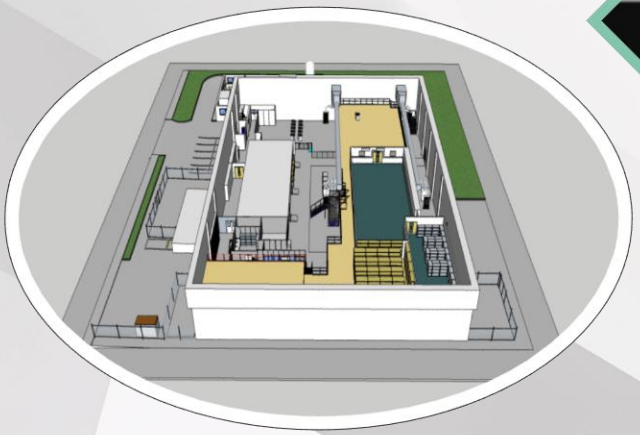
LTS



LTS PROPOSAL

Stem Cell Biorepository Design Considerations

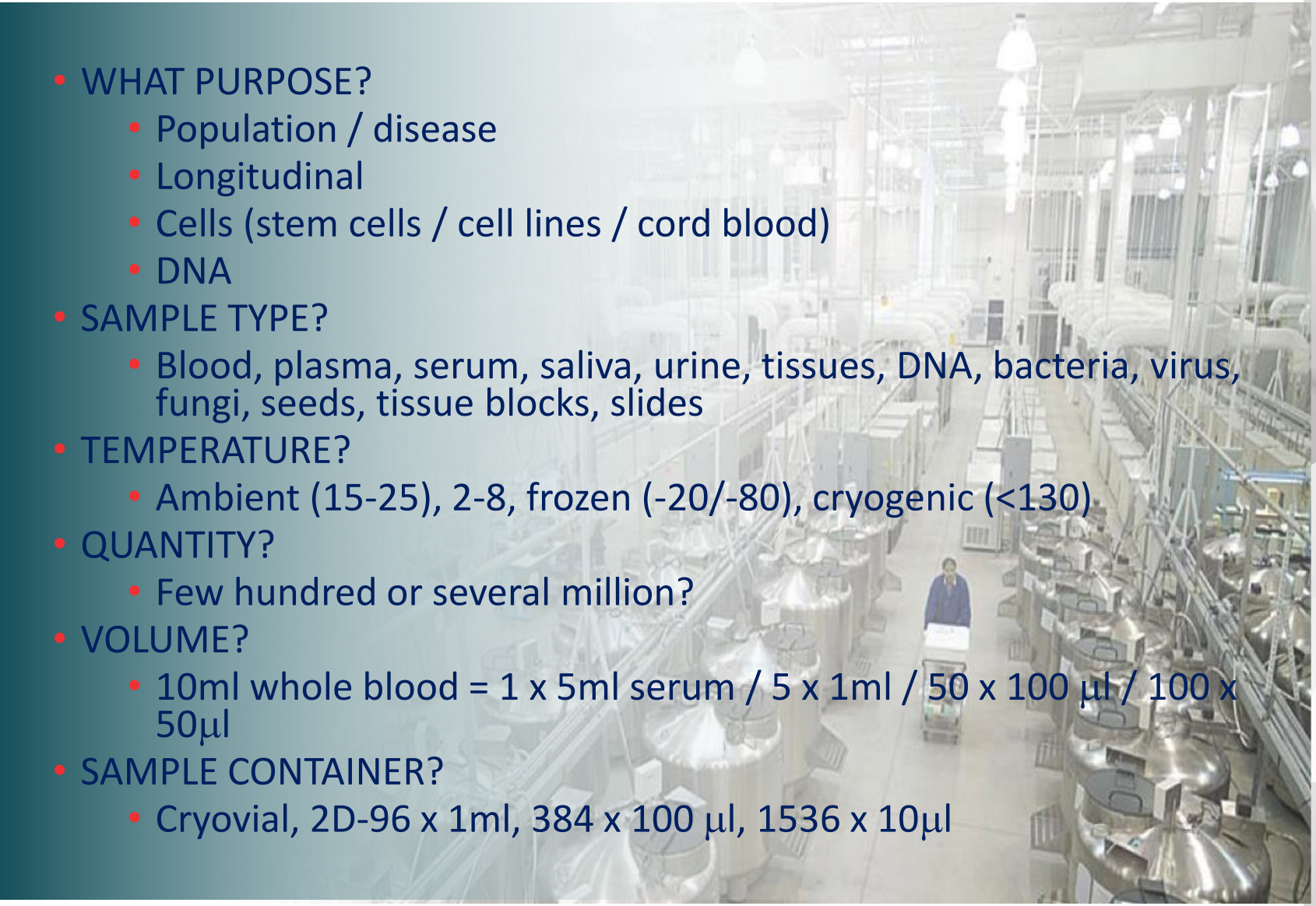
LTS

... IS A BUSINESS ADVISORY AND PERFORMANCE IMPROVEMENT ALLY.

At **LTS**, our **Vision** is to be the **global ally** of choice for businesses requiring exceptional and efficient solutions that **maximise industrial and human potential.**

DESIGN CONSIDERATIONS

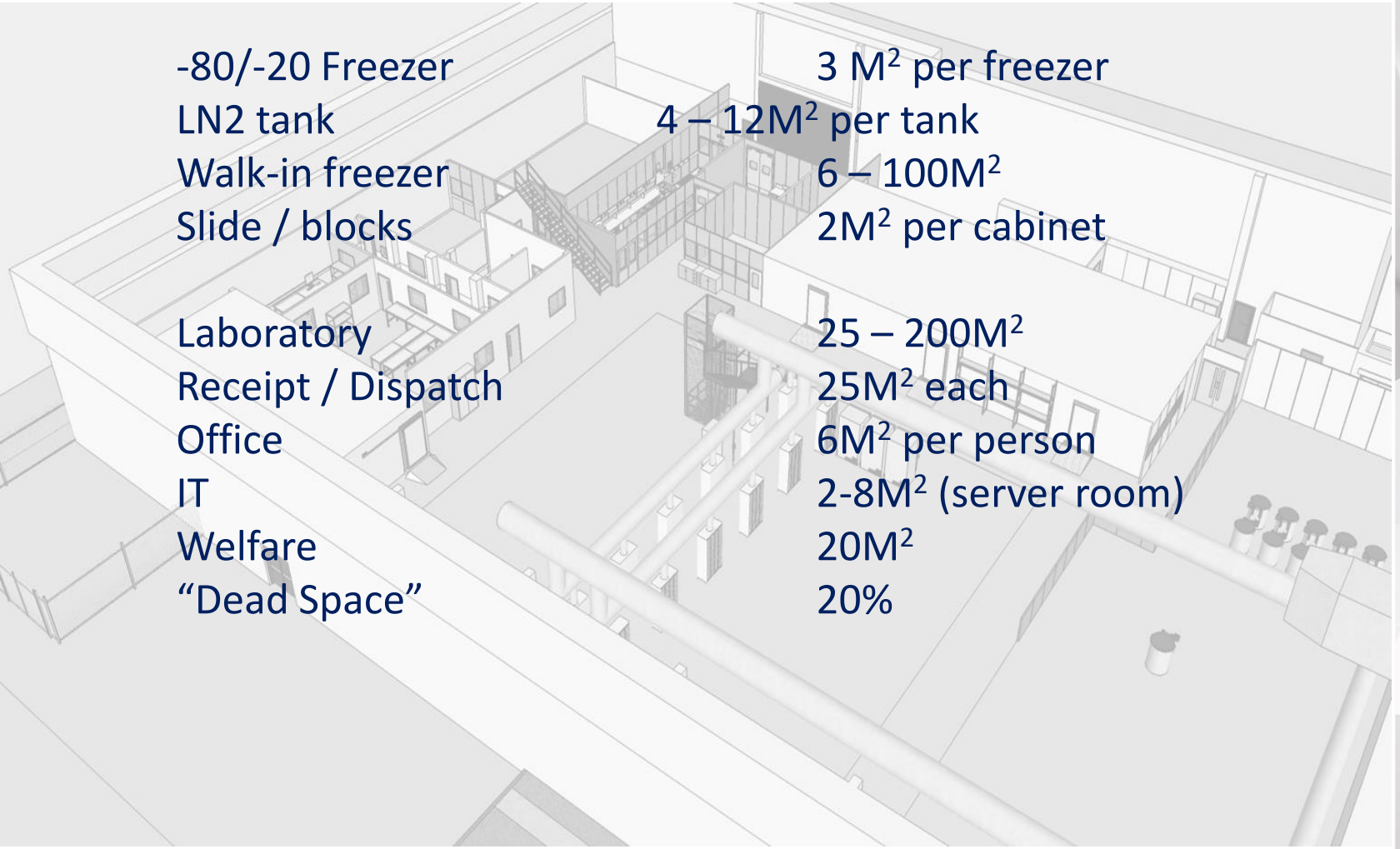
Where do you start…?



- WHAT PURPOSE?
  - Population / disease
  - Longitudinal
  - Cells (stem cells / cell lines / cord blood)
  - DNA
- SAMPLE TYPE?
  - Blood, plasma, serum, saliva, urine, tissues, DNA, bacteria, virus, fungi, seeds, tissue blocks, slides
- TEMPERATURE?
  - Ambient (15-25), 2-8, frozen (-20/-80), cryogenic (<130)
- QUANTITY?
  - Few hundred or several million?
- VOLUME?
  - 10ml whole blood = 1 x 5ml serum / 5 x 1ml / 50 x 100 µl / 100 x 50µl
- SAMPLE CONTAINER?
  - Cryovial, 2D-96 x 1ml, 384 x 100 µl, 1536 x 10µl

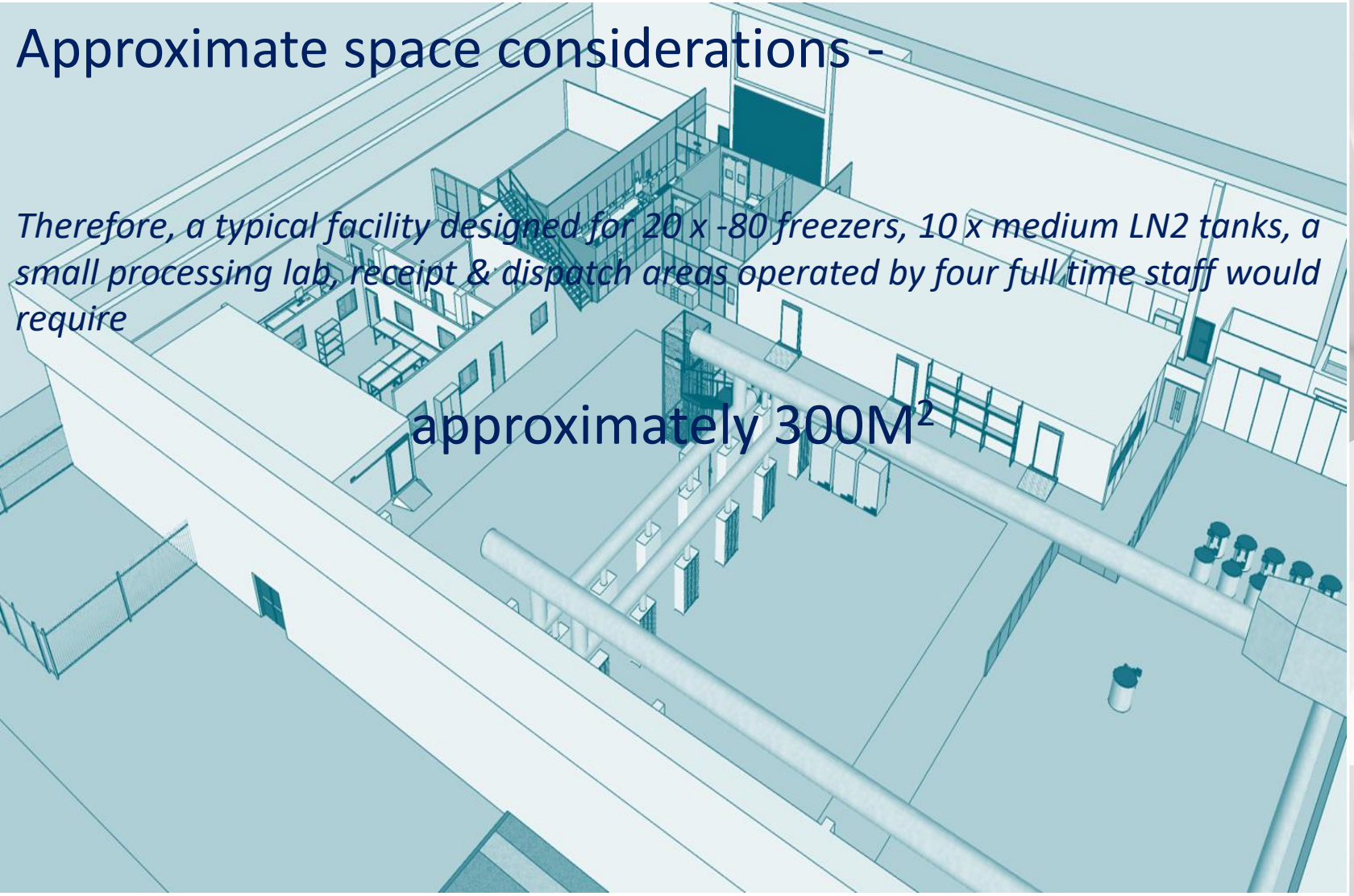
Space Requirements (Dedicated Facility)

Approximate space considerations -



-80/-20 Freezer	3 M^2 per freezer
LN2 tank	4 – 12M^2 per tank
Walk-in freezer	6 – 100M^2
Slide / blocks	2M^2 per cabinet
Laboratory	25 – 200M^2
Receipt / Dispatch	25M^2 each
Office	6M^2 per person
IT	2-8M^2 (server room)
Welfare	20M^2
“Dead Space”	20%

Space Requirements (Dedicated Facility)

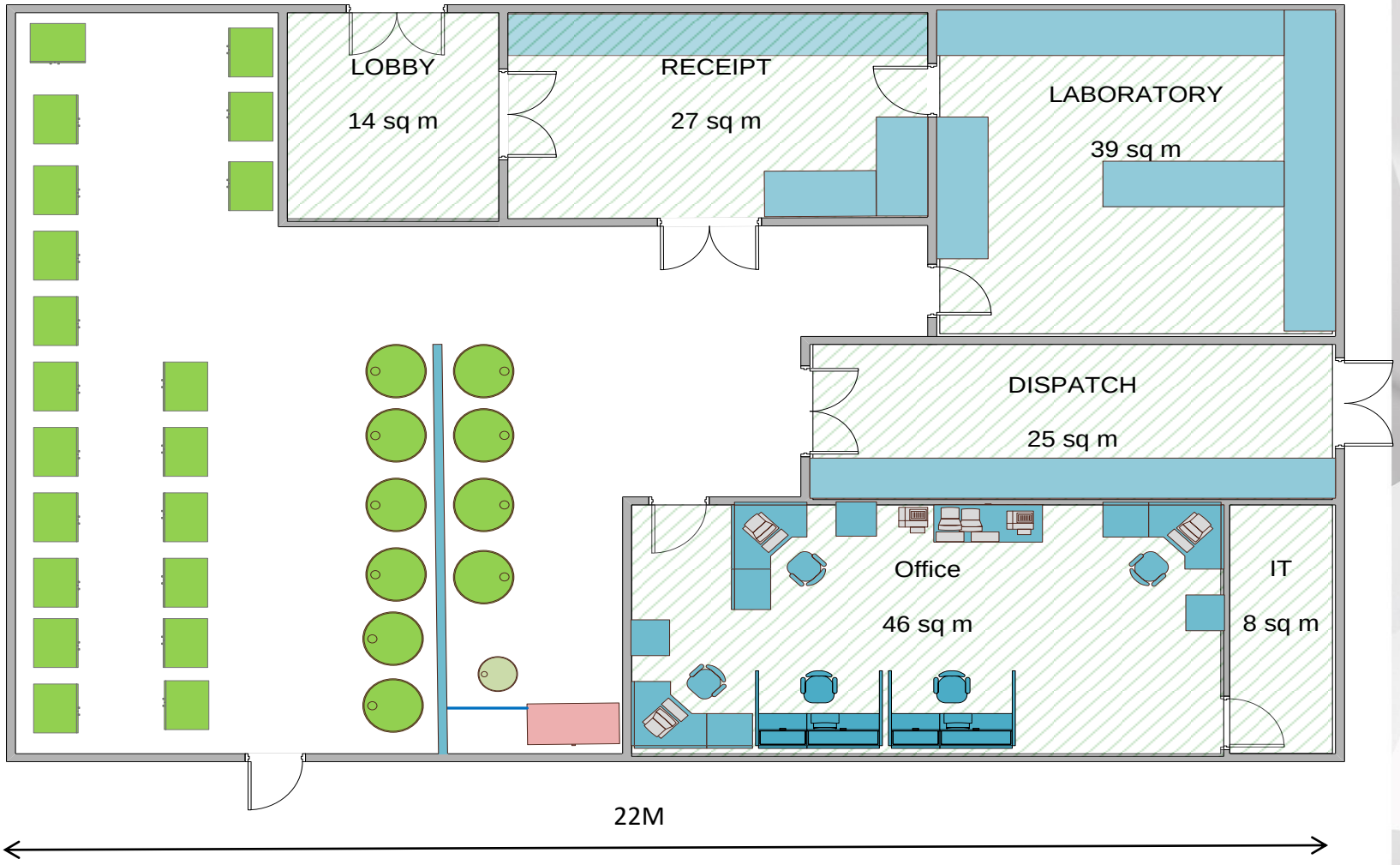


Approximate space considerations -

Therefore, a typical facility designed for 20 x -80 freezers, 10 x medium LN2 tanks, a small processing lab, receipt & dispatch areas operated by four full time staff would require

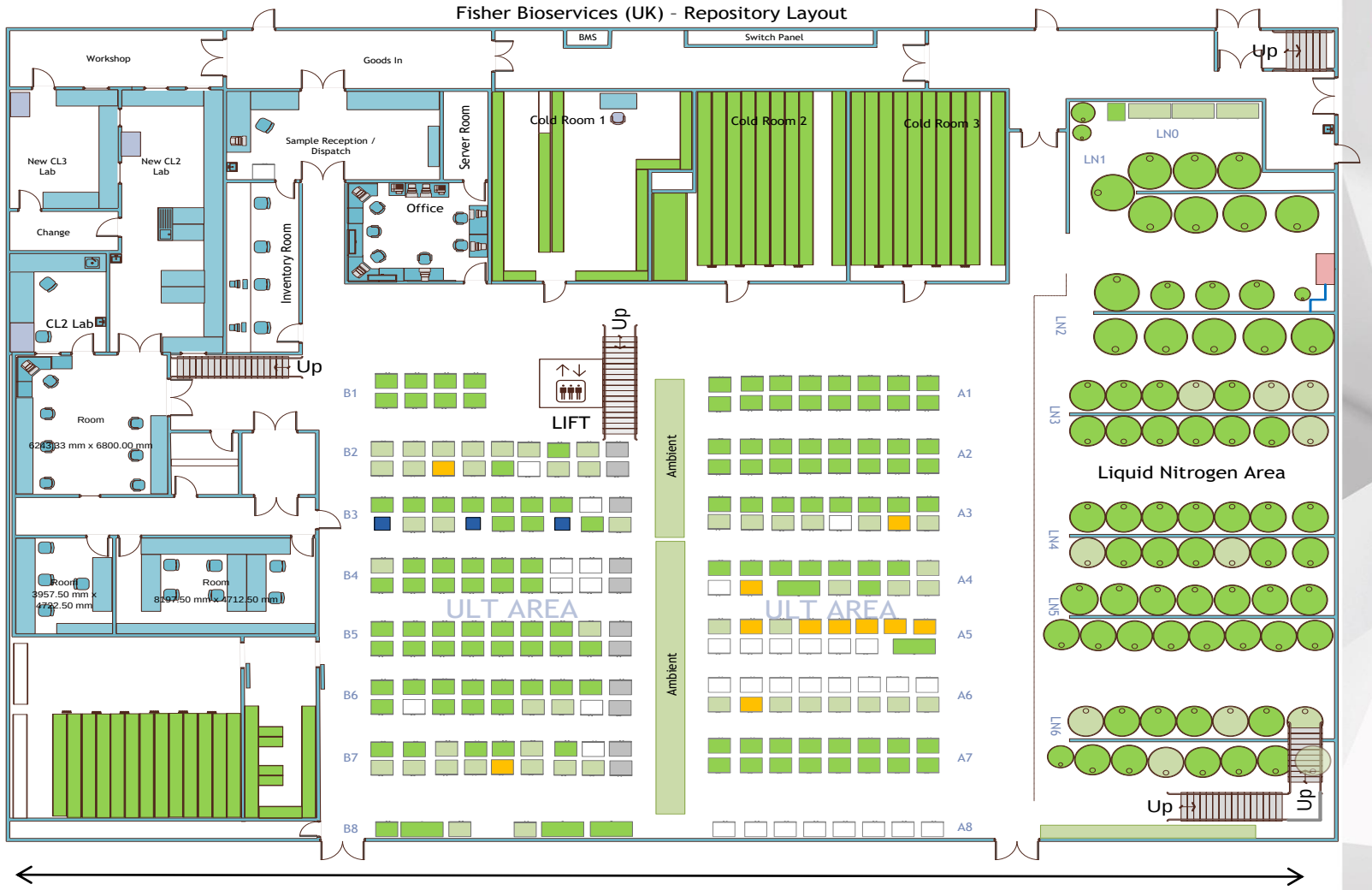
approximately 300M^2

Space Requirements (Dedicated Facility)



Total Area = 308M^2

Space Requirements (Dedicated Facility)



Total Area = 2,200M^2

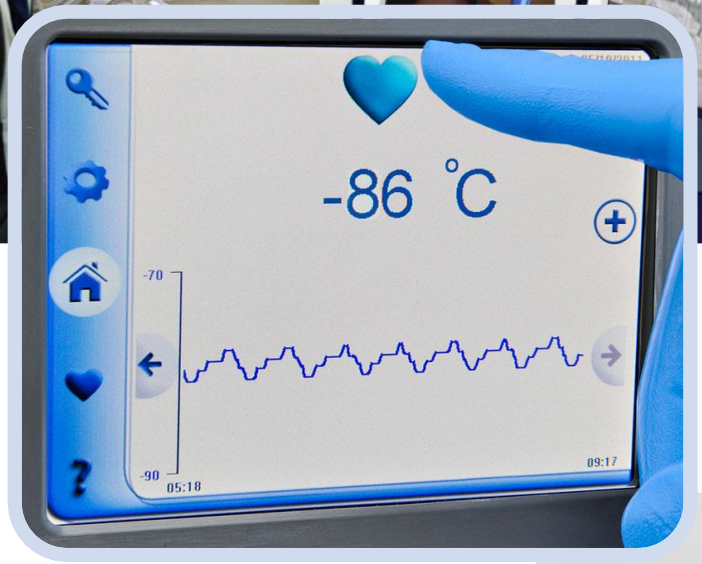
Fisher BioServices

LTS

Other considerations…

- **Security**
  - Building security access and CCTV monitoring
  - Point of access security & escort policy
  - Emergency generators back up total system infrastructure
  - Bulk LN2 storage (2 weeks)
  - Back-up storage capacity available for all temperature ranges

- **Temperature Monitoring**
  - Temperature monitoring & alarm system
  - 24/7 temperature monitoring on all equipment
  - Fully validated system (eg 21CFR11)
  - Temperatures logged continuously
  - Historical reporting capability

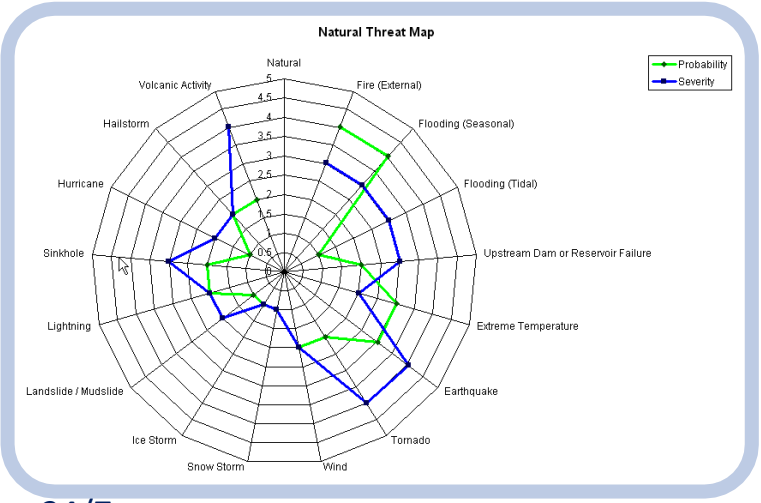


Other considerations….

- HVAC
  - Provides constant temperature control in building
  - ULT freezers must remain <25° C at all times
  - Must include redundancy in case of failure
  - Must include extract and fresh air
  - Incoming air should be filtered to reduce dust
  - Creates ventilation
  - Reduces humidity
  - Fire alarm activation must deactivate air handling
  - Must include Oxygen monitoring in LN2 used
  - O2 monitoring system must isolate LN2 supply in the event of low oxygen levels (<18%)
  - O2 alarms must be present inside and outside facility

Other considerations…

- Risk Mitigation
  - Site specific Incident Response Plan (IRP)
  - Threat assessments
  - Infrastructure & business continuity



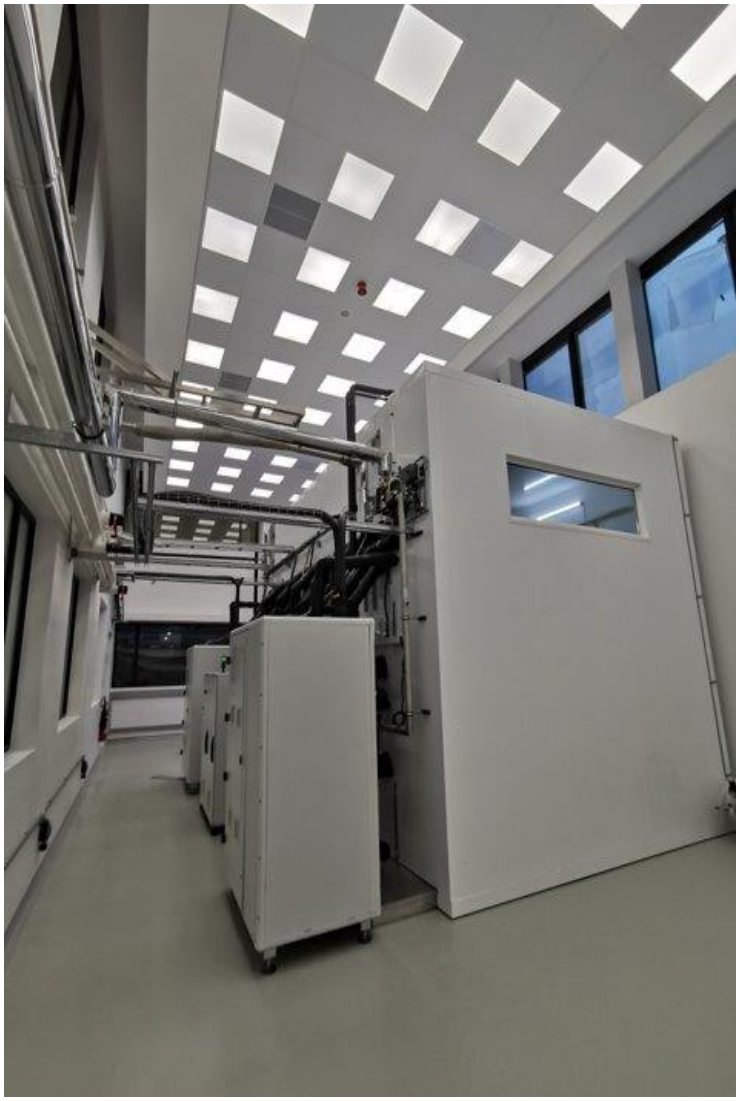
Redundancy

- Back-up storage units ready at all temperature 24/7
- Ample reserves of LN_2, dry ice, generator fuel on site

Service & On-site Engineering

- Qualified vendors provide 24/7 emergency response
- Equipment serviced twice a year
- Equipment maintained and repaired using manufacturers' parts
- Planned replacement of units

Automation Options



For more information, please contact:
Menno Schagen Pr.Eng
+27 21 913 8959 (Office)
+27 83 264 6093 (Mobile)
menno@LTSconsulting.com
www.LTSconsulting.com