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Just – Evotec Biologics

Delivering low-cost flexible manufacturing to biologics

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Historically, our industry has used large-scale facilities to reliably produce and supply biologics

Substantial fixed assets and fit-for-purpose facilities that are now aging and inflexible

Nominal production bioreactor volumes of 20kL are some of the largest commercial scale for biopharmaceutical manufacturing

Unfortunately, this approach has not provided everyone access to these vital medicines

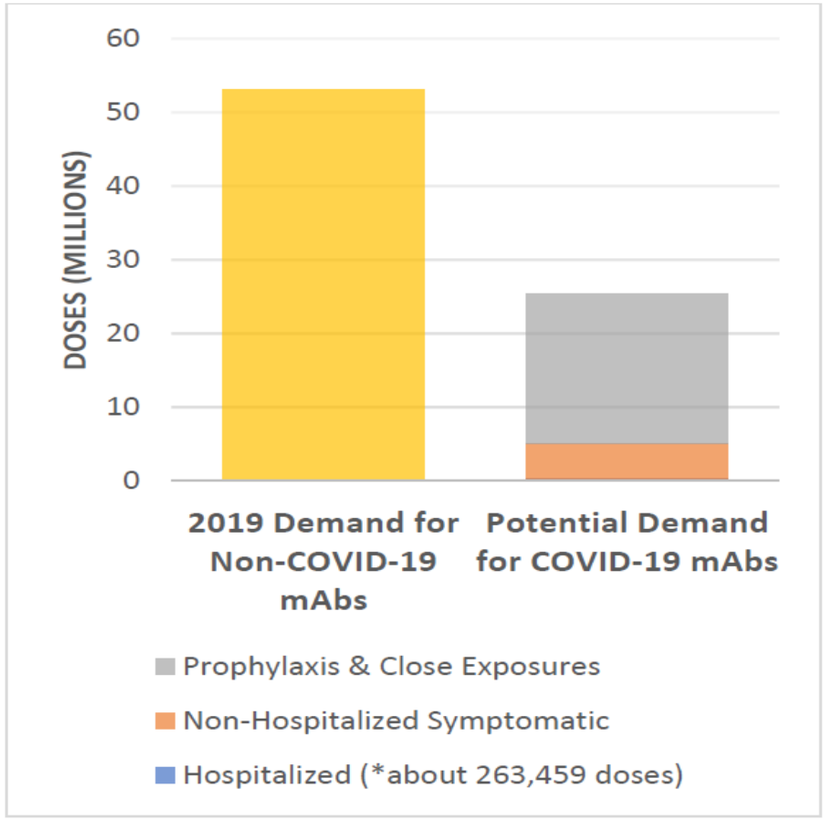
Macro trends are impacting affordability

- **80% of the Planet**
  - Cannot afford most of the breakthrough therapeutics of modern biotechnology
- **$2.6 Billion**
  - Cost to develop and gain marketing approval of a new biotherapeutic drug – *PhRMA (2015)*
- **Combination Therapy**
  - with biologics will dramatically increase the cost of a course of therapy
- **Precision Medicine**
  - will reduce treatable patient populations and put enormous pressure on pricing of breakthrough therapies

Rapid response efforts also strain existing biologics manufacturing capacity

Speed and flexible capacity solutions are necessary to mitigate potential constraints

Potential U.S. Demand for COVID-19 mAbs (using current epidemic levels)[4]

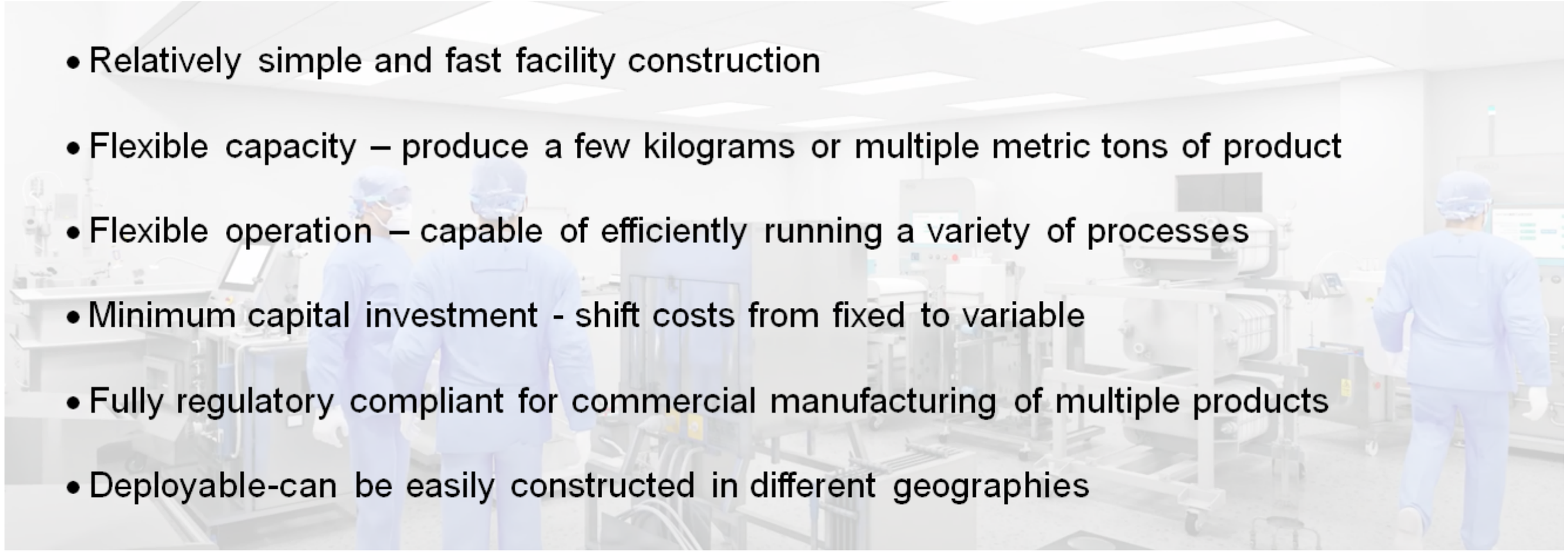


The challenge for our industry is how to meet maximal and timely production of effective COVID-19 therapies without creating shortages of important non-COVID-19 biologics

* Isha Sharma, Marta Wosińska, Adam Kroetsch, Haley Sullivan, and Mark McClellan of the **Duke-Margolis Center for Health Policy**. Issue Brief: "COVID-19 Manufacturing for Monoclonal Antibodies." Ensuring Sufficient Manufacturing Capacity for COVID-19 Therapeutics workshop. June 2020.

New biologics manufacturing approaches are necessary to aggressively meet these challenges

New plant design principles shift the complexity of the plant to the process



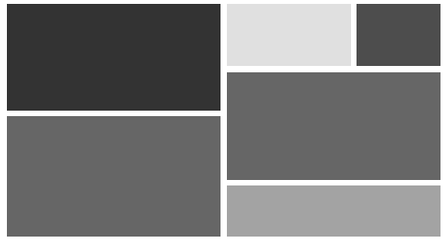
J.POD facilities reduce capital expense and shift operating costs from fixed to variable

J.POD – lower cost, flexible and deployable manufacturing approach

$500M+
3-5 years build & qualify
800k+ ft^2

QC Lab	Utilities
Mechanical Support	Warehouse
Manufacturing	Admin & Amenities

$200M+
<18 months build & qualify
200k+ ft^2



$100M+
<18 months build & qualify
100k+ ft^2

Fixed Cost → Variable Cost

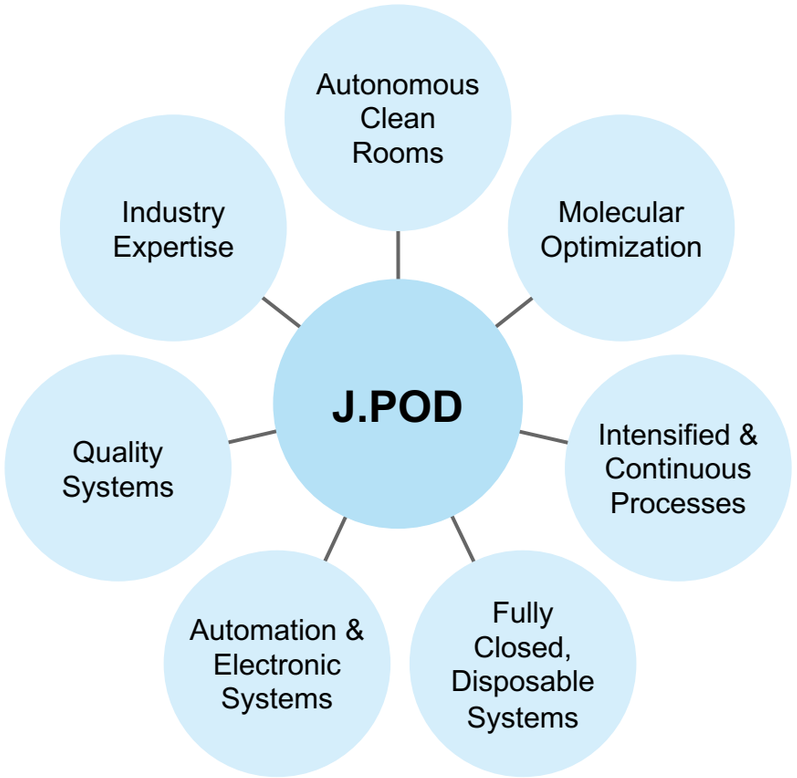
Conventional Facility
1st Generation

Flexible Facility
2nd Generation

Deployable Facility
3rd Generation

It’s more than a rapidly deployed building

Applied technologies are foundational for the platform

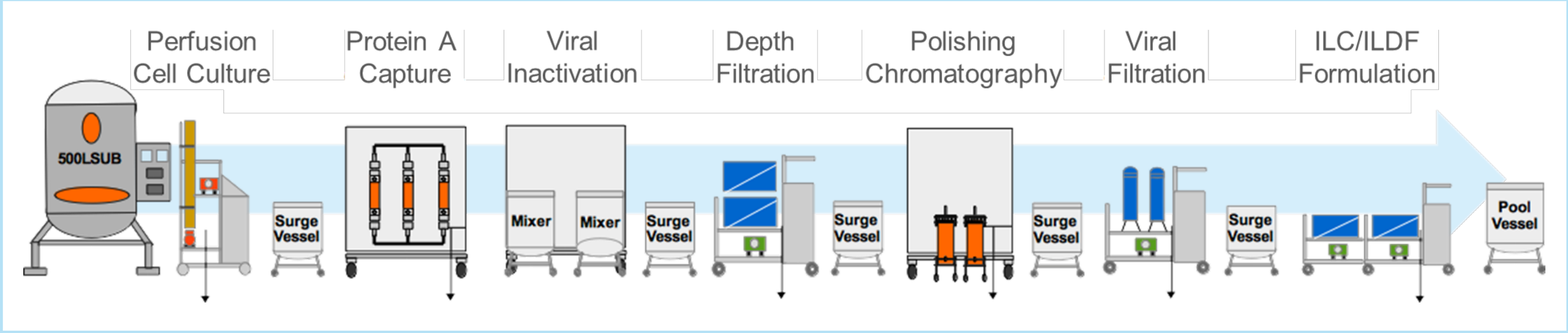


Flexible and cost-effective production (kilos to metric tons) of high-quality biologics drug substance

Continuous processing enables a small footprint, while delivering high mass output

Leverages traditional batch operations

- Reoccurring traditional batch operations using connected equipment and automation for continuous processing
  - Simplifies approach to scale down qualification, and thus viral and process validation
  - Large intermediate pool tanks become small single-use surge vessels (SUSVs)
- Drive to fully/functionally closed systems for bioburden control of long duration processing



Shifting complexity and cost from the facility to the process

No central CIP and SIP systems and associated piping are required

PD Labs

Quality Labs

Shell Space

Controlled Space

- Ballroom w/PODs
- Media and Buffer Prep
- Warehouse
- Standard & Clean Utilities

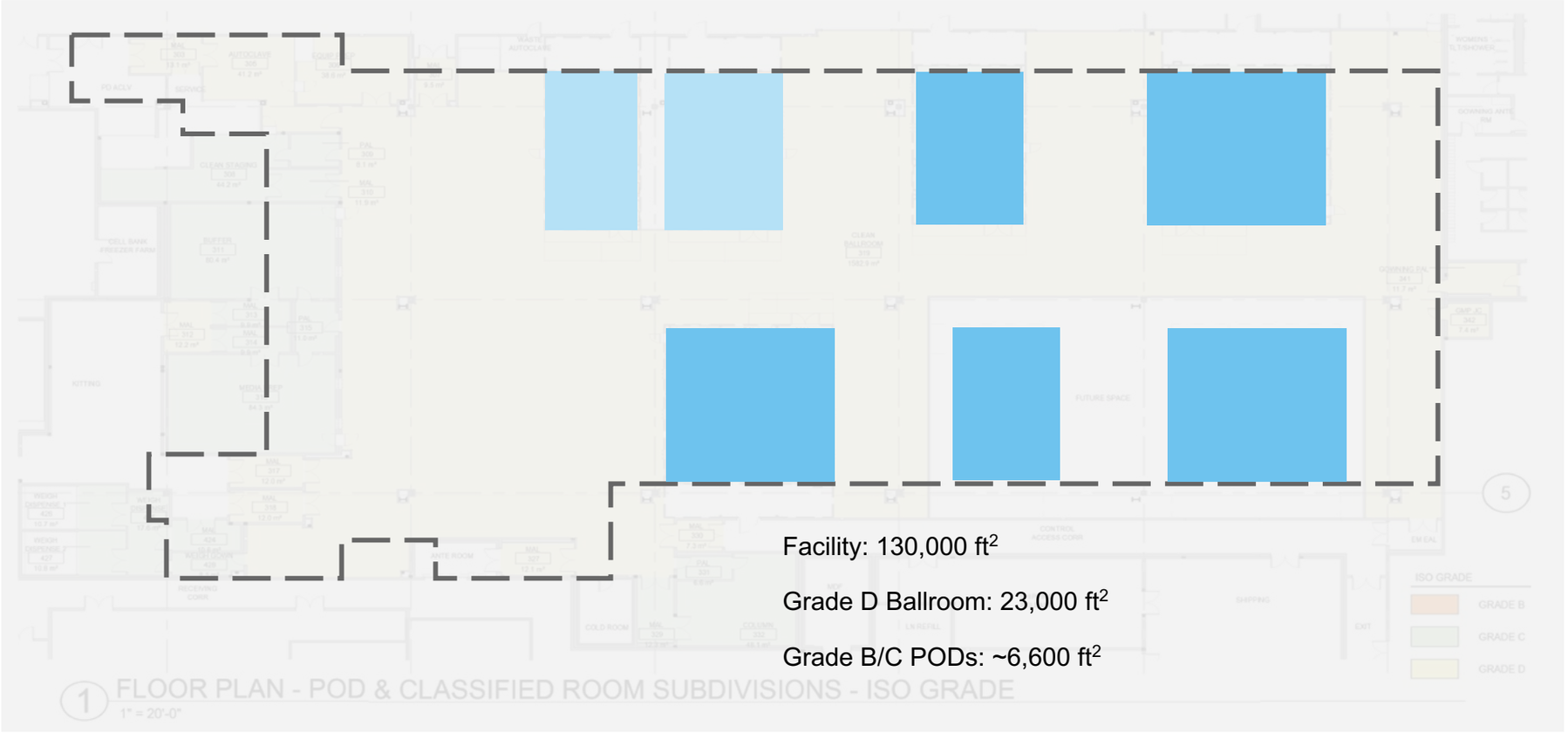
Clean & Standard Utilities

130,000 SF facility

Processing space is expensive to build and operate, but will only be a small fraction of the facility footprint

Total Grade B and Grade C space represents <10% of the total site footprint

PODs can be added, removed, or reconfigured to adjust capacity for maximum flexibility



An appropriately sized warehouse can serve as the building shell

Advanced manufacturing technologies applied in a simple facility design

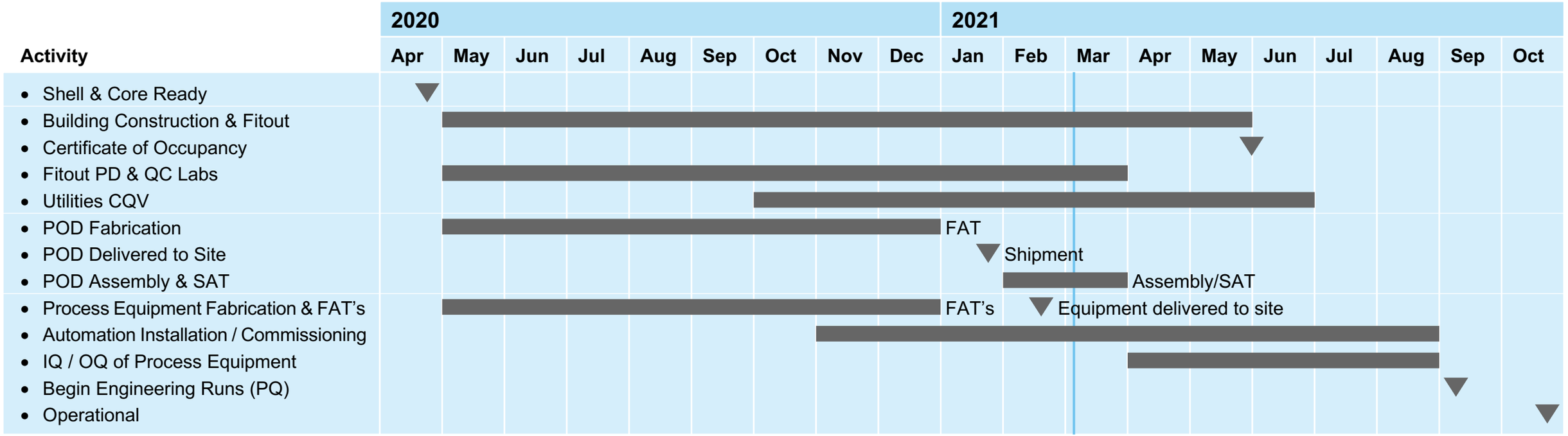
View of Building Shell Exterior

View of Building Shell Interior

This approach can enable regional deployment into different geographies

Rapid build: 16 months from shell & core to engineering (PQ) runs

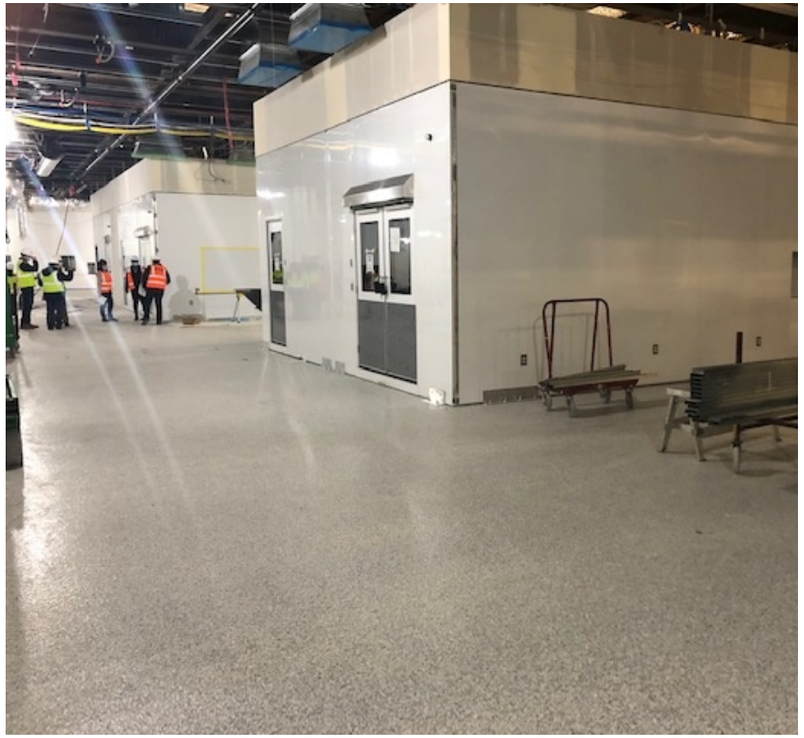
J.POD construction and fabrication schedule



- Parallel construction, fabrication, and CQV activities facilitate speed
- Lessons learned will be leveraged to reduce future facilities timelines

POD delivery and placement into facility

Twelve modules, forming 5 PODs, placed in ~12 hours

POD Delivery	PODs moving into facility	PODs moved into place
		

When completed it will look something like this

3-D rendered views from detailed design drawings

View of PODs from Grade D Ballroom

Inside View of Grade C POD

Closing Remarks

- New approaches to biologics manufacturing are necessary to meet the challenges we currently face, as well as those we may meet in the future
- Advanced technologies applied in well designed and relatively simple and inexpensive manufacturing facilities will deliver flexible capacity for manufacturing high quality biologics at a reasonable cost

Design and apply innovative technologies to dramatically expand global access to biotherapeutics

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Questions?

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