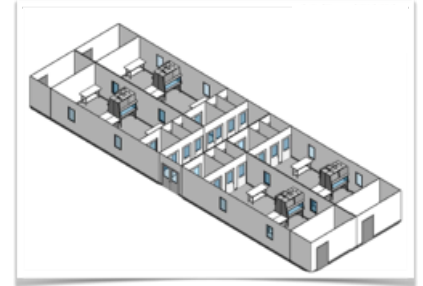


# Facility and Process Flexibilities – The Benefits of Modular and Prefabricated Cleanroom Structures in a New Era of Therapies

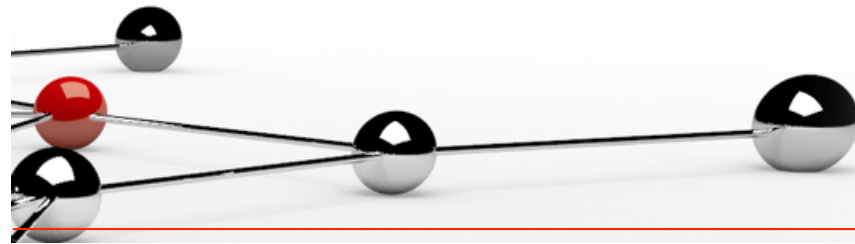


**Maik W. Jornitz**

CEO G-CON Manufacturing Inc



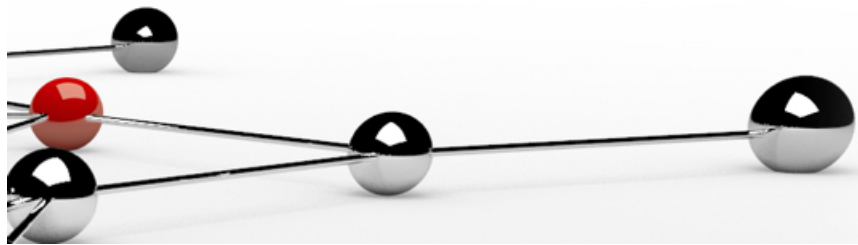
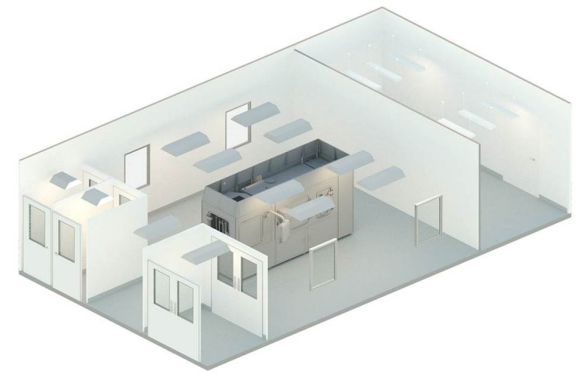
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# Agenda

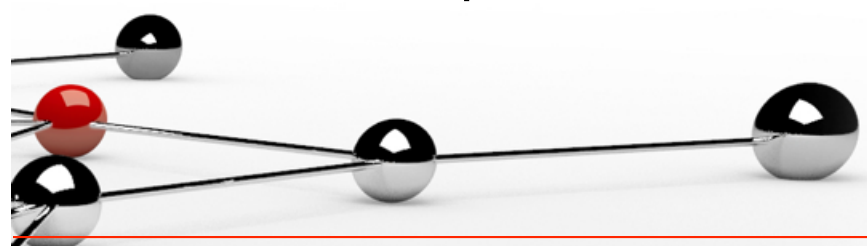
- **New Needs Voiced**
- **The Facility Options of the Past**
- **The Facility Options of Now**
- **Rethinking the Options**
- **Some Examples**
- **I Like, I Like, I Wonder...**
- **Conclusion**





# Facility Needs Voiced

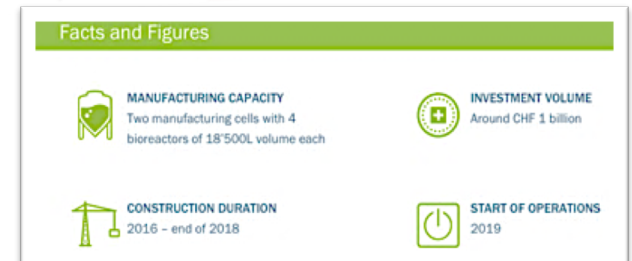
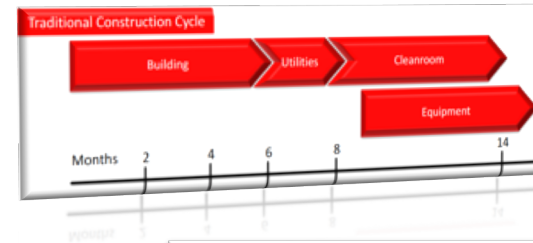
- Delivery time and budget proposals for facilities and cleanrooms require to be robust
- Man hours and other hidden costs need to shift off-site
- Facilities require to be rapidly deployable (6-12 months)
- Scaling of the facility should not disrupt existing processes
- Infrastructure require to be repurposable, instead of being sunk asset
- Cloning of facilities and infrastructures help design abbreviation, personnel training and regulatory familiarity



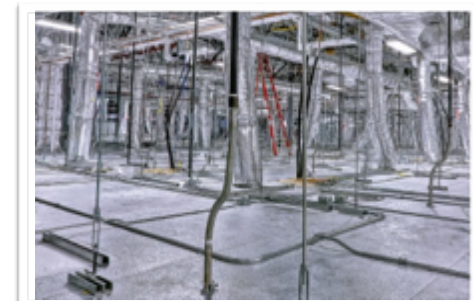


# The Options - Past

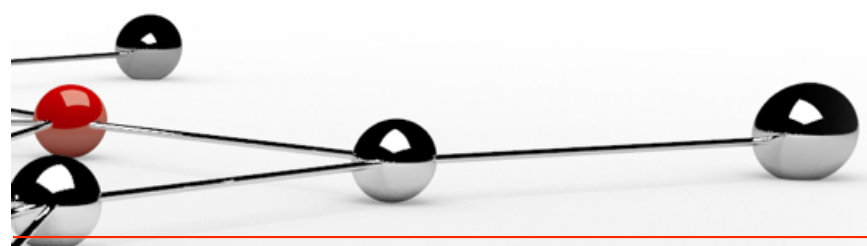
- High CAPEX/higher OPEX
- Extensive time-to-run (>3 years)
- Product dedicated
- Inflexible, often difficult to expand
- Extensive design phases
- Difficult containment, high complexity
- Complex maintenance & aging
- Difficult tech transfer & cloning



Latest Experimental Alzheimer's Drug Fails Testing (WSJ 03/21)



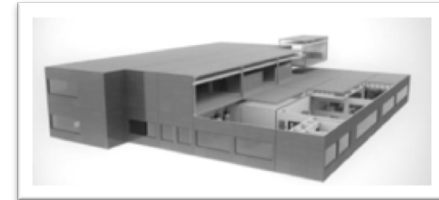
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# The Options - Now

- Potentially predesigned, like KuBio or iCON
- Time-to-run 12 – 18 months
- Delayed investment due to faster build
- Flexible and scalable\*
- Predefined design phases
- VHP sanitizable containment\*
- Clonable
- Predictable cost budgets and delivery times





# Rethinking – Facility (Infrastructure) Concepts

## Standardization

↳ 8 different configurations mass produced

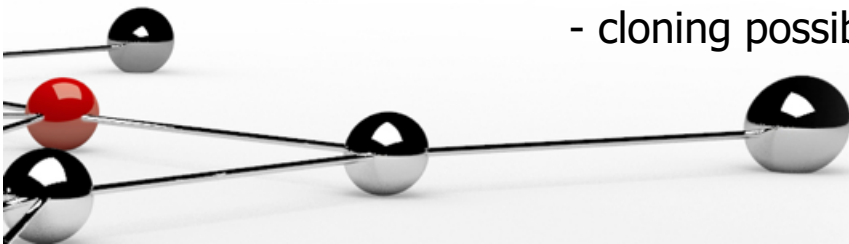
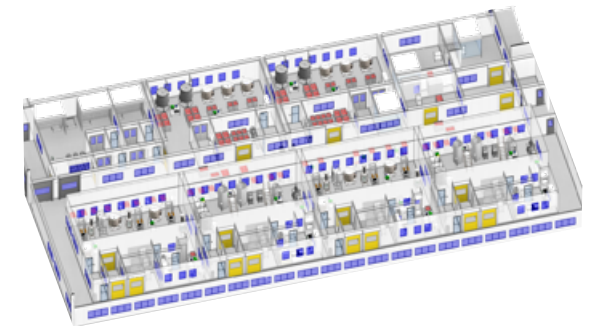
- Benefits:
- deliverable within weeks
  - much lower cost
  - no design timelines & costs
  - prequalification packages



## Predesigned Platforms

↳ Catalogue of different application turnkey platforms

- Benefits:
- greatly abbreviated design efforts
  - much faster delivery
  - reduced costs due to repeat built
  - cloning possibilities





# New Solution - Examples



Pediatric gene therapy – 14 units – 8 months  
Phase 2 – 10 units – 5.5 months



Aseptic filling site – 4 units – 10 months



Bioprocess site – 10 units – 10 months

## Other Projects:

Bioprocess – 8 units – 8 months

CAR T – 1 unit – 3.5 months

CAR T – 3 units – 7 months

Gene therapy – 8 units – 6 months



# "I Like, I Like, I Wonder..."

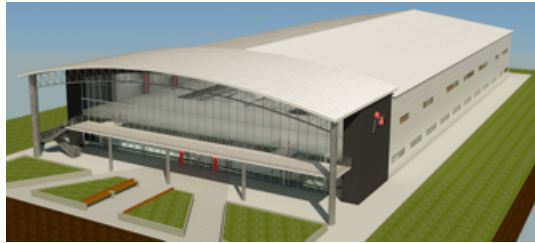


vs.

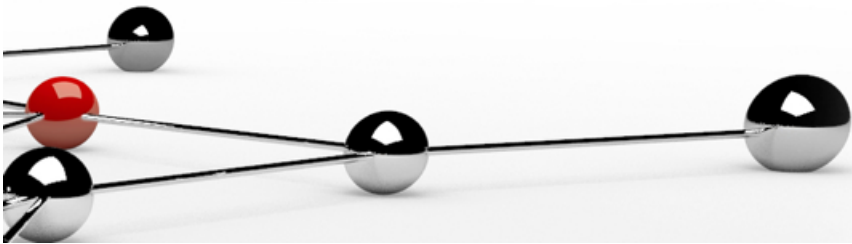
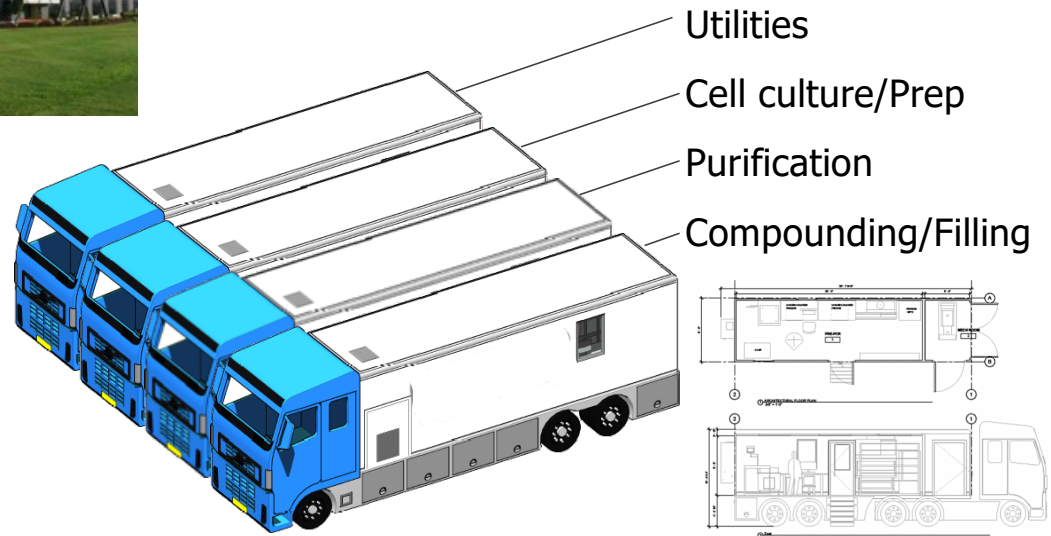


- ✓ We can lease cars
- ✓ We get cars delivered in weeks
- ✓ We can configure cars online
- ✓ We can check them in showrooms

Functionality (\$) vs.



Looks (\$\$\$)





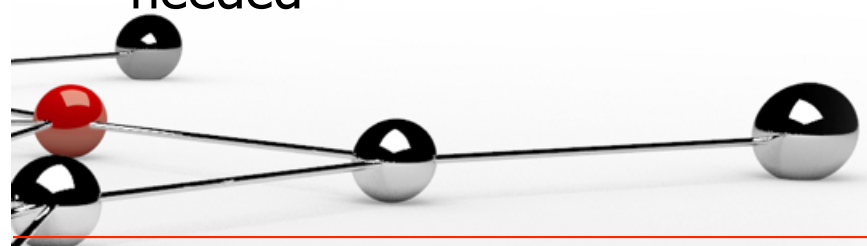
# Conclusion

- In a new era of therapies, the “old and traditional” does not fit
- Single-use process flexibilities required to be transformed to facilities
- Rapid deployment of facilities is necessary and possible off-site mass production could accelerate delivery time
- Segregation is essential to scale w/o interruption and contain when needed
- Most importantly; to develop and implement new technologies collaboration of all (industry, regulators and suppliers) is needed

“Alone we can do so little;  
together we can do so  
much”  
Helen Keller



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# Thank you !

*A pessimist sees the difficulty in every opportunity;  
an optimist sees the opportunity in every difficulty.*

*Sir Winston Churchill*

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