS OF COLD STORAGE



FREEZER FARM



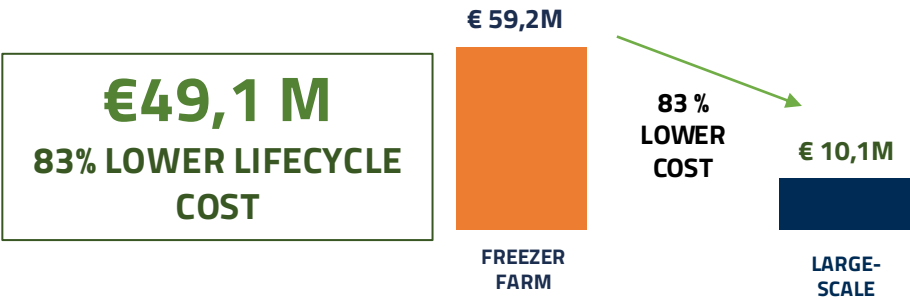
LARGE-SCALE INTEGRATED



GMP COLD ROOM

FINANCIAL COMPARISON

METRIC	FREEZER FARM*	LARGE -SCALE**	COLD ROOM***
Initial CAPEX	€10.1 M	€5.7 M	€5.7 M
Operating cost (25 years)	€39.5 M	€4.4 M	€7.1 M
Replacement Cost (25 years)	€9,6 M	€0 M	€0 M
TOTAL LIFECYCLE COST	€59.2 M	€10,1 M	€12,8 M



*Source, avg. of consolidated 18 different upright freezer brands on the market
**LOWENCO Large-Scale Storage Solution
*** LOWENCO GMP Cold Room

CAPEX:

INITIAL CAPEX INVESTMENT

PRICING FOR PURCHASING

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
No. Units	218 units	6,0 units	1 cold room
Unit Price	22.210 €/unit	804.000 €/unit	4.000.000 €/unit
Total Prince Units	4.841.000 €	4.824.000 €	4.000.000 €

*Source, avg. of consolidated 18 different upright freezer brands on the market

**LOWENCO Large-Scale Storage Solution

***LOWENCO GMP Cold Room

ADDITIONAL CAPEX INVESTMENT TO GET A SOLUTION UP RUNNING

PRICING OF BUILDING

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
Total footprint (m²)	530 m²	165 m²	391 m²
Total footprint (feet²)	5705 feet²	1771 feet²	4209 feet²
Building price pr feet²	400 €/feet²	400 €/feet²	400 €/feet²
Bulding price	2.282.102 €	708.402 €	1.683.474 €

HVAC PLANT

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
Total heat to release to ambient warehouse	7.625 Kw/day	115 Kw/day	153 Kw/day
Pricing HVAC plant	300 €/Kw	300 €/Kw	300 €/Kw
Total pricing HVAC plant	2.287.575 €	34.560 €	45.903 €

BMS CONNECTION NUMBERS OF UNITS:

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
Numbers of units	218 units	6 units	1 Cold Room
Pricing per BMS connection	1000 €	1000 €	1000 €
Total price for BMS connections	218.000 €	6000 €	1.000 €

ELECTRIC FEEDS

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
Numbers of units	218 units	6 units	1 Cold Room
Numbers og electrical feeds (incl. Redundancy)	218 feeds	42 feeds	15 feeds
Pricing per electrical feed	2.000 €	2.000 €	2.000 €
Total price for electrical feed	436.000 €	84.000 €	30.000 €

OPEX:

Annual Operating Costs (1 Year)

**PRICE
ELECTRICITY**
0,5 €/Kw

**1
YEAR**
365 days

PRICING FOR ELECTRIC CONSUMPTION OF FREEZERS:

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
No. units	218 units	6 units	1 units
Average compressor utilization	74%	74%	74%
Total power consumption	2.121 Kw/day	771 Kw/day	1.233 Kw/day
Total electric consumption price (freezers)	387.024 €/year	140.722 €/year	224.993 €/year

PRICING FOR ELECTRIC CONSUMPTION & HVAC PLAT:

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
Total heat release to ambient warehouse	7.625 Kw/day	115 Kw/day	153 Kw/day
Average compressor utilization	74%	74%	74%
Total power consumption HVAC	5.643 Kw/day	85 Kw/day	113 Kw/day
Total electric consumption price (HVAC)	1.029.790 €/year	15.558 €/year	20.664 €/year

VALIDATION OG BMS PROBES:

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
Number of units	218 units	6 units	1 Cold Room
Pricing per validation	500 €	500 €	500 €
Total price for validation	109.000 €	3.000 €	500 €

LEASING COST BUILDING:

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
Leasing cost pr m²	530 m²	165 m²	391 m²
Total footprint m²	100 €/m²/year	100 €/m²/year	100 €/m²/year
Total leasing cost	53.004 €	16.453 €	39.100 €

1 YEAR TOTAL COST OF OPERATION

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
	1.578.817 €	175.733 €	285.257 €

*Source, avg. of consolidated 18 different upright freezer brands on the market

** LOWENCO Large-Scale Storage Solution

*** LOWENCO GMP Cold Room

TOTAL COSTS OF OWNERSHIP 25 YEARS:

LIFECYCLE
UPRIGHTS
EXPECTANCY

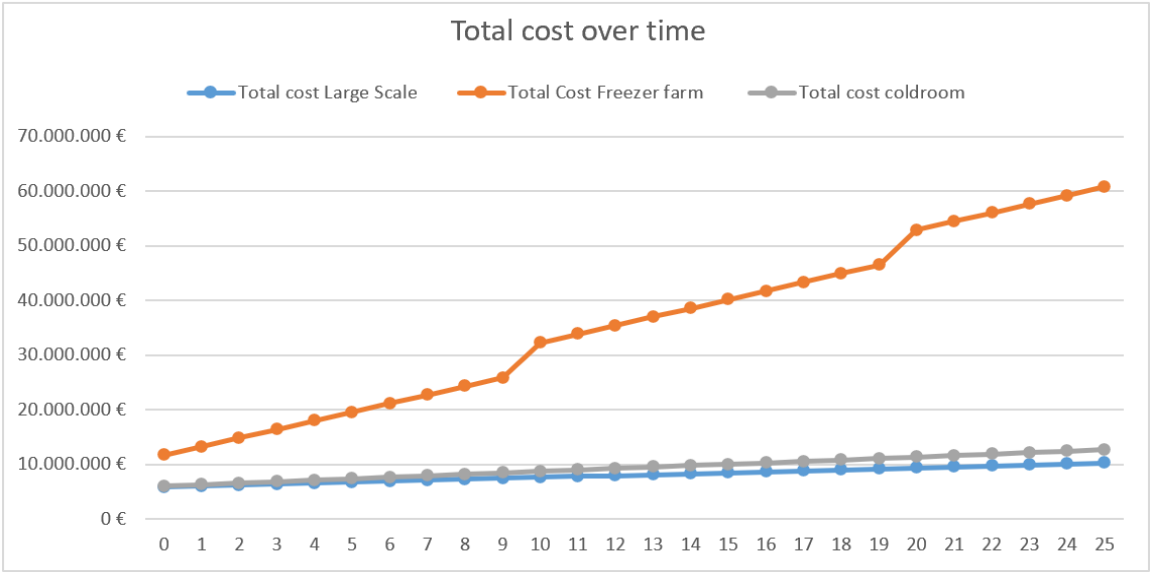
10
years

LIFECYCLE
LSSU
EXPECTANCY

25
years

LIFECYCLE
GMP COLD
ROOM
EXPECTANCY

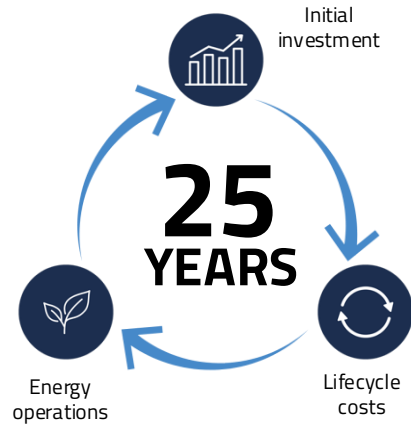
25
years



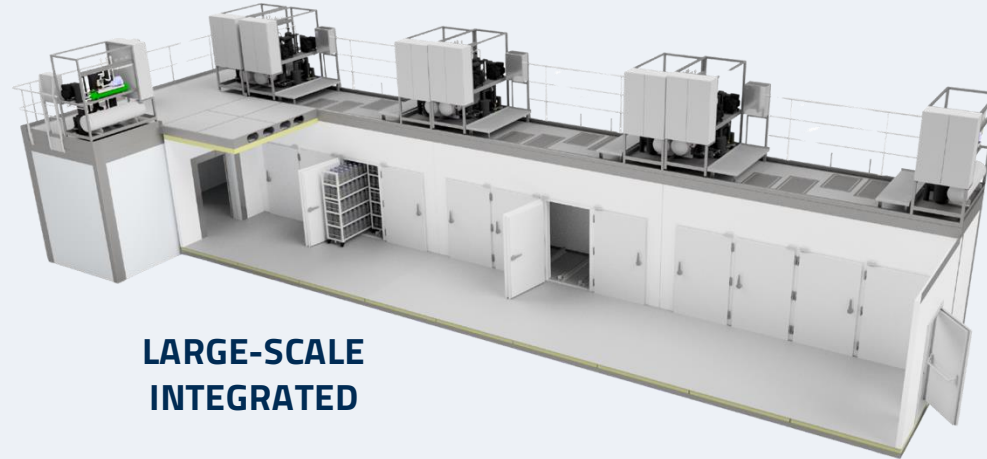
*Source, avg. of consolidated 18 different upright freezer brands on the market
**LOWENCO Large-Scale Storage Solution
***LOWENCO Cold Room

BALANCES LIFECYCLE ECONOMICS WITH PRODUCT PROTECTION

FINANCIAL VALUE



GMP COLD ROOM



LARGE-SCALE INTEGRATED

RISK ASSESMENT



LIFECYCLE ECONOMICS



OPERATIONAL FLEXIBILITY



REACH-IN | PEOPLE PROTECTION



$\pm 1^{\circ}\text{C}$ PRODUCT-TEMPERATURE UNIFORMITY

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READY FOR THE NEXT 25 YEARS?

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WE STARTED
BY LOOKING
BACK

THE NEXT 25 YEARS START WITH THE CHOICES WE MAKE TODAY...



More research



Faster approval time

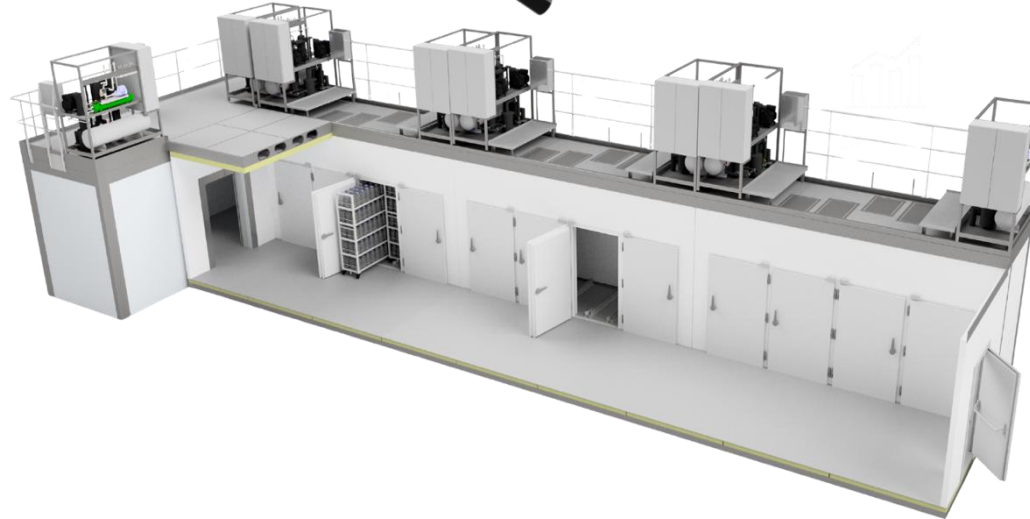


More biologics to market



Greater product complexity

PHARMA 4.0 LENS TODAY



Choose infrastructure that can develop with your product portfolio, protect product integrity and remain a strong investment - whatever the next 25 years bring.



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FROM TODAY'S SESSION

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THANK YOU FOR YOUR TIME!

Area Sales Directors / LOWENCO

Questions?

Ryan Pridgen



Jon Parfrey



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