

Concept designs for vaccine facilities:

Conciliation of local and global expectations

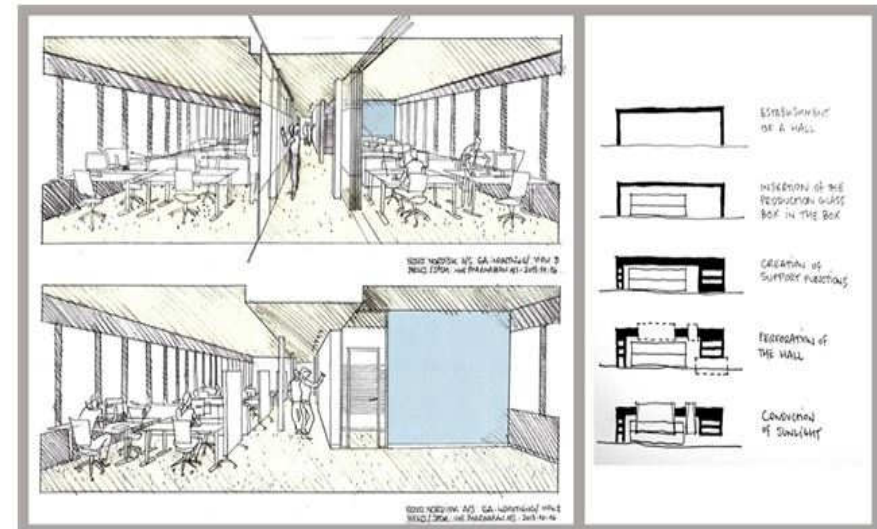
DCVMN conference

Klaus Hermansen,
Aeby Thomas
27-30 October 2014, New Delhi

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Engineering for a healthier world

Outline

- Why Conceptual Design?
- What are the objectives of a Conceptual Design?
- Vaccine facility design.
- Local/ Global expectations.
- Case study: From Conceptual Design to Build



About NNE Pharmaplan

- With 80 years of experience we are passionate about our services to the pharma and biotech industries
- Consulting and engineering for Pharma and Biotech
- > 200 with hands-on development or production experience
- 30 office locations
- 17 countries
- 2,929 projects in 2013 (all activities)
- Center of Competence (COC) in Bangalore, India for Global vaccine projects



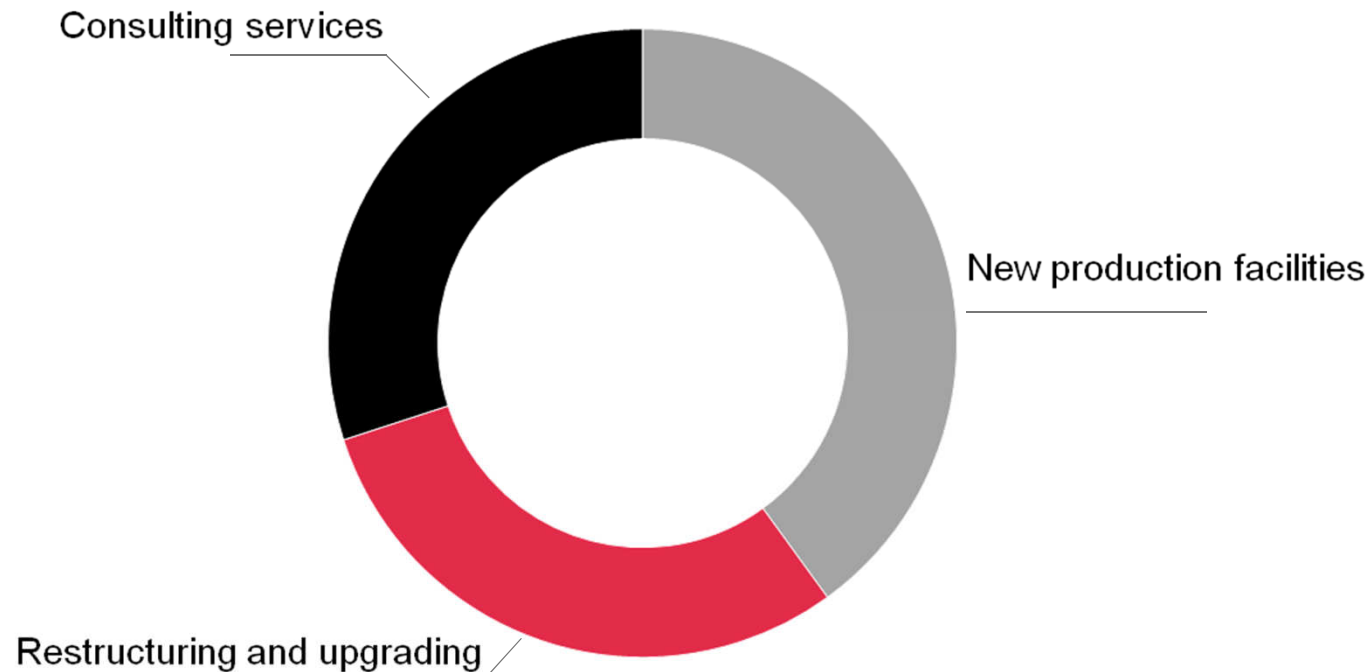
Closer to our customers



NNE Pharmaplan employs close to 1,700 people at more than 30 locations in 16 countries around the world.

97% of our revenues come from the pharma and biotech industries

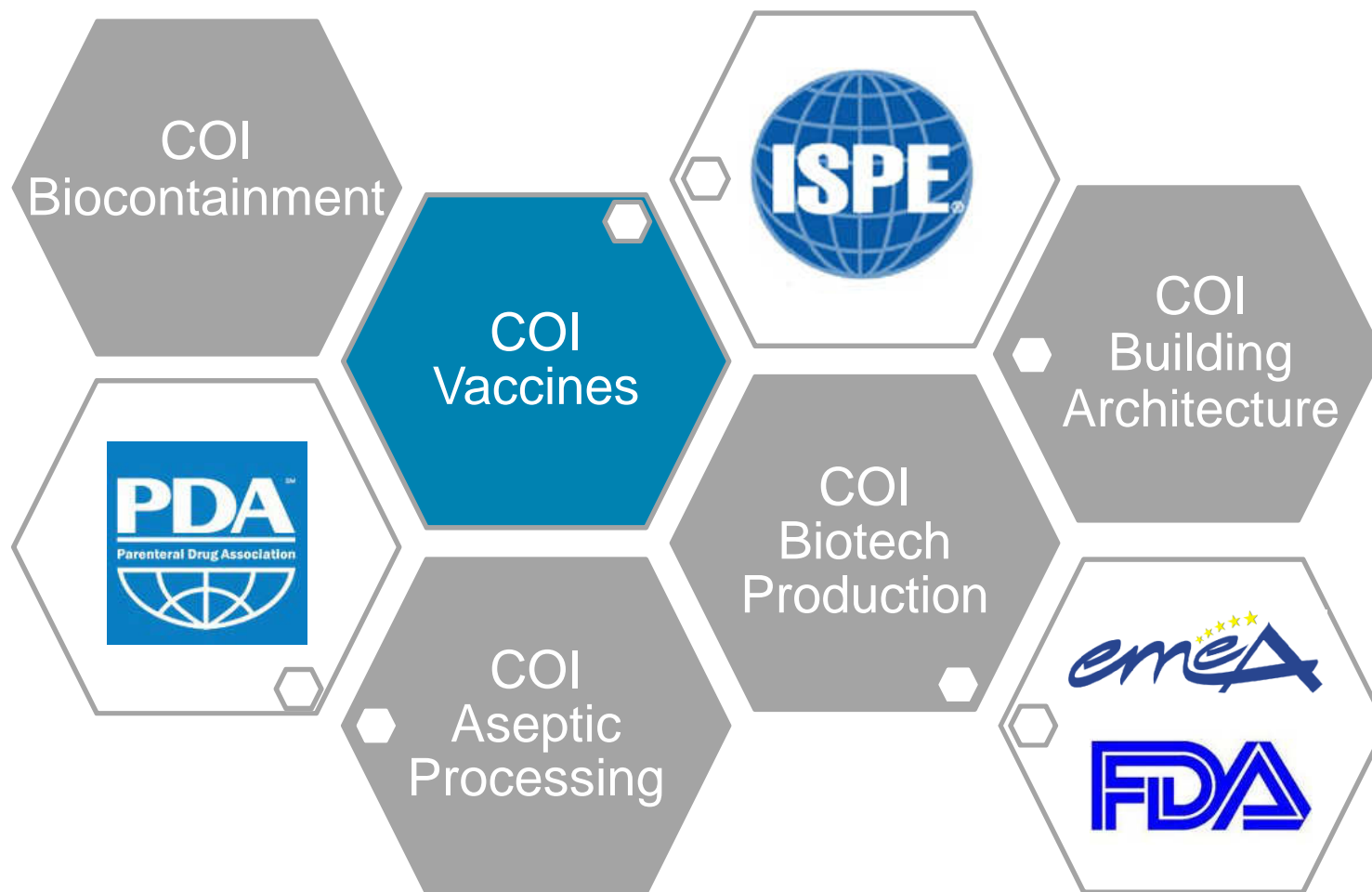
Our work split



The main part of our employees have a background in pharmaceutical production companies.

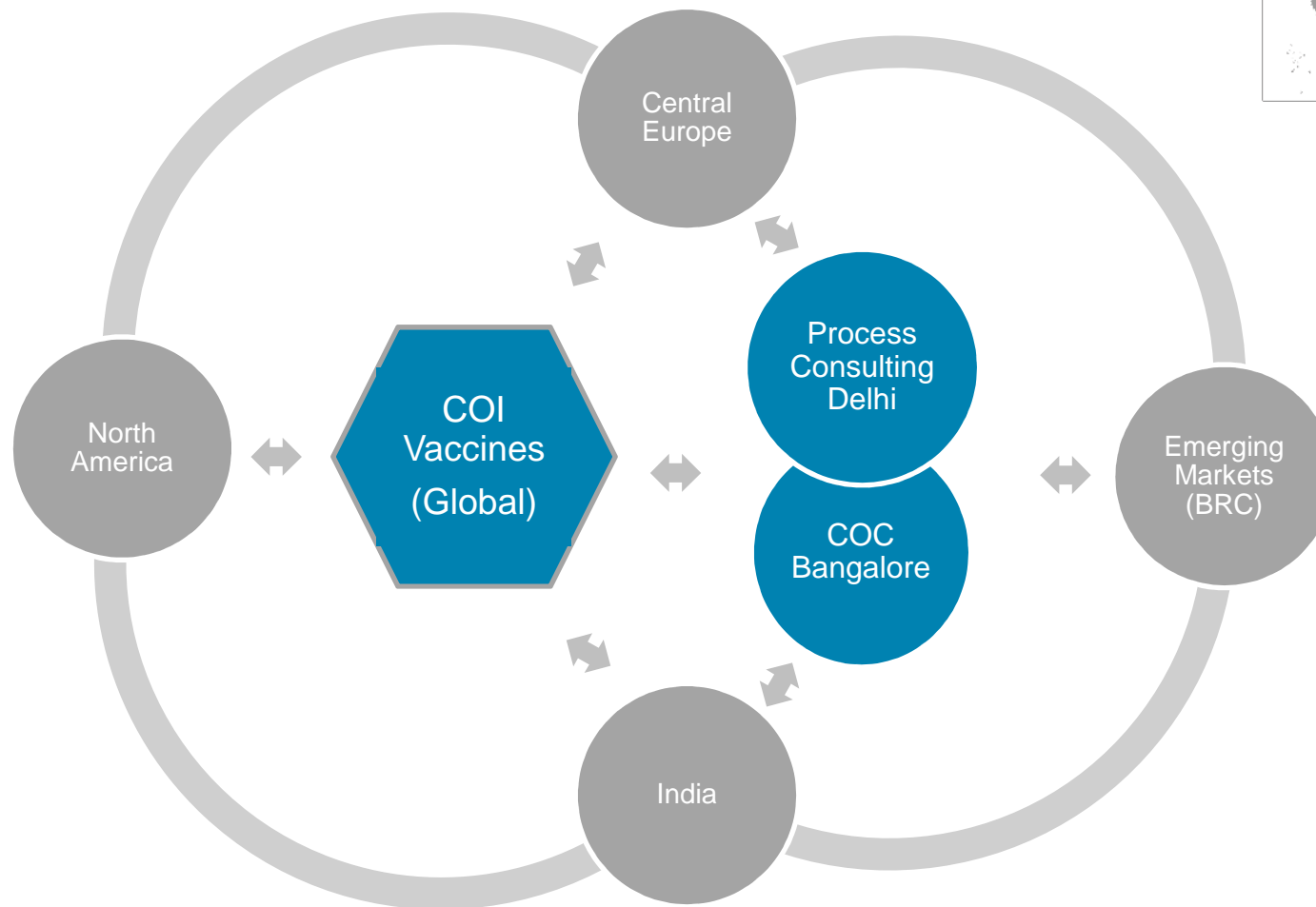
NNE Pharmaplan
offer only vendor
independent
design solutions

NNE Pharmaplan; **75 COI's**, global network –



Next: Session outline

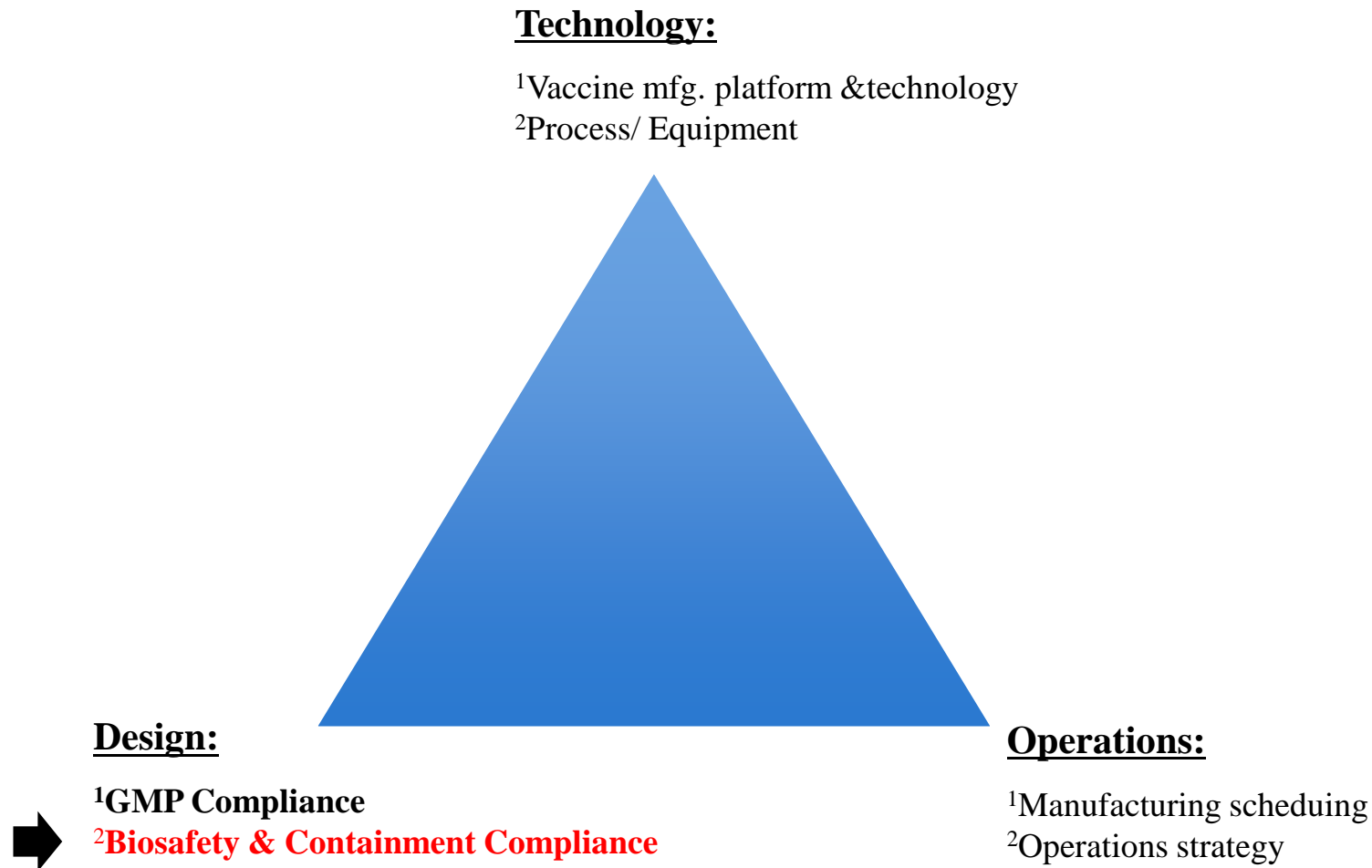
Centre of Competence (COC) for Vaccine Projects (Bangalore)



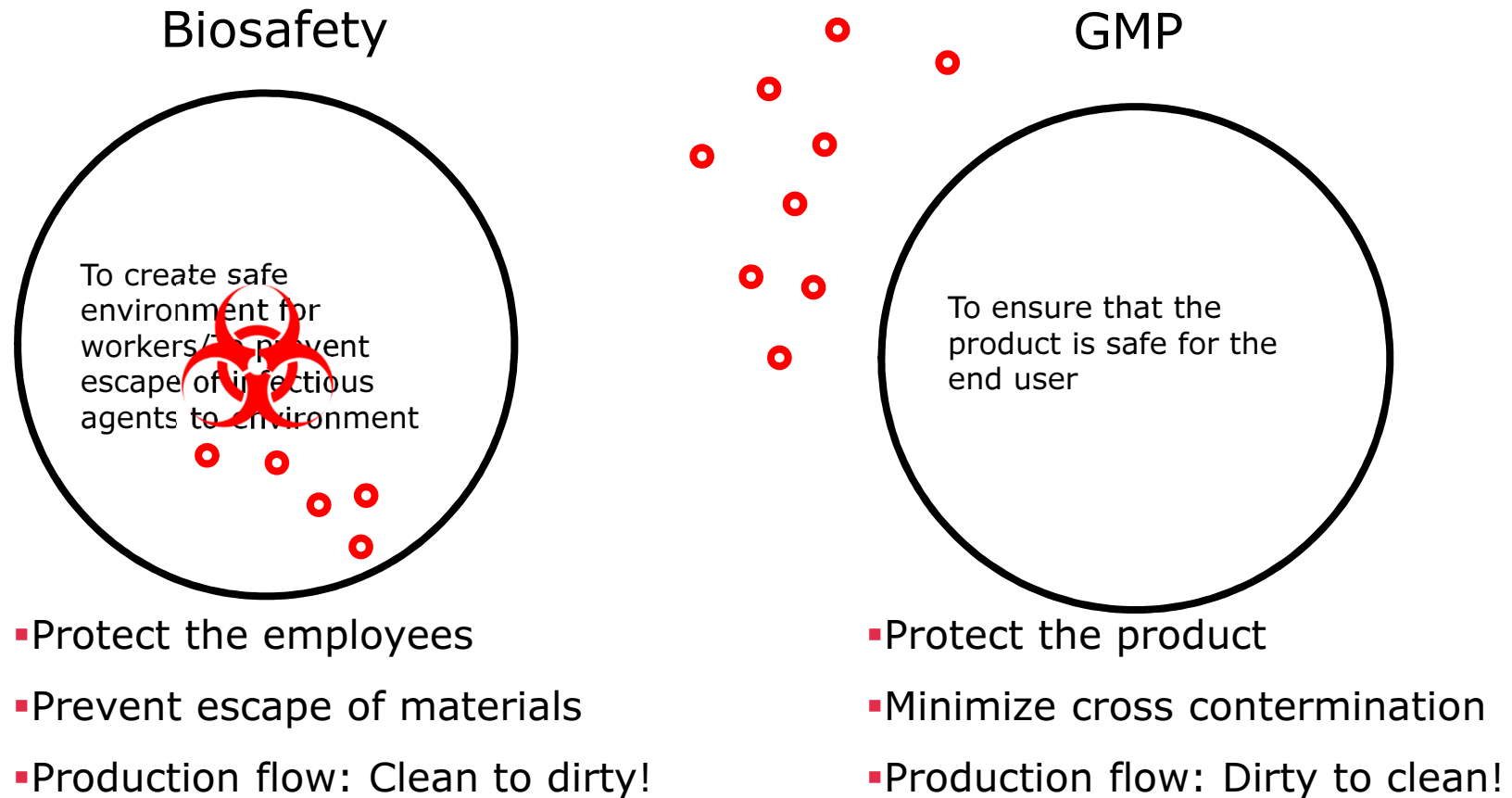
What we do – when we do Conceptual Design



Conceptual design of vaccine facilities: 3 principal facets

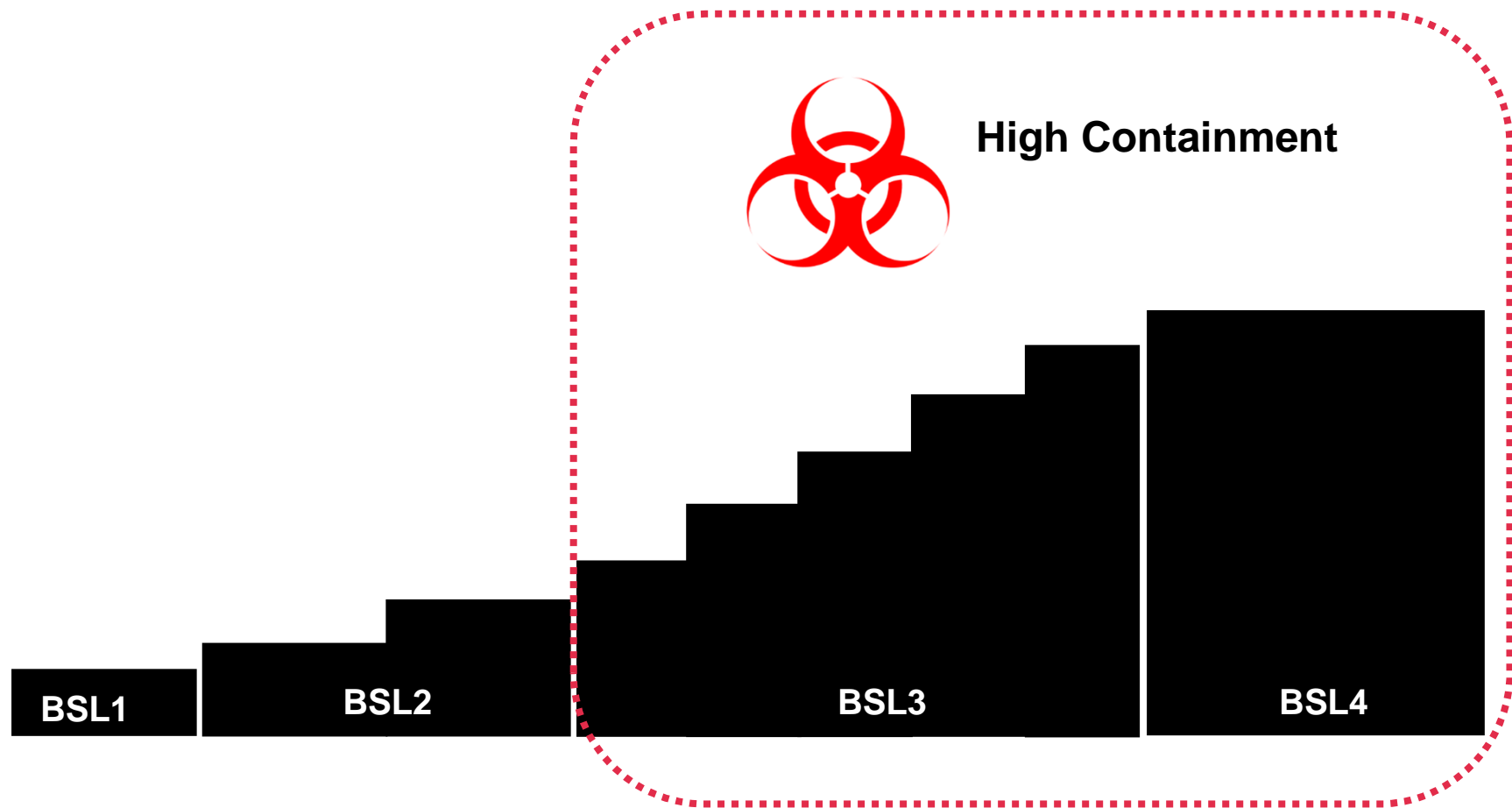


Biosafety versus GMP – an illustration



Biosafety Level – ‘Steps’ in Engineering & Operational complexity

(related to risk groups of biological agents)



Why Conceptual design for vaccine facilities?

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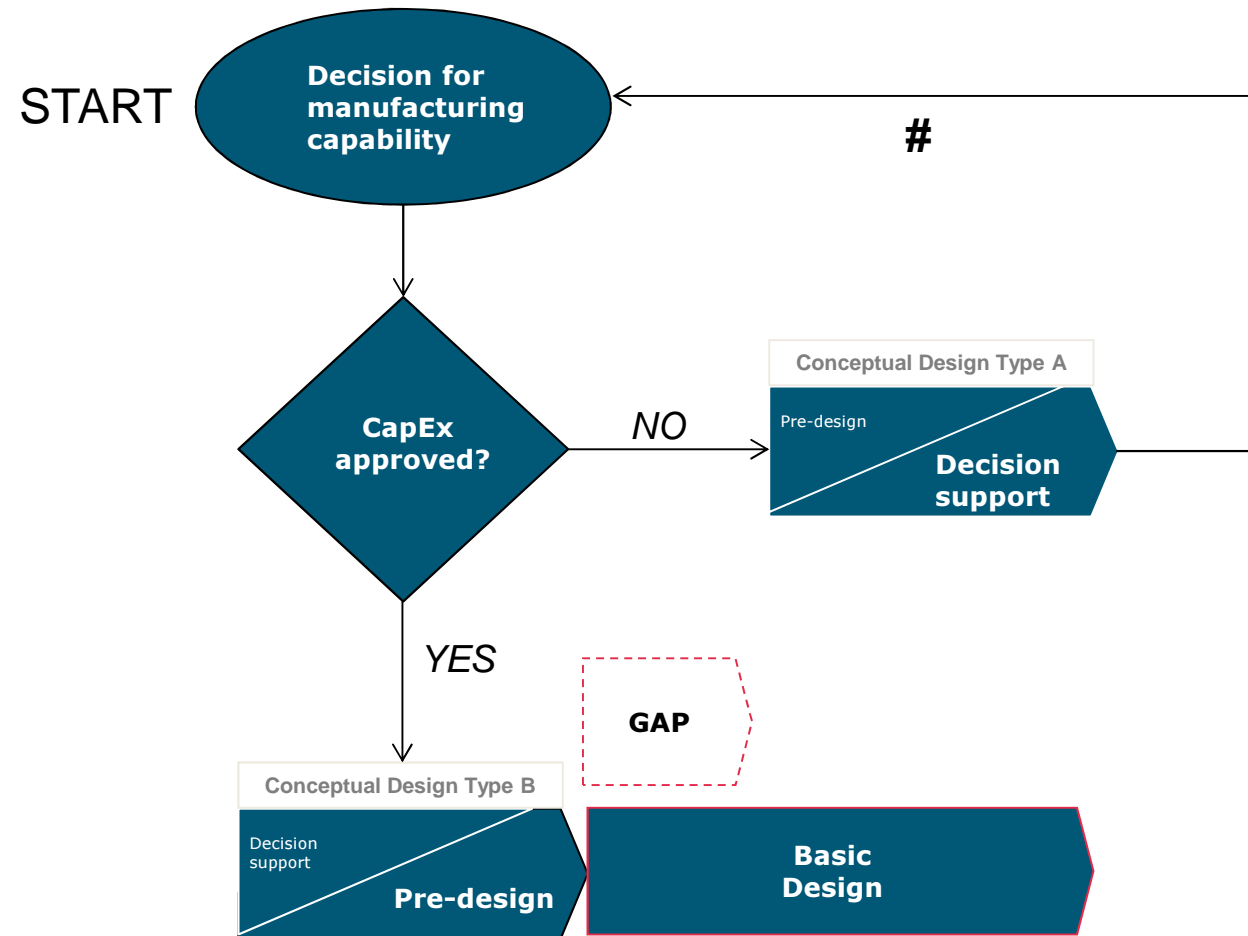
Why Conceptual Design?

The most important investment, because it ensures:

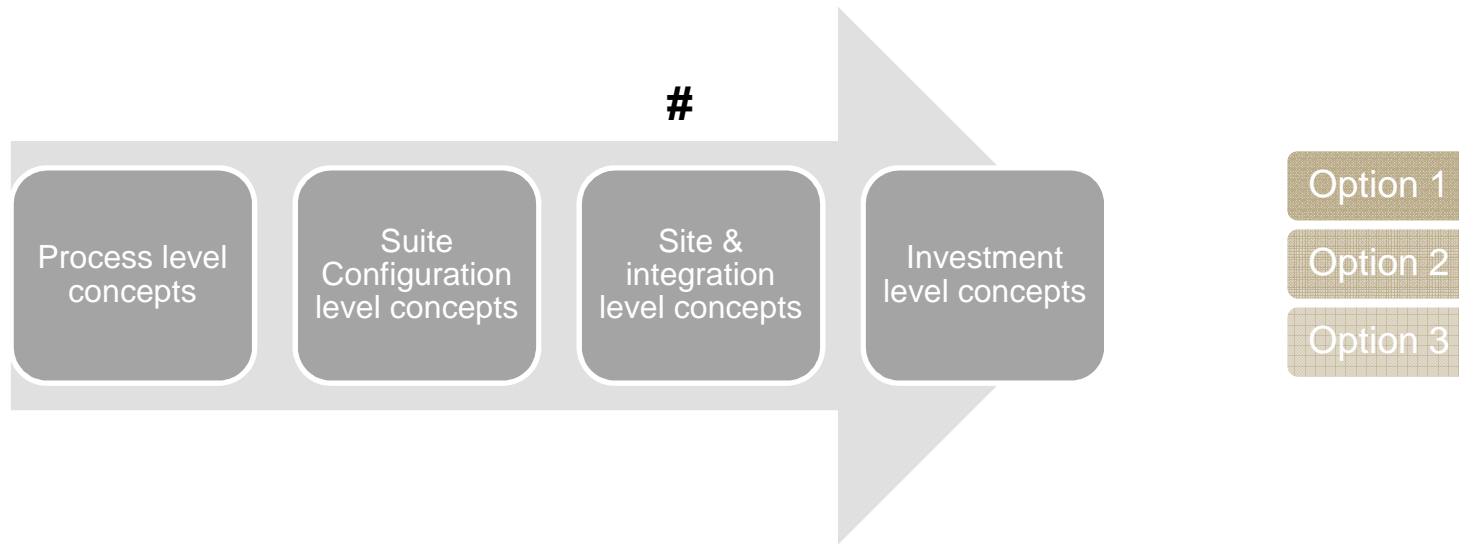
- **Fit for purpose**
 - Technology fit for purpose, manufacturing fit for purpose <broad level of uncertainties>
 - Understanding of biological agent translated to design measures
- **Risk reduction**
 - Limitations and possibilities are identified from the start, facilitating **choice awareness**
 - The project is ensured **minimum sensitivity** to changes during the planning phase
 - A CD maps possibilities now and going forward, ensuring a **firm and time robust solution**
- **Economy control**
- **Holistic project approach**
 - A CD provides a **cross-disciplinary design** which take into account all relevant areas
 - An overall overview of **all project elements** is created from the outset
- **Sustainability**
 - **Environmental considerations** are integrated in the project
 - The sustainability issue might have high impact on **image** development
- **Alignment with business strategy**

Conceptual design:

Basis for **Decision** v/s Basis for **Design**

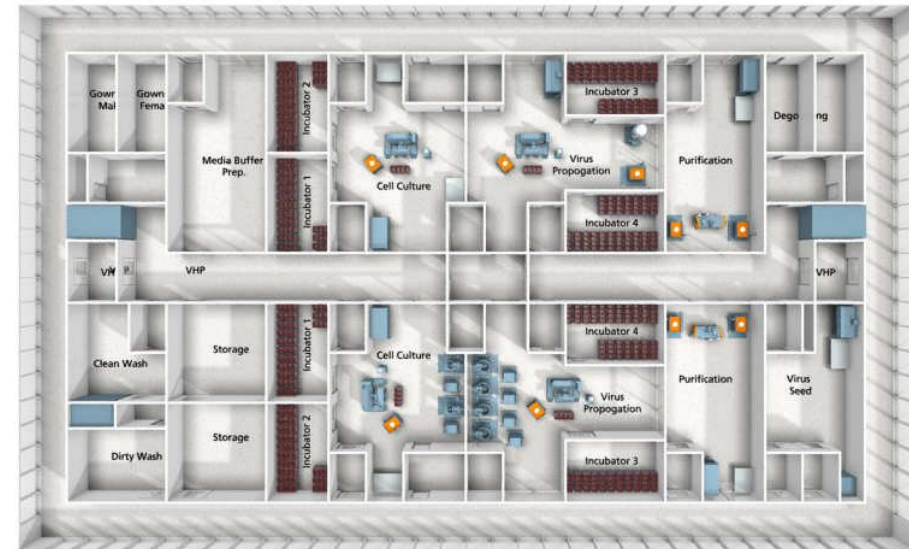


4 principal Conceptual foci

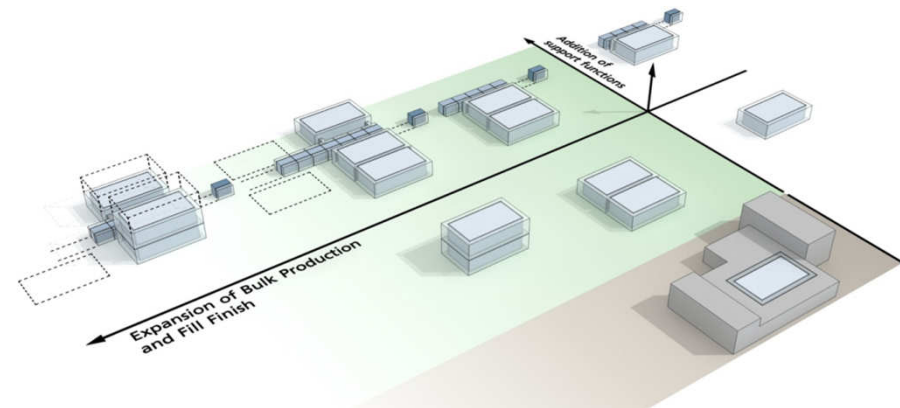


- Note: Production program is *key* to Process level feasibility & Configuration level feasibility.

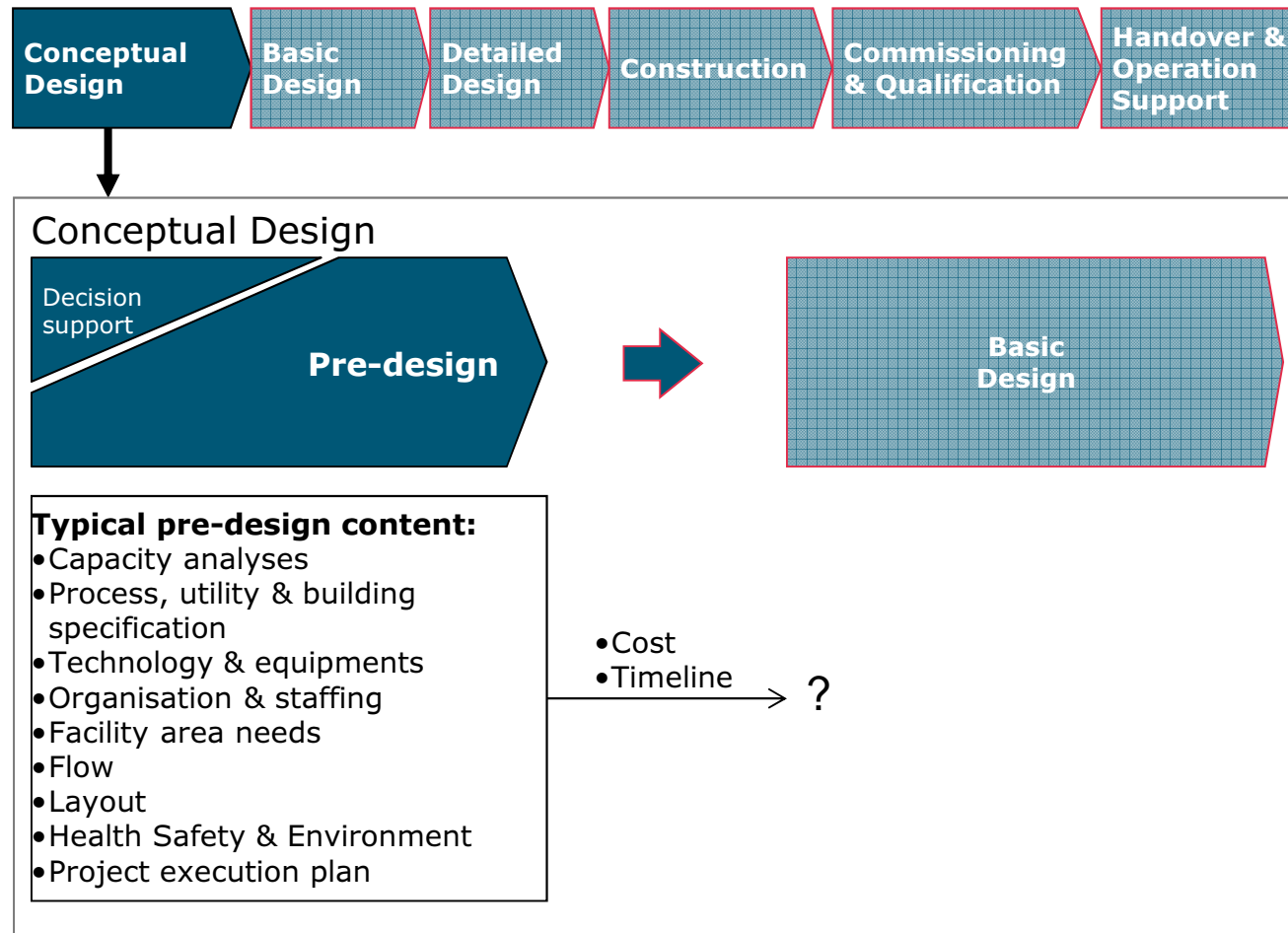
What concept makes the best business case?



**\$ - \$\$\$
\$/ dose**

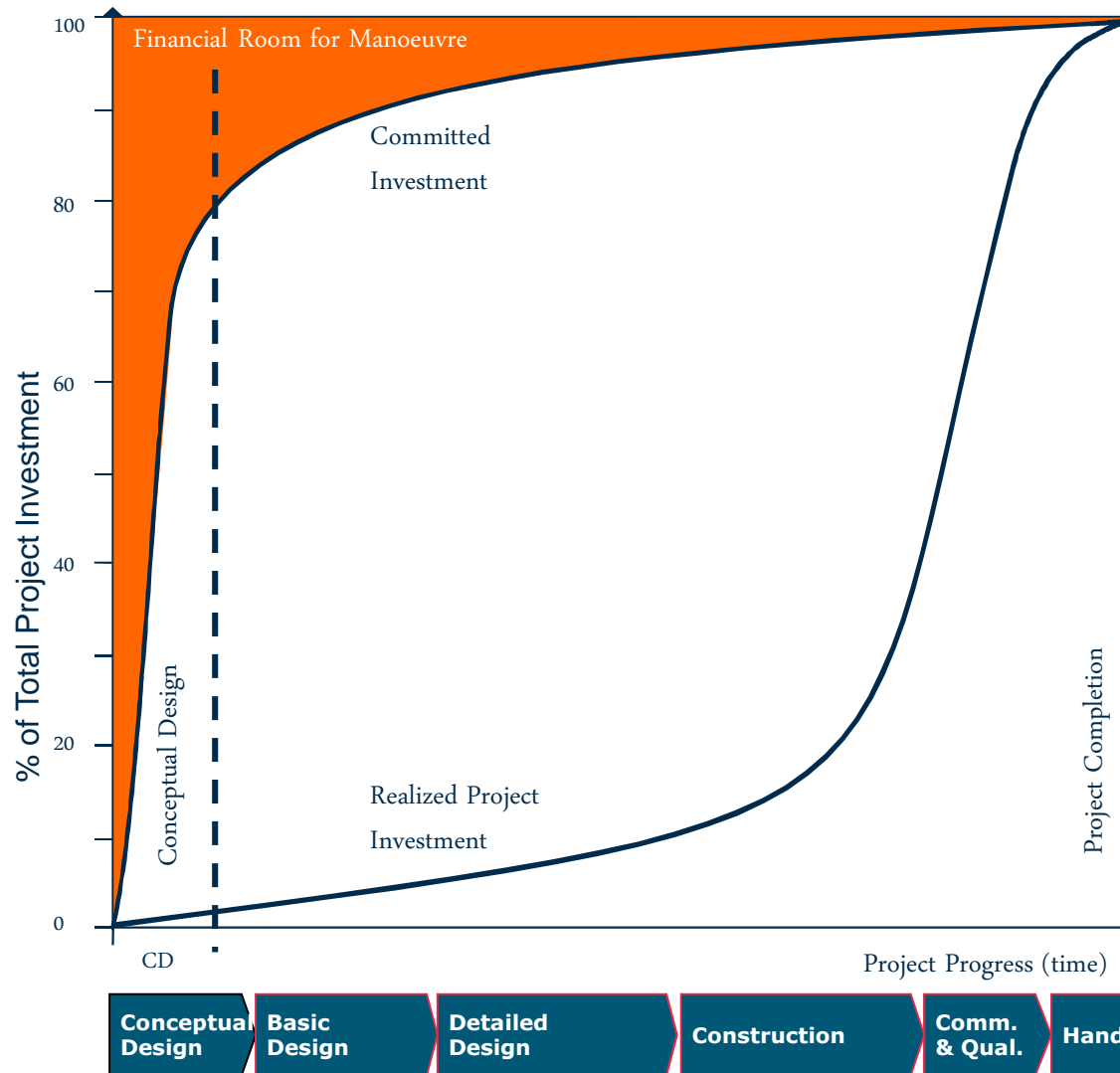


Conceptual Design end-points



Investment & Commitment Timeline

Early decisions have most impact on the Investment

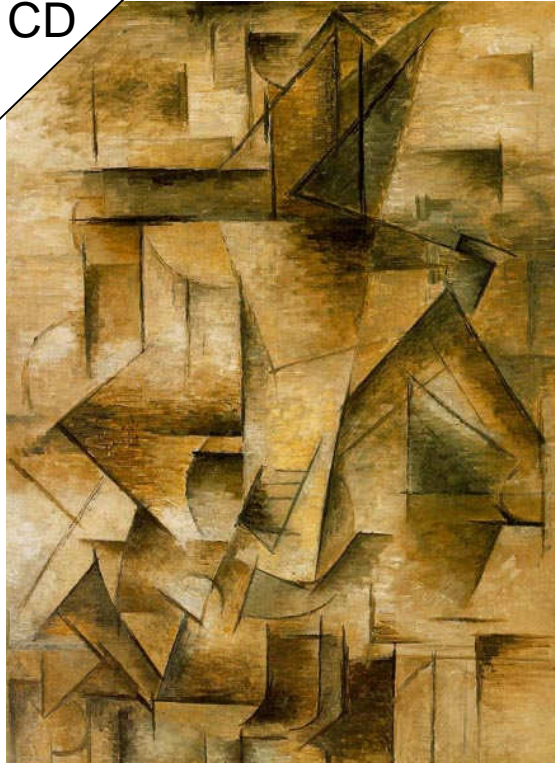


Maximum room for manoeuvre for lowest possible cost

The graph illustrates that the major part of investment committed to a project will be determined very early in the project phases, i.e. the very early decisions will have the strongest impact on investment level

Conceptual design philosophy

CD



Picasso "A guitar Player"

- Possibilities/Inspiration
- Open ends
- A selection of scopes
- Without specific requirements to functions, etc.

BD



Vermeer "A guitar Player"

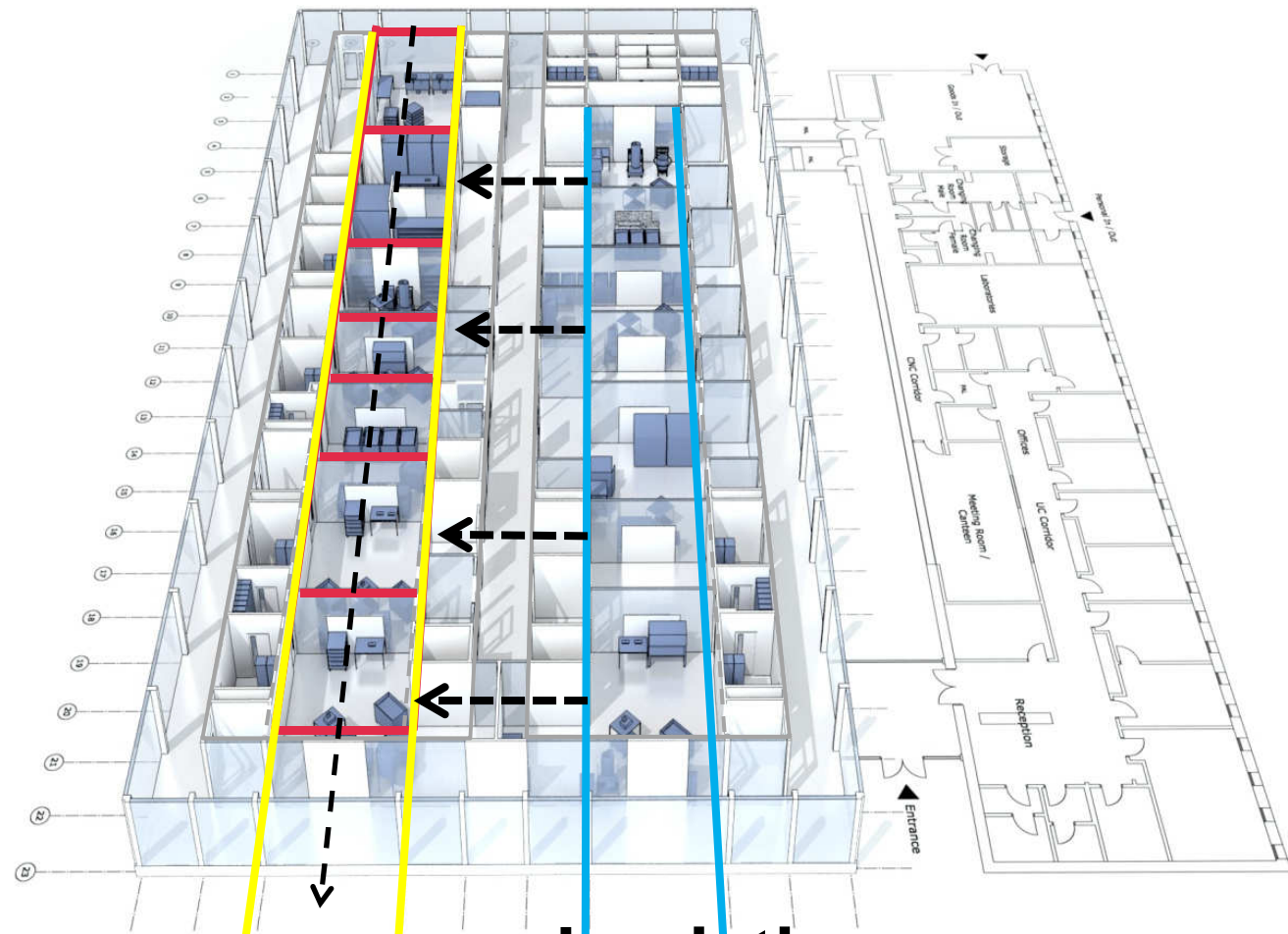
- Fixed cost +/- 10%
- Without open ends
- Well defined scope
- Buildable

Standardised vaccine facilities

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Standardised vaccine facility:

Flexibility, compliance & construction modularity

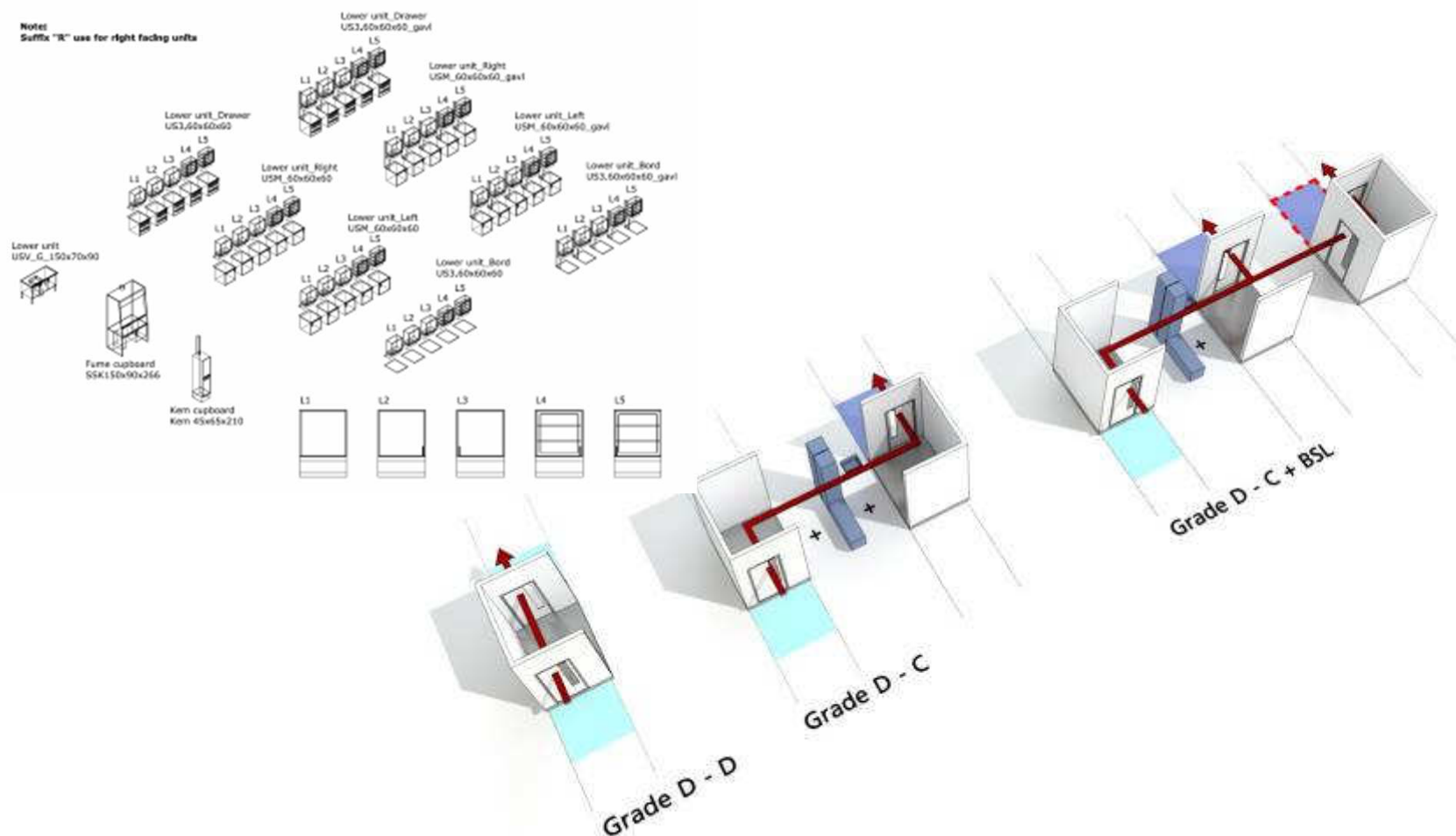


**Main
process** **Logistics
+ Support**

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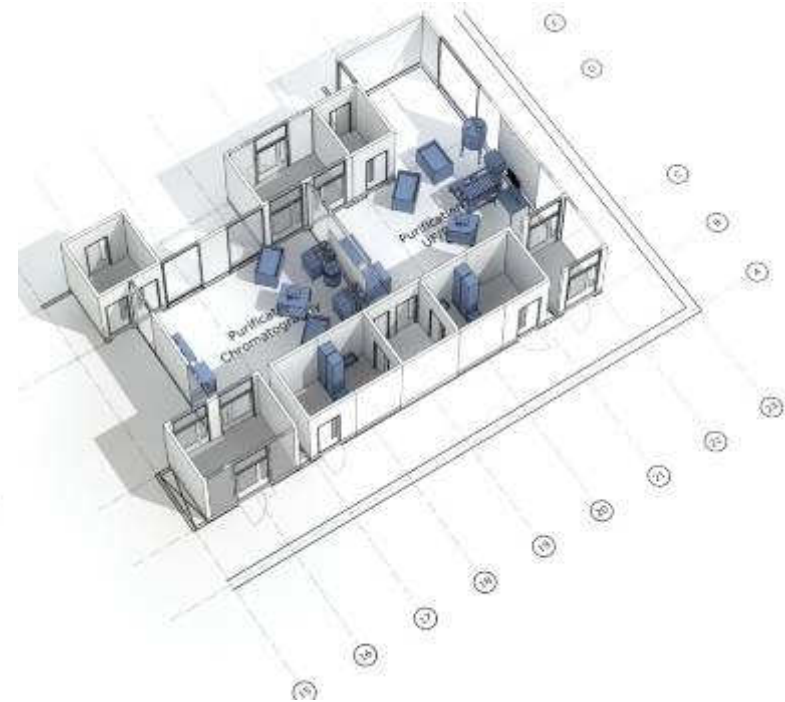
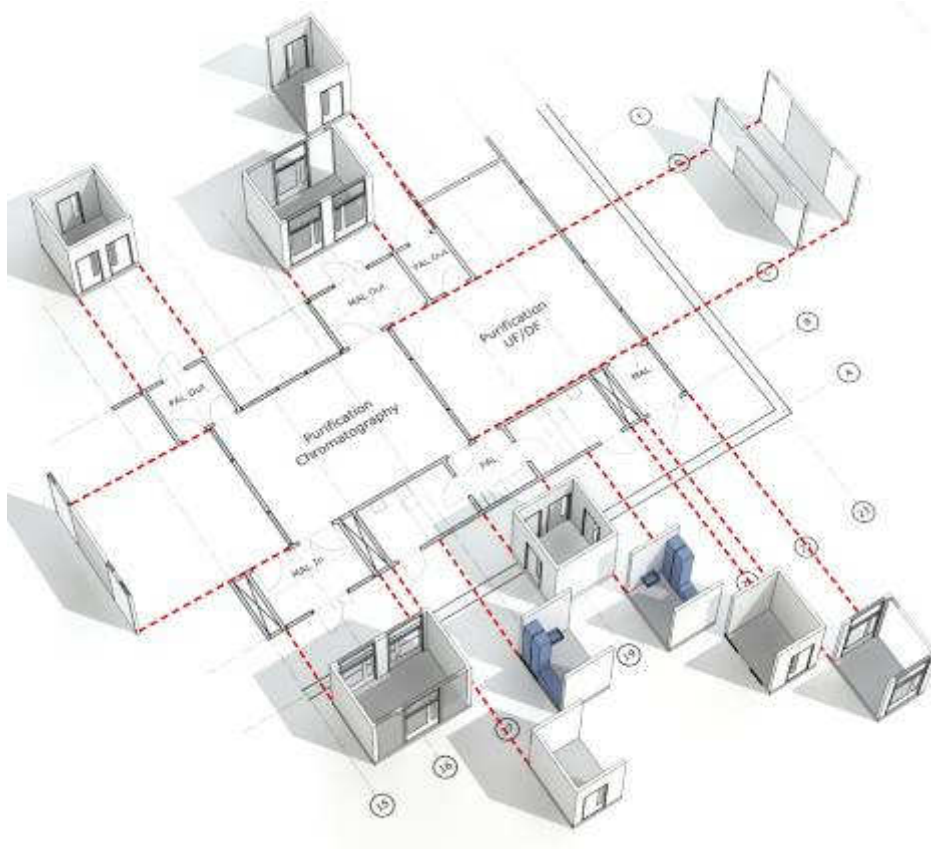
Standardised vaccine facility:

Flexibility, compliance & construction modularity



Standardised vaccine facility:

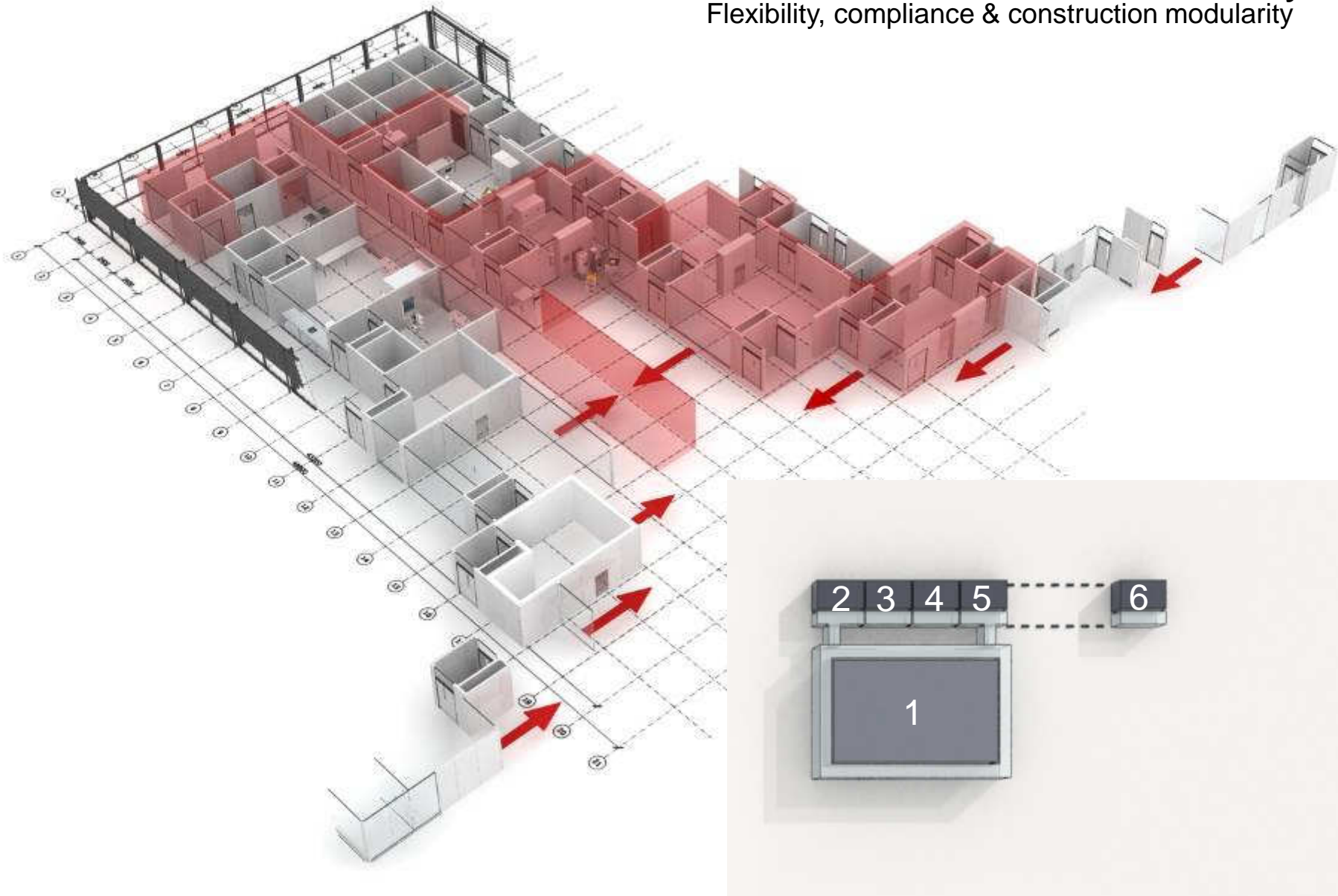
Flexibility, compliance & construction modularity



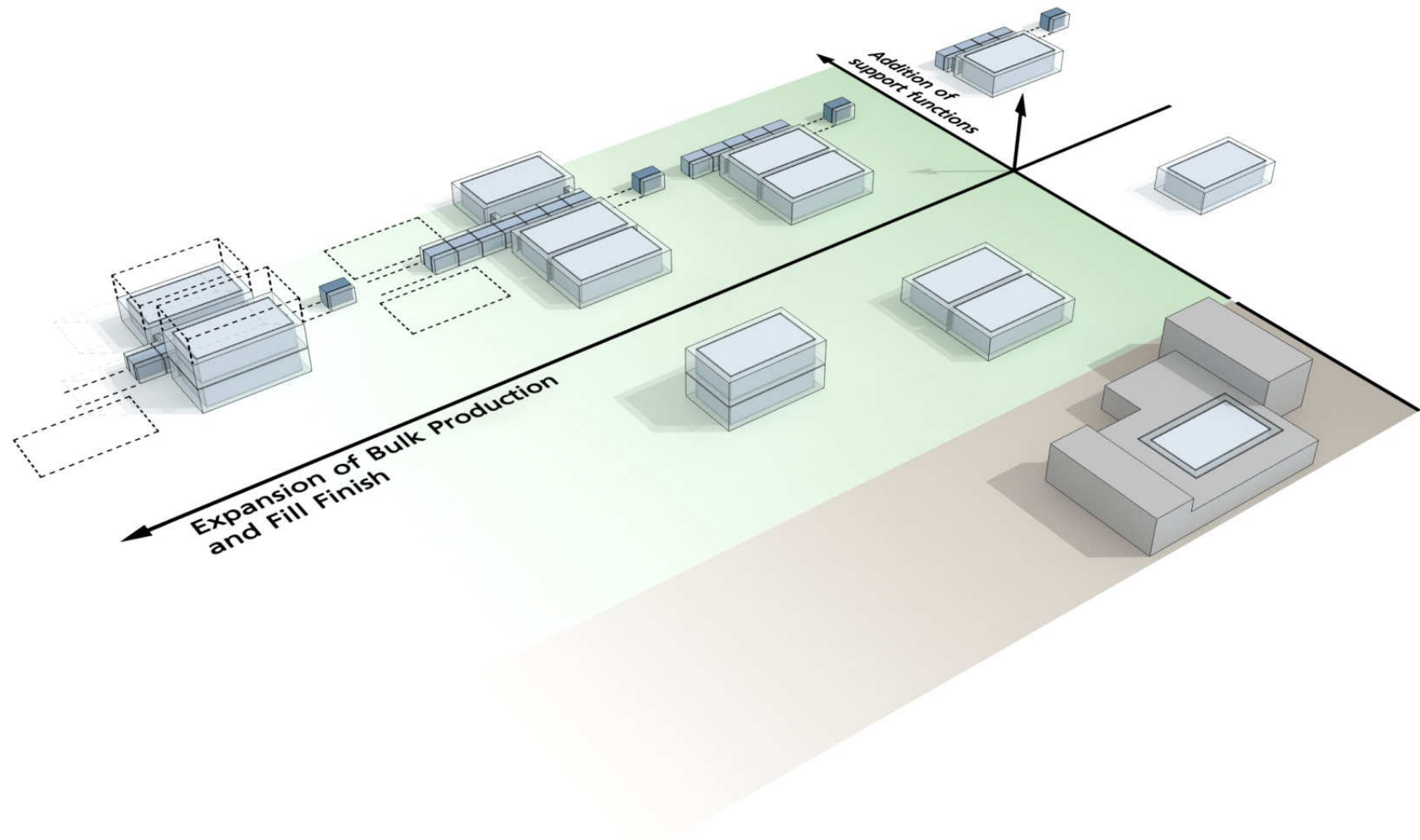
Purification chromatography + purification UF/DF rooms = product specific

Standardised vaccine facility:

Flexibility, compliance & construction modularity



Site/integration level feasibility



Case Study



基亞生物科技股份有限公司
MEDIGEN BIOTECHNOLOGY CORP.

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Medigen vaccine facility, Taiwan

- Medigen vaccine facility
- Designed for viral vaccines: EV71 and Flu
- Option for other Viral products
- Designed for Formulation and Filling
- State of art facility
- Project start: 2012
- Expected completion: 2015



Design strategy, design drivers

- Vaccine manufacturing units:
 - Designed as Multi-product facility
 - Designed for flexibility and high level segregation
 - cGMP
 - BSL2+ for bulk 1
 - BSL2 for bulk 2
 - Single use technology where appropriate
 - Common support functions
 - Closed system approach in order to lower room classification



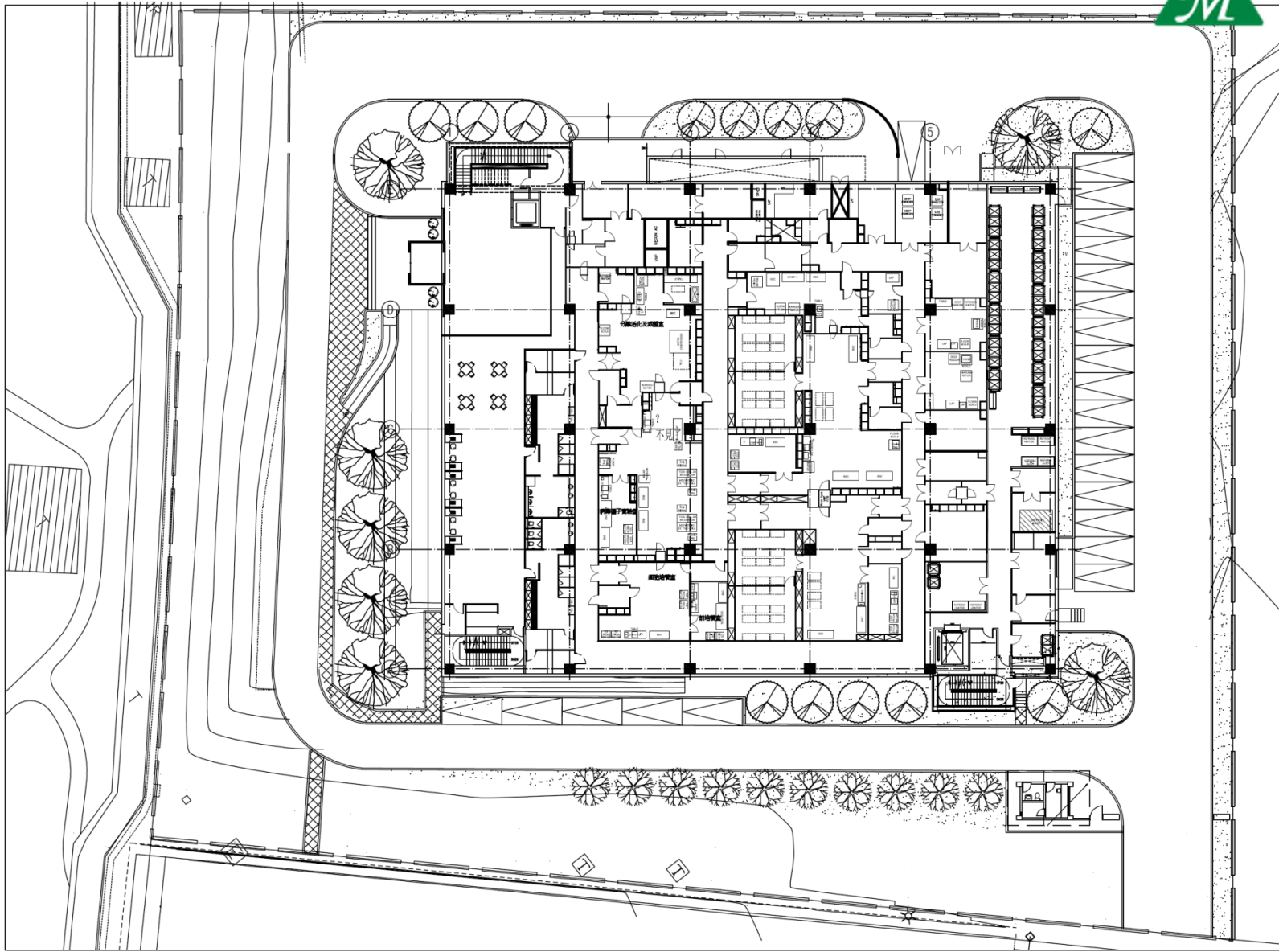
Containment strategy for vaccine pilot units

- Maximal segregation by:
 - Dedicated HVAC units for each unit
 - 100% fresh air for BSL areas
 - Advanced pressure regime with lowest pressure in the return corridor
 - Uni-directional flow of people for all BSL area
 - Access control for all airlocks
 - Dedicated operators for each pilot unit
 - Decon-area for solid waste in connection to return corridor
 - Two step de-gowning area before leaving the BSL area
 - Kill system in basement for decon of liquid waste
 - Risk based approach
 -

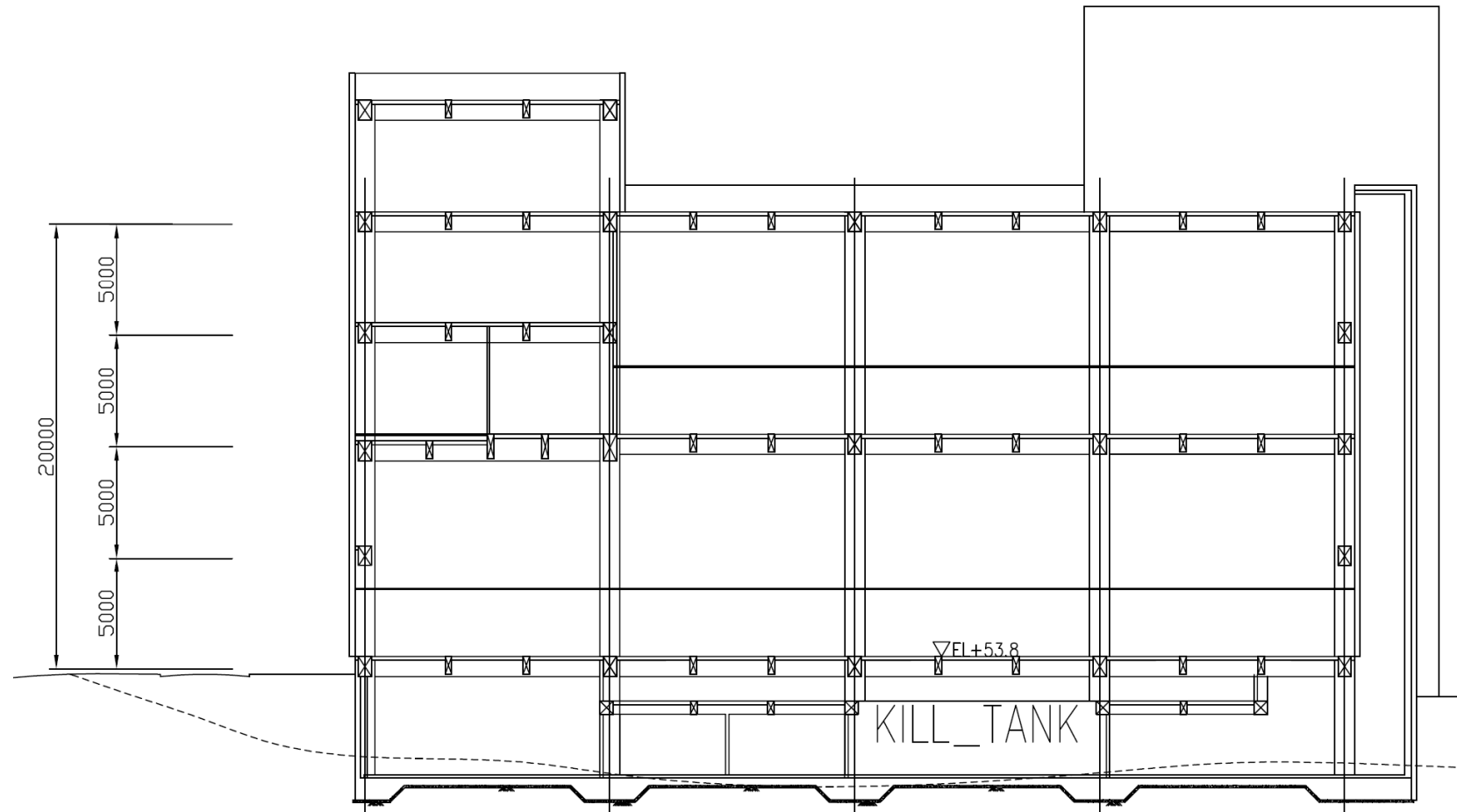




Site Plan



Section



Slides withheld

- Customer confidential

Slides withheld

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- Customer confidential



Work in progress: Today



“Rigorous conceptual designs are the foundations strategic vaccine manufacturing capabilities”

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Consulting Services - Overview

