- ISPE @ EASE ,,,
- Facility Design ,,,

What is EASE?

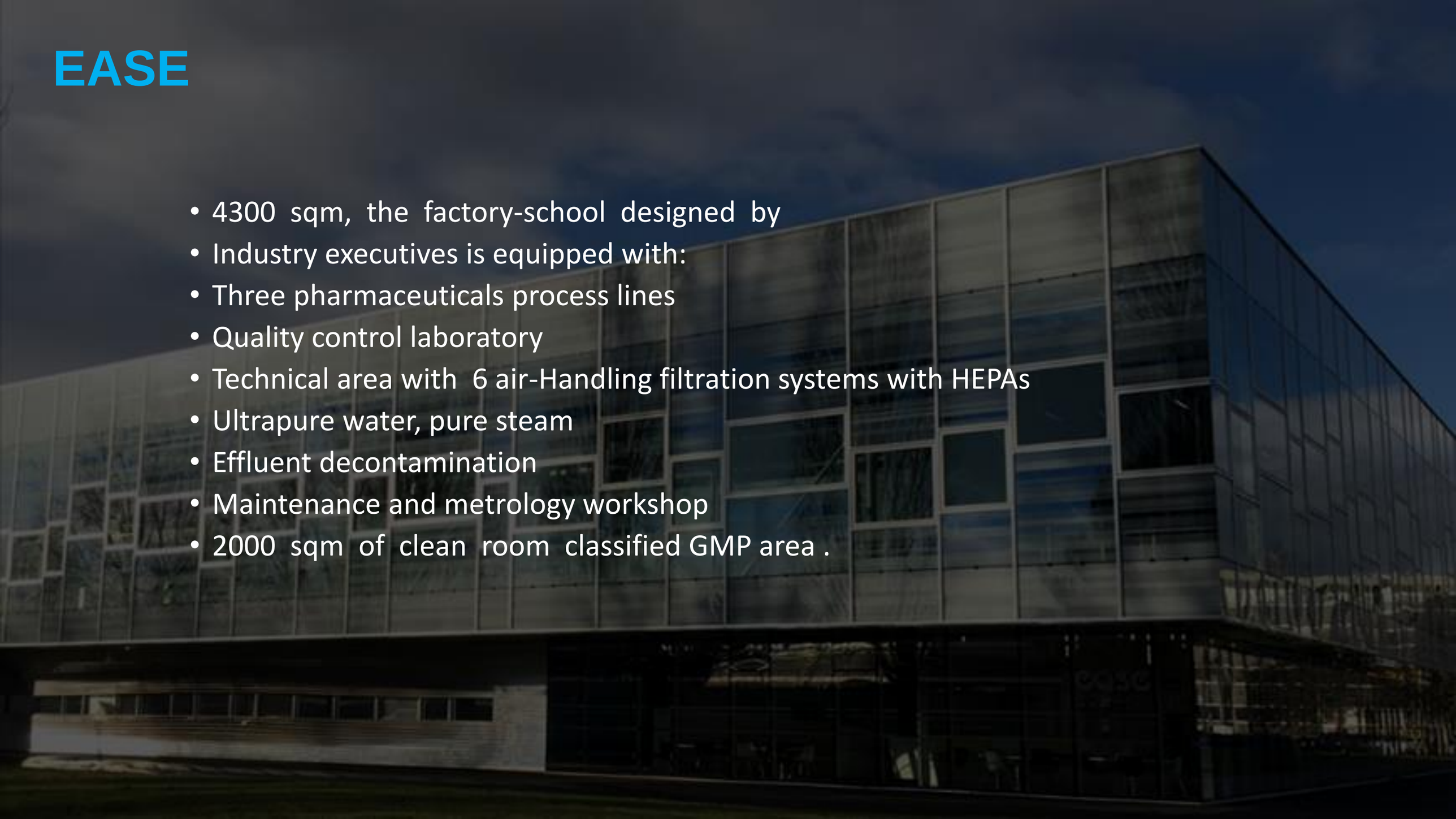
European Aseptic and Sterile Environment Training Center (EASE)

EASE

- In Strasbourg
- Close to Strasbourg **train station** and **airport**
- Directly served by 3 h **DGV ride from CDG**

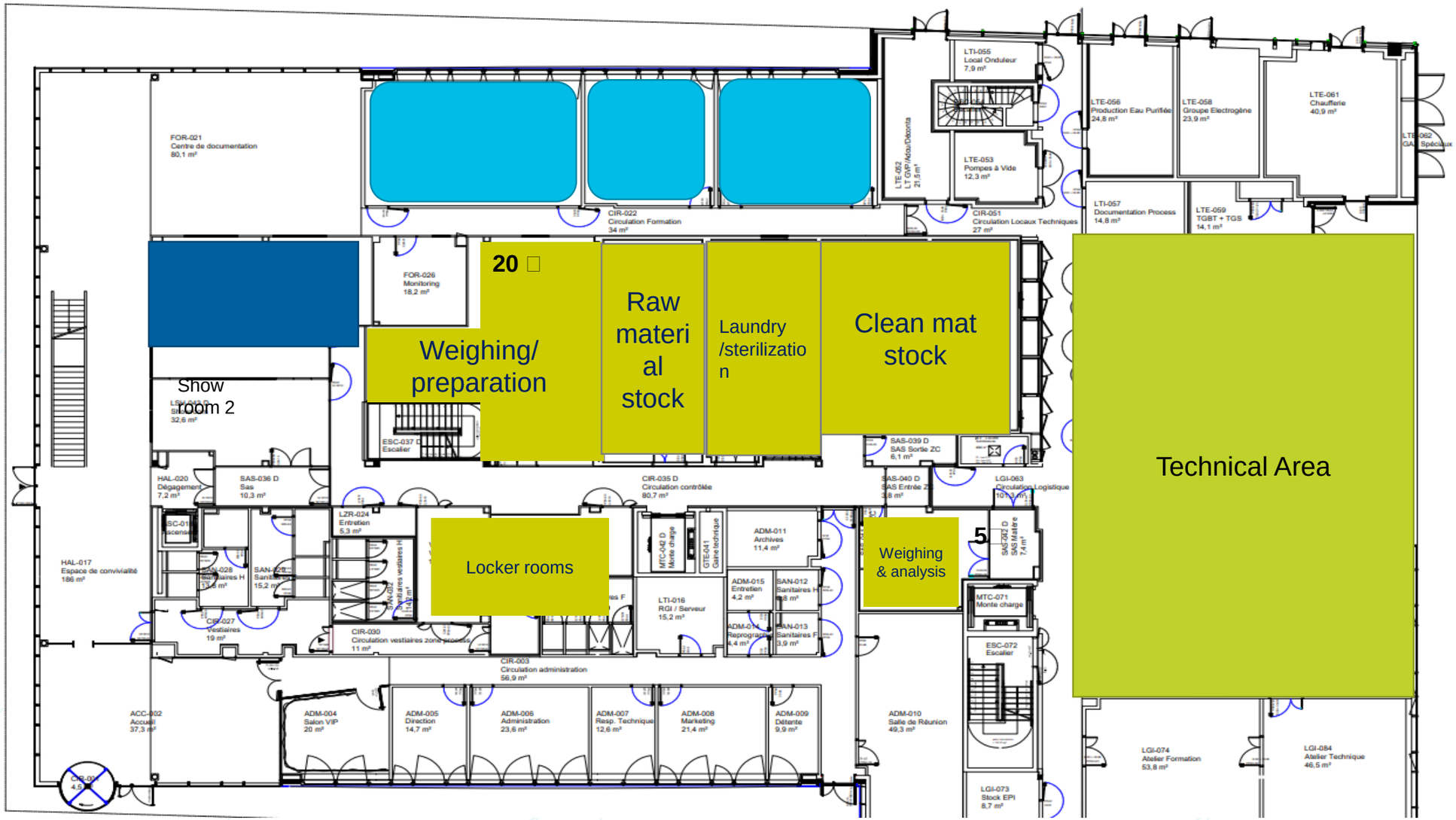
ISPE FOUNDATION

EASE



- 4300 sqm, the factory-school designed by
- Industry executives is equipped with:
- Three pharmaceuticals process lines
- Quality control laboratory
- Technical area with 6 air-Handling filtration systems with HEPAs
- Ultrapure water, pure steam
- Effluent decontamination
- Maintenance and metrology workshop
- 2000 sqm of clean room classified GMP area .

EASE – Ground Floor



EASE – Production and QC Areas

EASE

Market

Industries
Start-ups
Public research laboratories
Training organizations for professional requalification and continuing education
Initial academic training (secondary and higher education)

Industrial sector

Pharma & Biopharma
Industry
Cosmetics
Hospital
Food and chemical industry

EASE is a meeting place, the totem pole at the interface of industry, academia, and innovation.

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ISPE/EASE Partnership 23- 2024

2023 vs. 2024 Training Format Optimization

2023 Pilot
Parallel Streams

Subjects	Day 1	Day 2
HVAC	Class + Practice	Class + Practice
Clean Utilities	Class + Practice	Class + Practice
C&Q	Class + Practice	Class + Practice
ATMP's	Class + Practice	Class + Practice
Biotechnologies	Class + Practice	Class + Practice
Aseptic Processes	Class + Practice	Class + Practice

2024
In Series Streams

Subjects	HVAC	Utilities	C&Q	ATMP's	Biotech	Aseptic
Day 1	X		X			X
Day 2	X		X			X
Day 3		X	X	X	X	
Day 4		X	X	X	X	

- Dark blue in clean rooms
- Light Blue in technical areas
- C&Q Commissioning and qualification
- ATMP Advanced Therapy Medicinal Products

Optimizing:

- This "In Series" format was developed based upon instructors as well as attendee feedback.
- Select classroom lecture materials will be provided as a pre-read.

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2024 Training Calendar – In Series Format

Feb 20-24
Courses:
- Aseptic Processing & Annex 1
- ATMP Manufacturing
- Instructor: Jean Francois Duliere

May 13-16
Courses:
- HVAC
- Pharmaceutical Water Systems
- Instructor: Stephan Neumann

Sep 9-14
Courses:
- Commissioning & Qualification
- Practical HVAC
- Instructor: Bruce Davis

Nov 6-9
Courses:
- Aseptic Processing & Annex 1
- Biopharmaceuticals
- Instructor: Jean Francois Duliere

*early industry Rate:
$5,000
Govornment1600
Student 1000

*Special Affiliate Rate:
$2,000

1 representative per
EU Affiliate

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Facility Design ,,,

Facility Design ,,,

1. Project Objectives
2. How to start the design
3. Surrounding Space
4. HVAC system options
5. Training & Qualification
6. Suppliers & Contractors
7. Project Changes
8. Project Plan and timeline

- **No 1 project objects**

- List the project short- and long-term management Goals to design for the future
- Do not only rely on one source of information ,challenge the market studies.

- Check & study all possibilities of changes and modifications of other options

- For negotiation purpures design should be based on more than one supplier

- **No 2 How to start the design**

➢ Talk to the people involved directly in the process and try to listen **As Much As Possible**

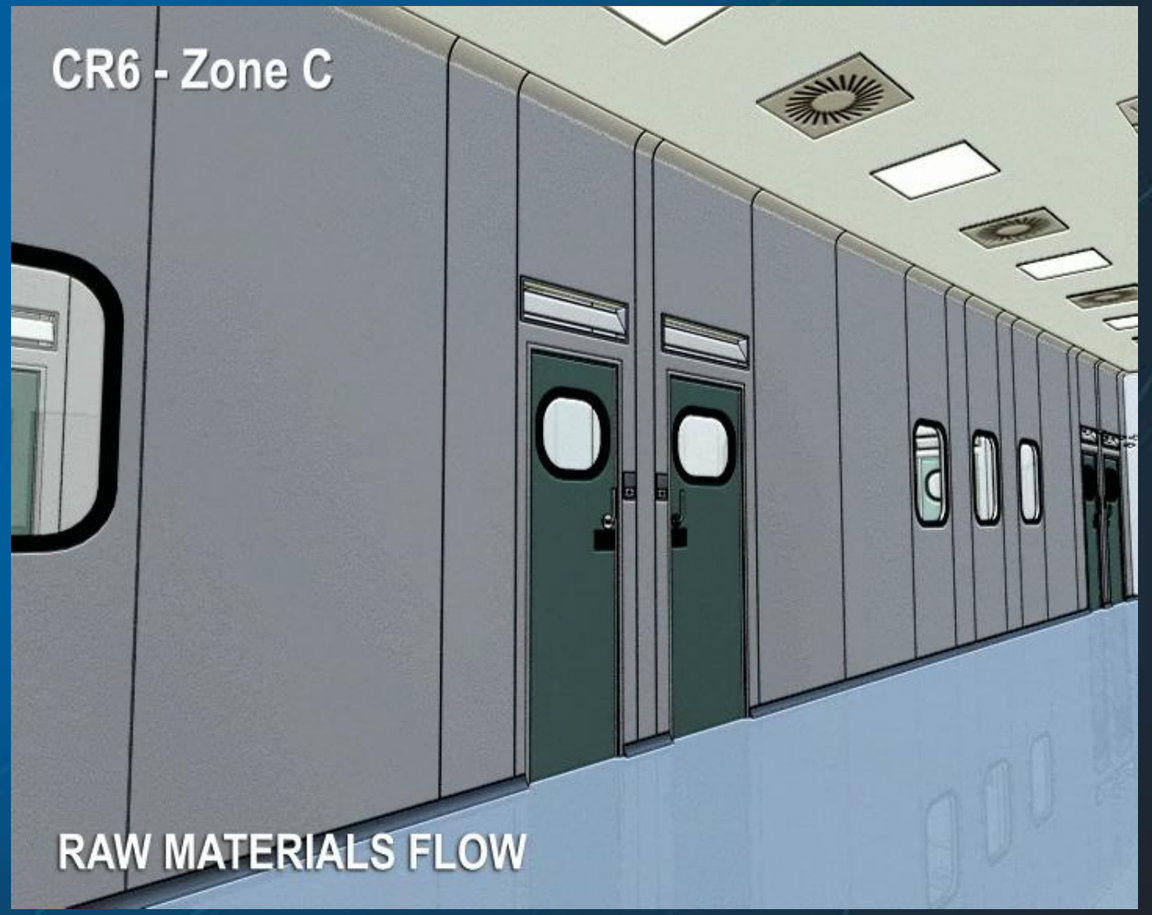
➢ Use **3 D Animation** as some people cannot give propre feedback based on normal flat drawings

➢ Use simulation Video to identify design flows

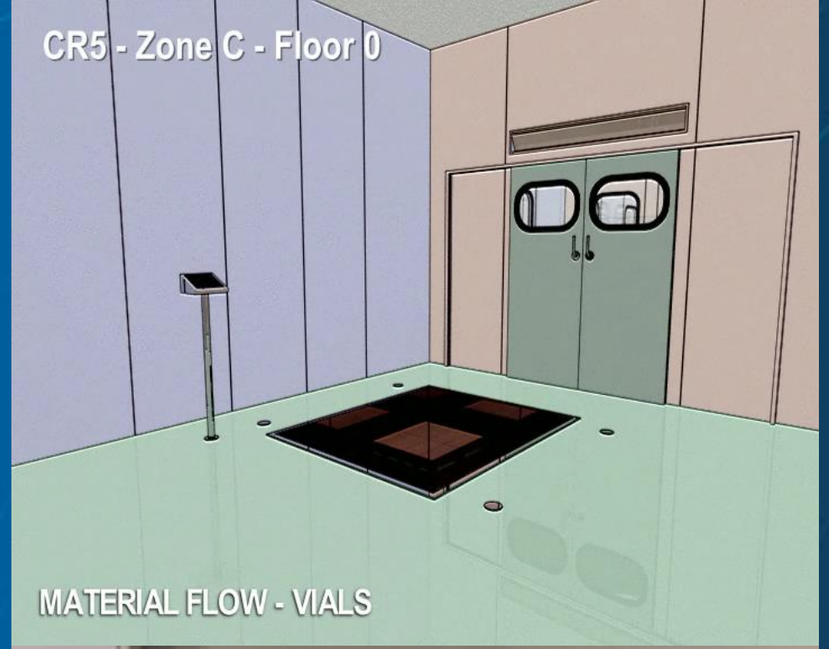
➢ Differentiate between Light and Heavy Martial flow

➢ Personnel flow , the design should be easy to follow

3D Animation API delivery



Vials delivery



3D Animation


00:35,97

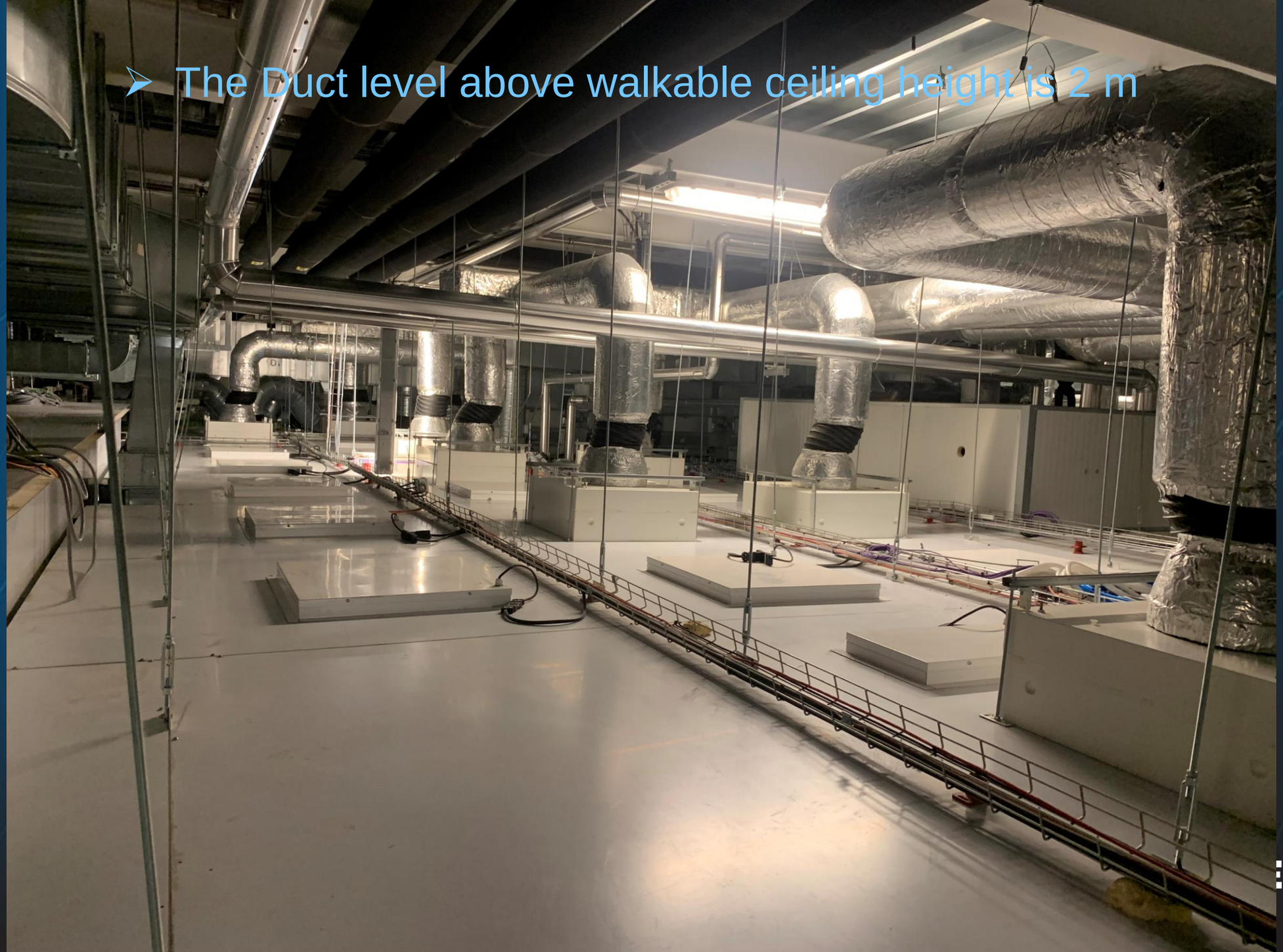
- No 3 surrounding Space

- Allocating enough space for Technical areas (AHU, Duct , Pipe work) space is critical to perform properly the electromechanical works now and in the future for Maintenance and future modifications

- The spaces above walkable ceiling is 2 m

- The surrounding corridor protect from outside conditions

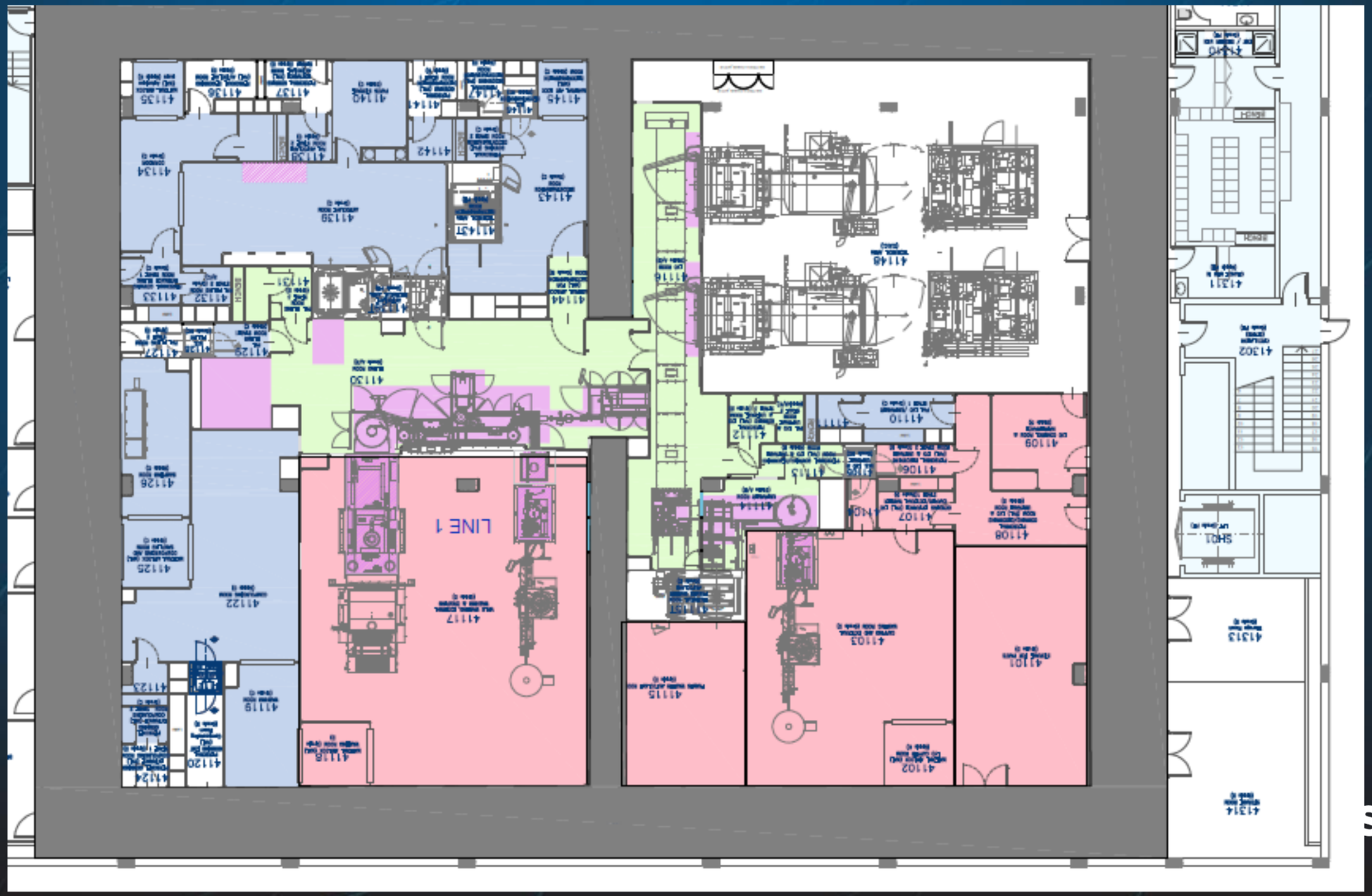
- The surrounding corridor provide good visible monitoring to the GMP area



- The Duct level above walkable ceiling height is 2 m

- The space above duct level is 3 m for AHU

- The surrounding corridor protect from outside conditions
- The inside corridors provide good visible monitoring to the GMP area



- No 4 HVAC options

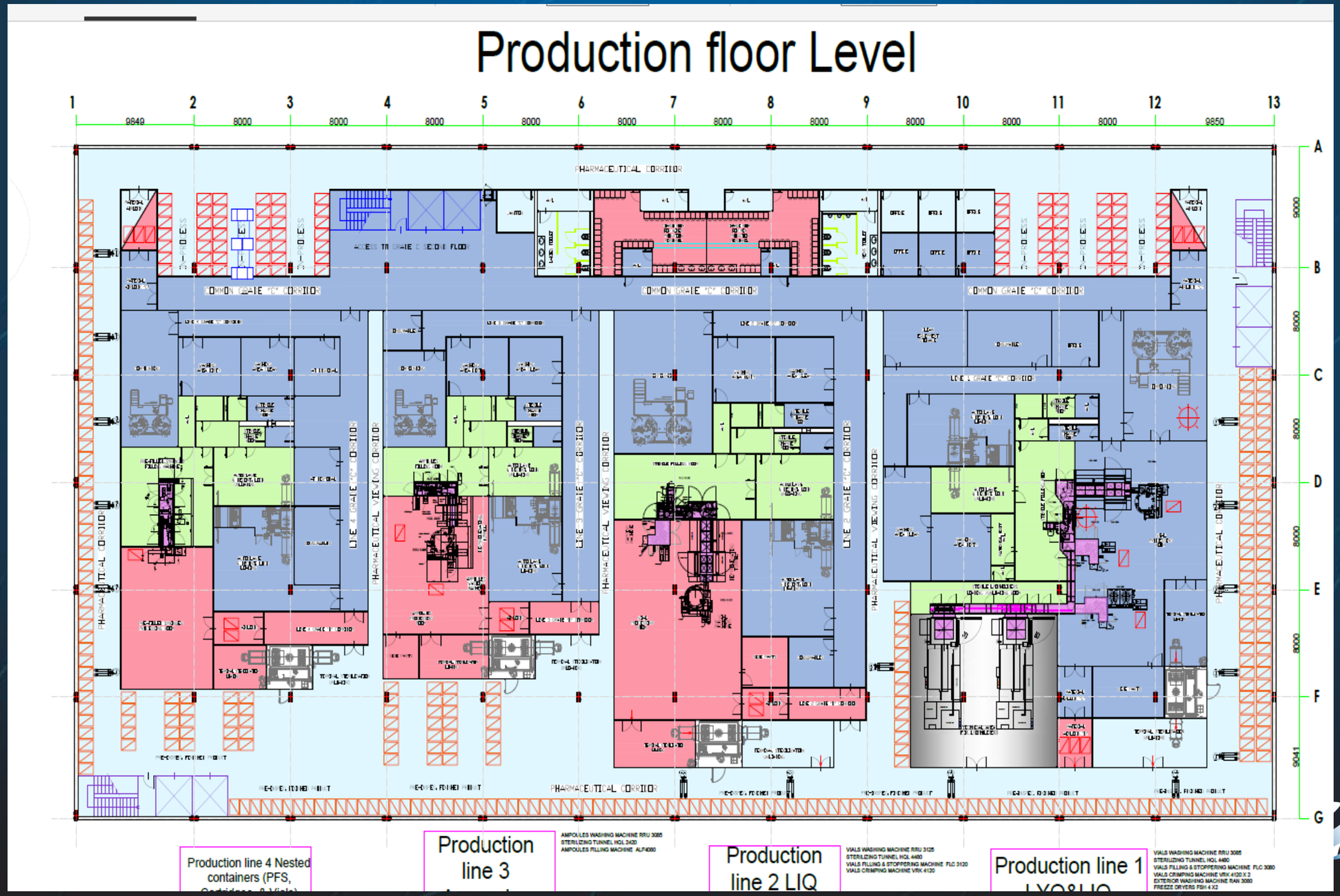
➢ Orals Manufacturing

➢ Sterile Manufacturing
- Total separated island
- Common **B** Corridor
- Common **C** corridor (most common)

➢ Potent Manufacturing

100 % fresh with extraction multi stage filtration

Sterile Manufacturing Common **C** corridor



- No 5 Training & Qualification

- It is important to attend the pre FAT runs by the field staff to identify set up techniques .
- I recommend to send technicians during machine / line assembly (manufacturing)

- The site should be heavily involved in the IOQ implementation.

Buying ready IOQ from the supplier might a good idea but the execution should be done with high % of internal involvement

- No 6 suppliers & Contractors

➢ We call them ``Partners`` and deal with them as such

➢ As the site grows the suppliers and contractors learning curve grow and they understand what is allowed and what is not from GMP point of view , changing S & C continuously will make the learning curve much longer and with a lot of mistakes and cost

- No 7 Project changes

- We must agree that there is always a project change that will happen no mater how good is the design

- The change can be driven by , engineering , market , finance , regulators , consultants , customers (CMO) , project timeline

- If no 1 (project objectives) is well studied the changes impact can be minimum

- No 8 Project Plan and timeline

- The project timeline depends on the coordination and sequence of different activates and contractors interacting with each other
- We should use simple planning tools to identify the problems early enough
- We should be able then to do the changes to go back on track
- it always about acting early enough

Questions?

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- No 1 The project objects

List the project short- and long-term goals and challenge your managment

- No 2 How to start the design

Talk to the people involve in the process directly and try to listen As Much As Possible

- No 3 Technical Space

Allocating enough space for Technical area is critical to perform properly the M/E, Maintenance and future modifications

- No 4 HVAC options

100 % fresh air or recirculated

- No 5 Training & paperwork

The site should be heavily involved in the IOQ and DQ and the plant staff should be involved in the writing process

- No 6 suppliers & Contractors

Partner with your suppliers and contractors as te learning curve is important as you grow

- No 7 Project changes

Control changes and if No 1 is done well no need for no 7

EASE

The EASE's DNA (ease-training.fr)

- EASE is an industrial and training Center of **4300 sqm** intended to immerse participants in a constraining pharmaceuticals production environment.

- Participants are surrounded by an industrial production environment in which they will be able to practice pharmaceutical procedures such as regular gowning in CAZ D, C and B (controlled atmosphere zone D, C et B), traceability rules for materials and single uses, follow up of standardized procedure for each process line, database recording of each processing step in a centralized computer system.

2024 Training Organization – Website Enhancement

4-I ˛ ıining Event at the European Aseptic and Sterile Environment

22 - 24 FEB 2024 | (EASE) Facility Strasbourg, France

Driven by the expanding biopharmaceutical market but also relevant to small molecule drug product and API manufacturing, aseptic processing is undergoing a technology evolution driven by the new EC GMP Guide Annex 1. Manufacturers which deliver drugs to Europe, must comply with this new regulatory requirement, which impacts all stakeholders. Additionally, suppliers must consider Annex 1 when supplying and installing new equipment or building new production facilities.

To meet the challenges of the new Annex 1 guidance while enhancing industry efforts to develop, manufacture, and reliably deliver quality medicines to patients, ISPE is conducting a 4-day interactive training event in a unique setting, the European Aseptic and Sterile Environment (EASE) Facility in Strasbourg, France. This training provides hands-on opportunities to interact with equipment in a facility built for training pharmaceutical industry workers. During the training sessions, attendees will have the opportunity to conduct aseptic processing steps as well as ATMP manufacturing exercises in the clean rooms at the EASE facility including preparation and aseptic manipulation inside biological safety cabinets.

2024 Training Organization – Website Enhancement

Who should attend this 4-Day hands-on training event?

- Production operators, quality assurance and quality control specialists, validation scientists, manufacturing supervisors, technical support personnel, engineers, and all levels of management having assigned ATMP-focused roles/responsibilities
- Managers of production and quality assurance
- Process engineers
- Engineers responsible for infrastructure and maintenance
- Quality managers
- Shop floor supervisors
- Suppliers for equipment and infrastructure of aseptic manufacturing plants
- A/E consultants in facility design
- Project/manufacturing engineering resources engaged in ATMP project execution
- Personnel who need an in-depth understanding of the potential risks around ATMP manufacturing
- Service organizations, suppliers, and vendors who serve pharmaceutical industry clients focused on ATMP manufacturing
- Academic Institutions engaged in ATMP development/manufacturing
- Vendors and suppliers of equipment/systems focused on the global ATMP "launch"
- Scale
- Closed systems & single-use
- Patient-specific therapies

REGISTER NOW!

Pricing

	Early Registration	Regular Registration
Member	$4,700.00	$5,000.00
Non Member	$5,000.00	$5,600.00
Government	$1,600.00	$1,600.00
Student	$1,000.00	$1,000.00

*Special Affiliate Rate: $2,000

1 representative per EU Affiliate

Space permitting

ISPE®