2026 ISPE ANNUAL MEETING & EXPO

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

ISPE



IS YOUR COLD STORAGE READY FOR PHARMA 4.0?

COLD STORAGE INFRASTRUCTURE IN THE ERA OF PHARMA 4.0.

LOWENCO

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

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

THE 25-YEAR LOOK BACK

MORE RESEARCH

1



REGISTERED STUDIES ON CLINICALTRIALS.GOV[1]

1,255 2000 > 1,255 2000

415x
increase

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



FDA NOVEL DRUG APPROVALS[2]

46 2000 > 62 2000

+35%
increase

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



MEDIAN FDA STANDARD REVIEW TIME[3]

19,9 month 2000 > 11,9 month 2000

~40%
shorter

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



GLOBAL PHARMA R&D SPEND[4]

$161B 2016 > $366B 2030

+127%
increase

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



BIOLOGICS SHARE OF GLOBAL SALES[5]

11% 2002 > 42% 2024

~4x
share

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.

6

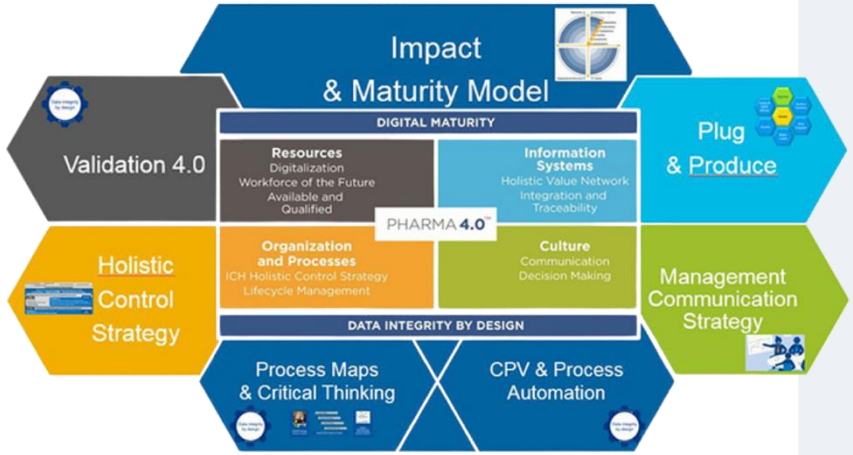
PHARMA 4.0

And a shift towards digital and automated operations...

OBJECTIVE OF PHARMA 4.0™

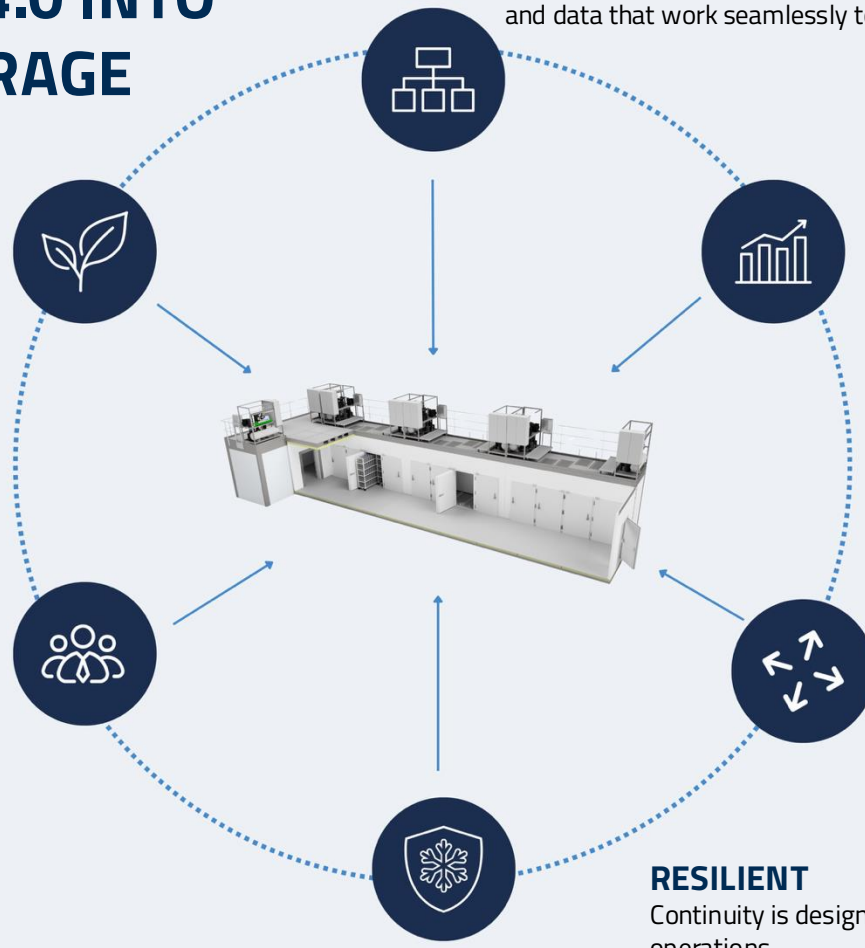
Leverage the full potential of digitalization to provide faster therapeutic innovations and improved production processes.

Source: ISPE Pharma 4.0™



TRANSLATION OF PHARMA 4.0 INTO COLD STORAGE

Source: LOWENCO A/S



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.

HUMAN -CENTRIC
Technology strengthens how people work.

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

THE COLD STORAGE COMPARISON

-THREE APPROACHES
-SAME EXPECTATIONS

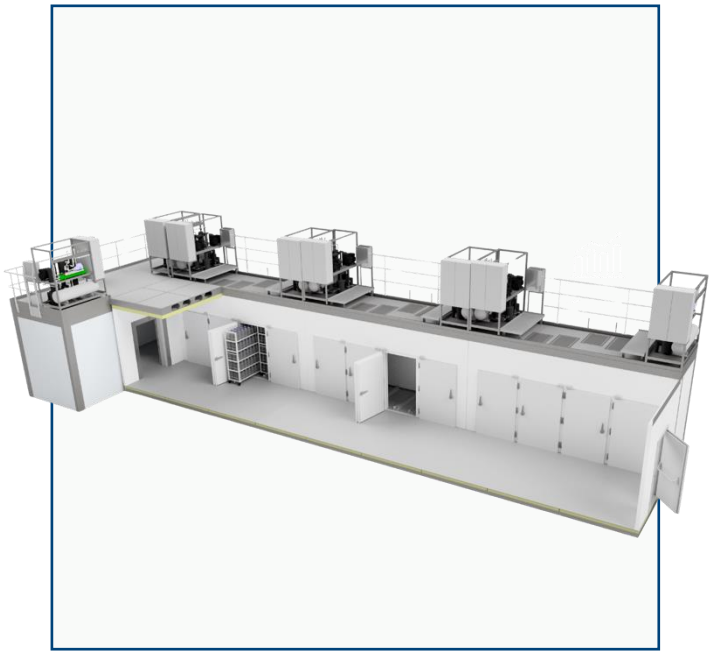
VIEWED THROUG
A PHARMA 4.0 LENS



3 WAYS TO BUILD COLD STORAGE CAPACITY



FREEZER FARM



LARGE-SCALE INTEGRATED



GMP COLD ROOM

CAN IT CONNECT & TURN DATA INTO INSIGHTS?

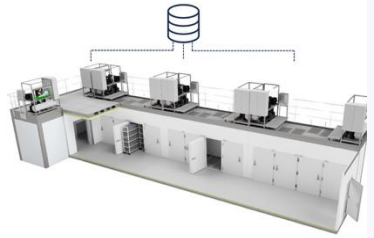
CONNECTED & DATA DRIVEN

Low impact

High impact

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

■□□□□ Low impact

■■■■■ High impact

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 accomodate future requrements	■■□□□	■■■■□	■■■□□

CAN IT SCALE WITHOUT ADDING COMPLEXITY?

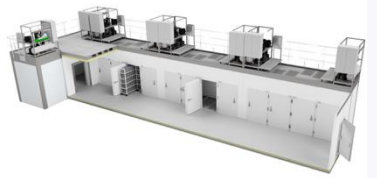
HUMAN-CENTRIC &
RESOURCE EFFECTIVE

■□□□□ Low impact

■■■■■ High impact

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?

Low impact ■□□□□ High impact ■■■■■

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?	■■■□□	■■■■□	■■■□□
RESILENT	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

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

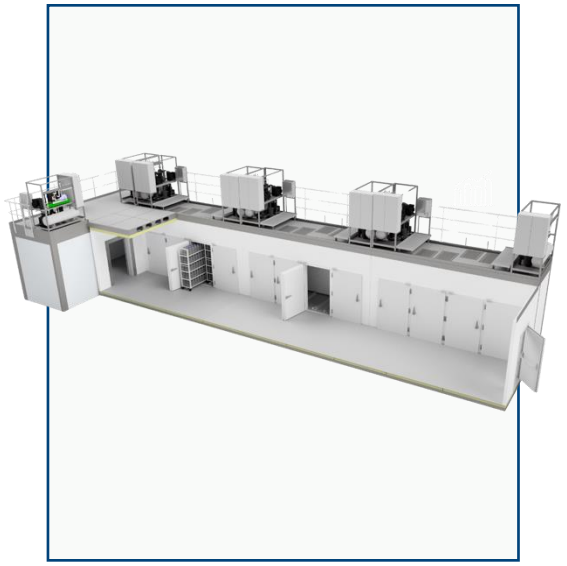
LIFECYCLE PERSPECTIVE

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

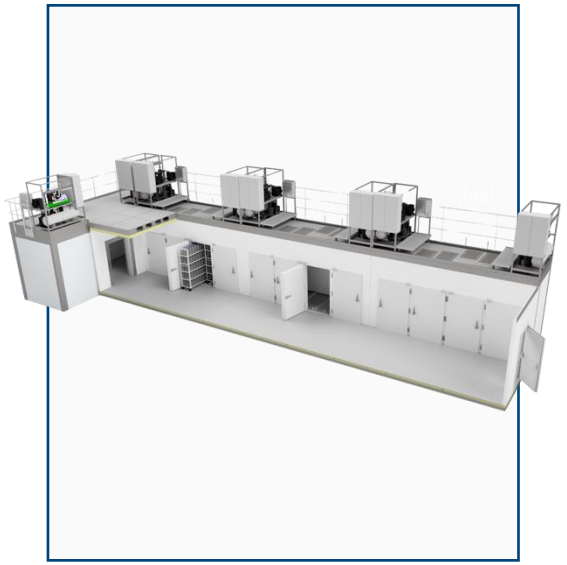
1 COLD ROOM

incl. ante-room

THE TRUE COSTS OF COLD STORAGE



FREEZER FARM



LARGE-SCALE INTEGRATED

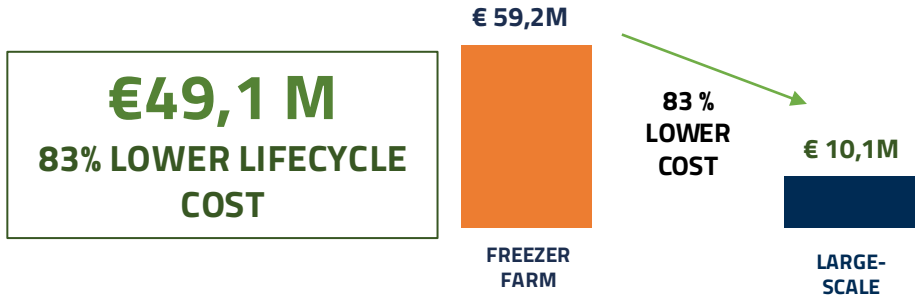


GMP COLD ROOM

FINANCIAL COMPARISON

METRIC	FREEZER FARM*	LARGE -SCALE**	COLD ROOM***
Intial 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**

€49,1 M
83% LOWER LIFECYCLE COST



*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 (m^2)	530 m^2	165 m^2	391 m^2
Total footprint ($feet^2$)	5705 $feet^2$	1771 $feet^2$	4209 $feet^2$
Building price pr $feet^2$	400 €/$feet^2$	400 €/$feet^2$	400 €/$feet^2$
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	1 YEAR
0,5 €/Kw	365 days

PRICING FOR ELECTRIC CONSUMPSION OF FREEZERS:

	FREEZER FARM*	LARGE-SCALE**	GMP COLD ROOM***
No. units	218 units	6 units	1 units
Average compressor utilzation	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 utilzation	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 m^2	530 m^2	165 m^2	391 m^2
Total footprint m^2	100 €/m^2/year	100 €/m^2/year	100 €/m^2/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

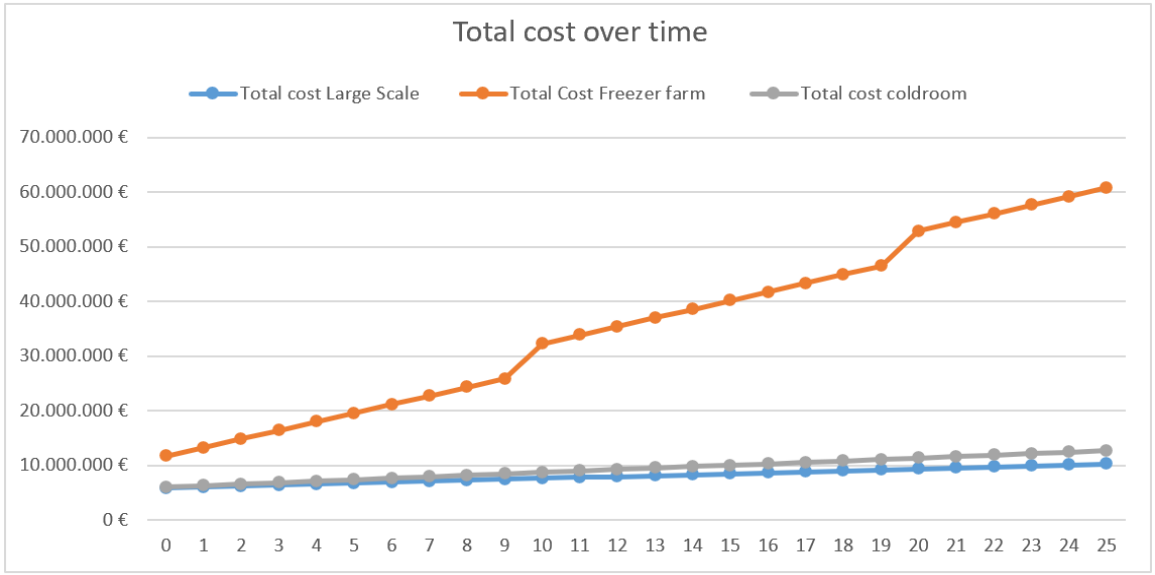
10 years

LIFECYCLE LSSU EXPECTANCY

25 years

LIFECYCLE GMP COLD ROOM EXPECTANCY

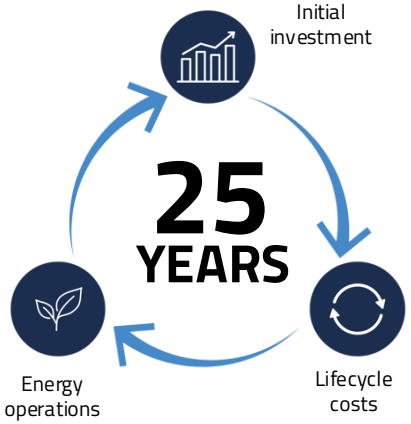
25 years



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

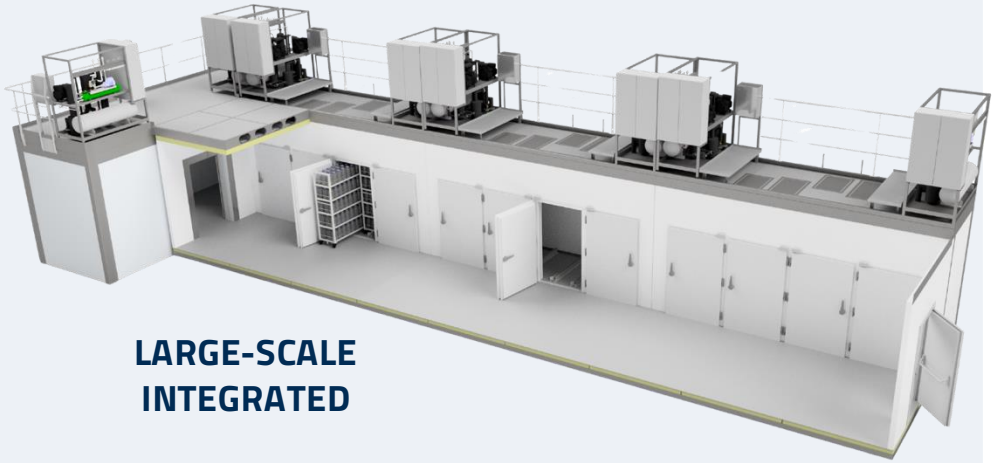
BALANCES LIFECYCLE ECONOMICS WITH PRODUCT PROTECTION

FINANCIAL VALUE





GMP COLD ROOM



LARGE-SCALE INTEGRATED

RISK ASSESMENT



- LIFECYCLE ECONOMICS
- OPERATIONAL FLEXIBILITY
- REACH-IN | PEOPLE PROTECTION
- ±1°C PRODUCT-TEMPERATURE UNIFORMITY

READY FOR THE NEXT 25 YEARS?

2026 ISPE ANNUAL MEETING & EXPO

ISPE

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

WE STARTED BY LOOKING BACK



More research

Faster approval time





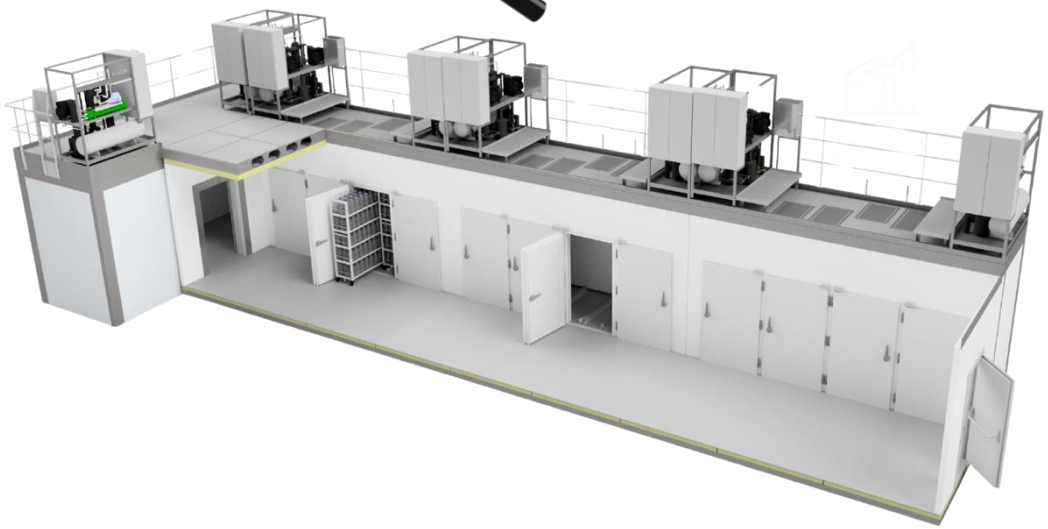
More biologics to market



Greater product complixity

PHARMA 4.0

LENS TODAY



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



THANK YOU FOR YOUR TIME!

Questions?

Area Sales Directors / LOWENCO



Ryan Pridgen



Jon Parfrey


LOWENCO
Creating a better world – one unit at a time