PDA
Parenteral Drug Association

MAY 2, 2024

Navigating Capital Projects:

WHEN AND HOW TO CONSIDER PREFABRICATED SOLUTIONS

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Agenda

- What are Prefabricated Solutions
- Advantages of Prefabricated
- What about stick built?
- How to Decide
- Case Study

What are Prefabricated Solutions?

PREFABRICATED SOLUTIONS

EQUIPMENT

SOFT SIDED

PRECAST & PEMB

MODULAR WALLS & CEILINGS

PREFAB MODULAR BUILDING

PREFAB - DECON, AIRLOCKS

Advantages of Prefabricated Solutions

ADVANTAGES

INHIBIT ORGANIC GROWTH

- Non-porous
- Inherently antibacterial

ADVANTAGES

MAINTAIN EXISTING OPERATIONS

- Reduced construction particulates from grinding/welding, drywall dust
- Reduced onsite activities on infill projects
- Reduced laydown area
- Reduced ongoing maintenance

ADVANTAGES

LIFETIME COST SAVINGS

- Accelerated time to market
- Shop labor vs field labor
- Early detection and resolution
- Reduced ongoing maintenance
- Capital vs expense

ADVANTAGES

EXPERTISE AND CONSISTENCY

- Consistent workforce
- Construction tolerances 2-5% rework
- High quality labor

ADVANTAGES

SCHEDULING

- Parallel fabrication
- Scheduled arrival of kitted parts
- Reduced CQV
- Enables timely access to lifesaving medications for patients

ADVANTAGES

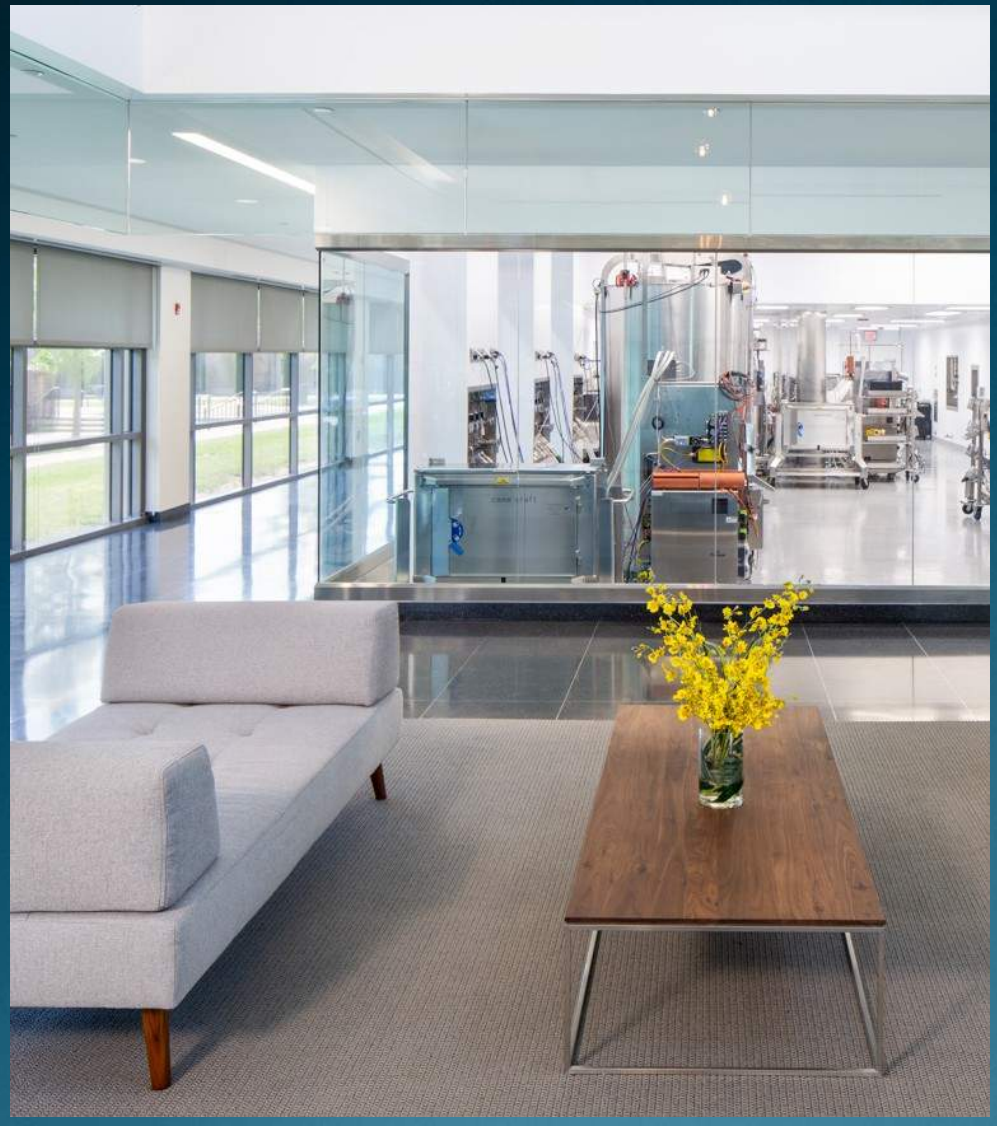
IMPROVED SAFETY

- Controlled factory environments
- Walkable ceilings

ADVANTAGES

SCALABILITY

- "Design once, build twice"
- Expansion
- Technology
- Adaptability



What About Stick Built?

STICK BUILT

Lowest first cost

How are you looking at cost?

- Initial cost vs lifetime cost
- Who is paying for the project

STICK BUILT

INTEGRATION WITH EXISTING FACILITIES

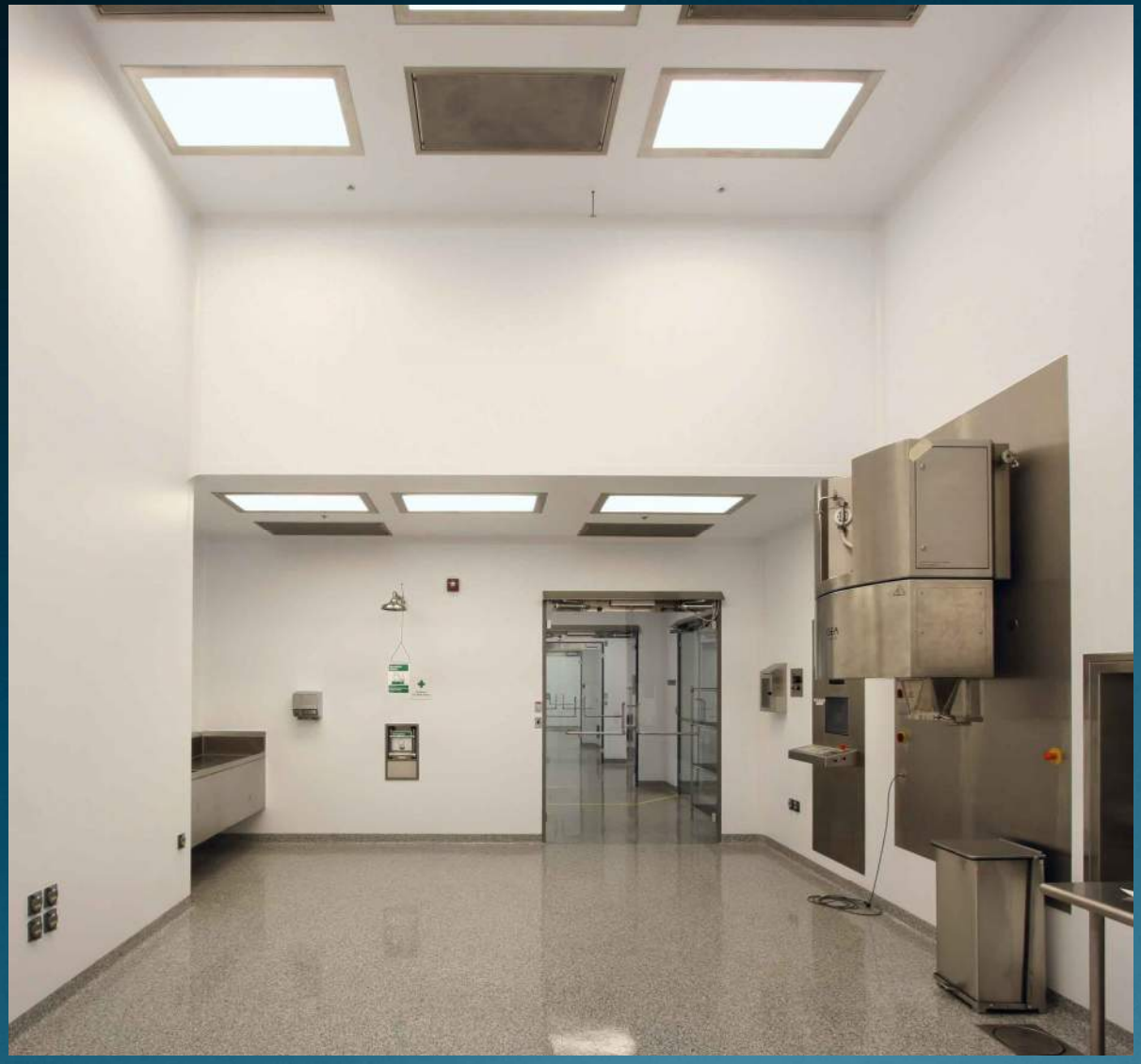
LOCAL LABOR POOL

- Future modifications on your schedule

STICK BUILT

SCHEDULE CONSIDERATIONS

- Greenfield vs infill
- Critical Path and Long lead times



How to Decide?

LEVEL OF PROJECT DEFINITION

30% to 40% of the cost of building a typical commercial building can be attributed to redesign and change orders resulting from issues identified during construction.

- Report from the National Institute of Standards and Technology (NIST)

DATABASE

Vendor 1	Vendor 2	Vendor 3	Vendor 4	Vendor 5	Vendor 6	Criteria / Demonstration	
						How long is typical design timeline?	General
						What is the typical installation time per square feet?	
						What is the smallest unit dimesion for your cleanroom system?	
						What are forced void (unusable) spaces in he design?	
						What are the limitations for equipment ntegration to your cleanroom system?	
						What are the limitations for cleaning agents? What chemicals are not allowed to	
						What are the offering for coved corneres?	
						s there any specific labor considerations or installing your cleanroom system?	
						How much dust/particles is generated durin construction?	
						How much extra storage is needed during construction?	
						s there need for special equipment or specially trained personnel to perform	
						s there any special limits or consideration or shipping of the materials?	
						How flexible is the system to field modify?	
						Can the cleanroom be moved and re-used? To what extent?	
						How do ceiling hangers connect to the clean oom ceiling grid and shell structure? Are they adjustable or fixed?	Ceiling
						What is the ceiling panel dimentions?	
						Are the ceiling panels removeable? How easy/fast?	
						What is the load restriction for the walkable ceilings?	
						What is the installation time for the ceiling? sqf/h)	
						How is the acess to the light fixtures? From clean side or from interstitial?	
						How easy it is to run cabels and conduits hrough the ceiling tiles?	
						What are the options for HEPA filter boxes?	
						Where are the HEPA DP ports? Clean side Interstitial / Both?	
						HEPA box grid mechanism.	
						How is the connection between ceiling and wall? Standard details	
						Are the parts custome made or over the shelf?	
						Does your company perform the installation or do you rely on sub-contractors to install	
						How thick is the ceiling?	
						What is the lead time for individual panels?	
						What is the lead time for project in our size From PO to ship of material)	
						What is the construction material/coating?	
						Do you use specific vendors for light ixtures or are there options?	
						How do you ground ceiling grids?	
						What is the leak rate of ceiling?	
						What building structure is required for ceiling panels?	
						Who corrdinate all installations on the ceiling?	
						What is the insulation rating of ceiling panels?	

Vendor 1	Vendor 2	Vendor 3	Vendor 4	Vendor 5	Vendor 6	Criteria / Demonstration	
						Are the wall panels removeable? How easy/fast?	Wall
						What is the installation time for wall panels? sqf/h)	
						How easy it is to run cabels and conduits hrough the wall panels?	
						How wide are the panels? Satndard panel dimentions?	
						How does the return inlets look like?	
						How does return inlets connect in the ceiling?	
						How is the connection between wall and loor? Standard details?	
						s there any protection guards for some areas? Standard design or custom?	
						Are the parts custome made or over the shelf?	
						How thick are the wall panels?	
						What is the lead time for individual panels?	
						What is the construction material/coating?	
						Who provides the recipticals? How they ook?	
						How does the glass look like and how they connect to the normal walls? Standard	
						What are the options for windows?	
						How thick are the glass walls?	
						How do the exit signs installed?	
						How do the material pass throughs look ?	
						Does your company provide cleanroom benches?	
						How do the step over benches look?	
						How does the closets in the gowning rooms ook?	
						What is the leak rate for walls?	
						How sealed are the recepticals?	
						How do you ground wall panels?	
						What is the insulation rating of wall panels?	
						Who provide the doors?	Doors and Interlocks
						What utilities are needed for the automatic doors?	
						Check the door tracks?	
						How thick are the sliding doors?	
						How easy it is to addjust the door sealing mechanisms?	
						What is the door control system?	
						How does the door share it's status?	
						What is the leak rate for different door ypes?	
						Does the door control have network connection?	
						How does the door bottons look?	
						How does the emergancy exit botton ook/work?	
						How easy it is to adjut the interlocks time?	
						Who provides the LFUs?	Laminar Flow Units
						How is the control system on the LFUs? Fan speed control / Air low speed control)	
						What sensors are installed on the LFUs?	
						What input and outputs are available on LFUs to be connected to BAS?	
						What is the communication protocol of the LFUs?	
						How does the LFU share it's status?	

DECISION MATRIX

- What Are The Project Drivers?
- Shared Vision Of Success

Decision Matrix													
Schedule			Host Facility						Scope				$
	Availability	Greenfield v. Renovation	FAT	Greenfield v Infill	Operational Facility	Laydown Area	Construction Access	Regional Considerations	Own, Lease, Move	Level of Customization	Program Definition	Process Equipment	Scalability	Cost
Stick Built														
Modular 1														
Modular 2														
PreFab 1														
PreFab 2														

Case Study

PROJECT SCOPE

INCREASED MARKET DEMAND FOR TIME CRITICAL VACCINE

Expansion for the 2nd presentation of the vaccine

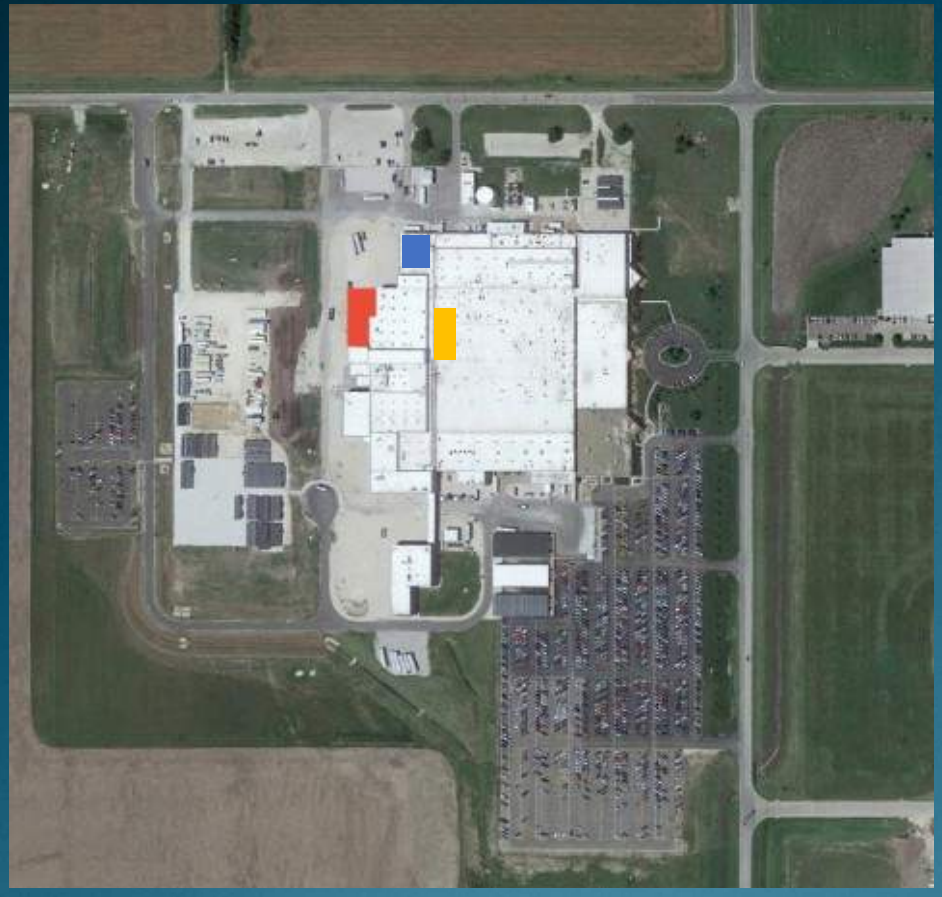
5X

Additional compounding capacity

Existing product commitments

IDENTIFY THE OPTIONS

- WAREHOUSE
- INTERIOR RENOVATION
- EXPANSION



FEASIBILITY EVALUATION

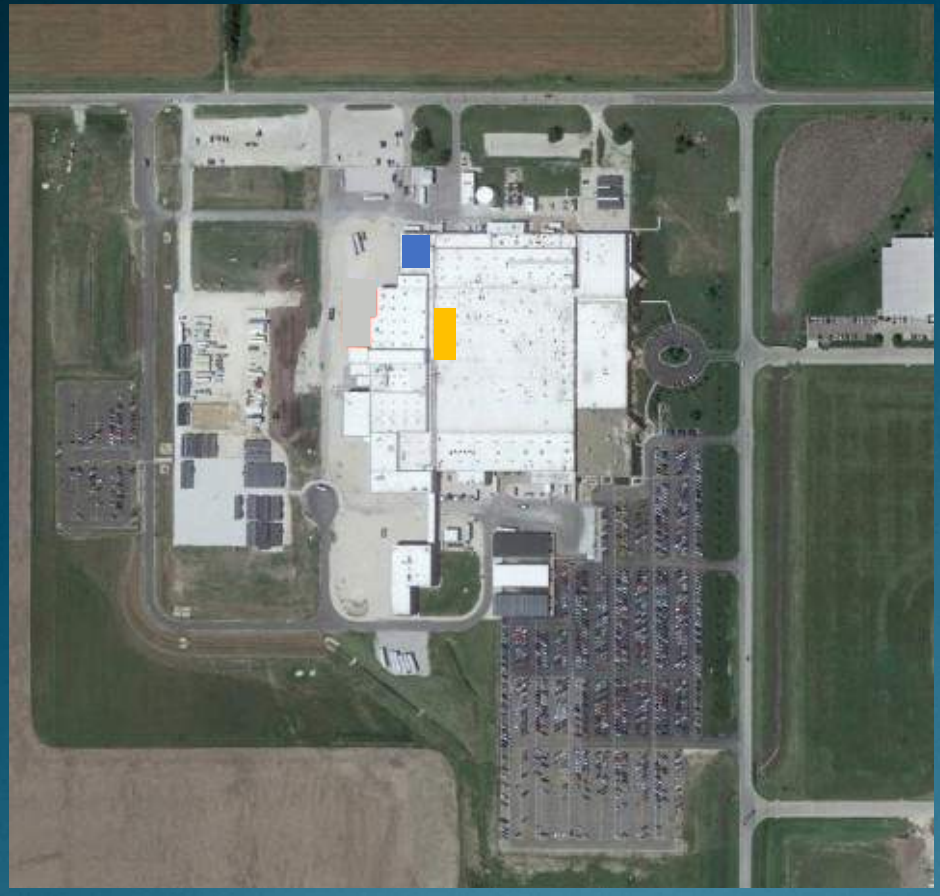
WAREHOUSE

	Schedule			Host Facility				$	Scope	
	Bandwidth	Greenfield v. Renovation	FAT	**Operational Facility**	Laydown Area	Construction Access	Own, Lease, Move	Cost	Program Definition	**Process Flow**
Stick Built	X	R		-	X	X		X	X	-
Modular 1	-	R				X				
PreFab 1	-	R		X	X	X	X	-	X	

FEASIBILITY EVALUATION

- WAREHOUSE
- INTERIOR RENOVATION

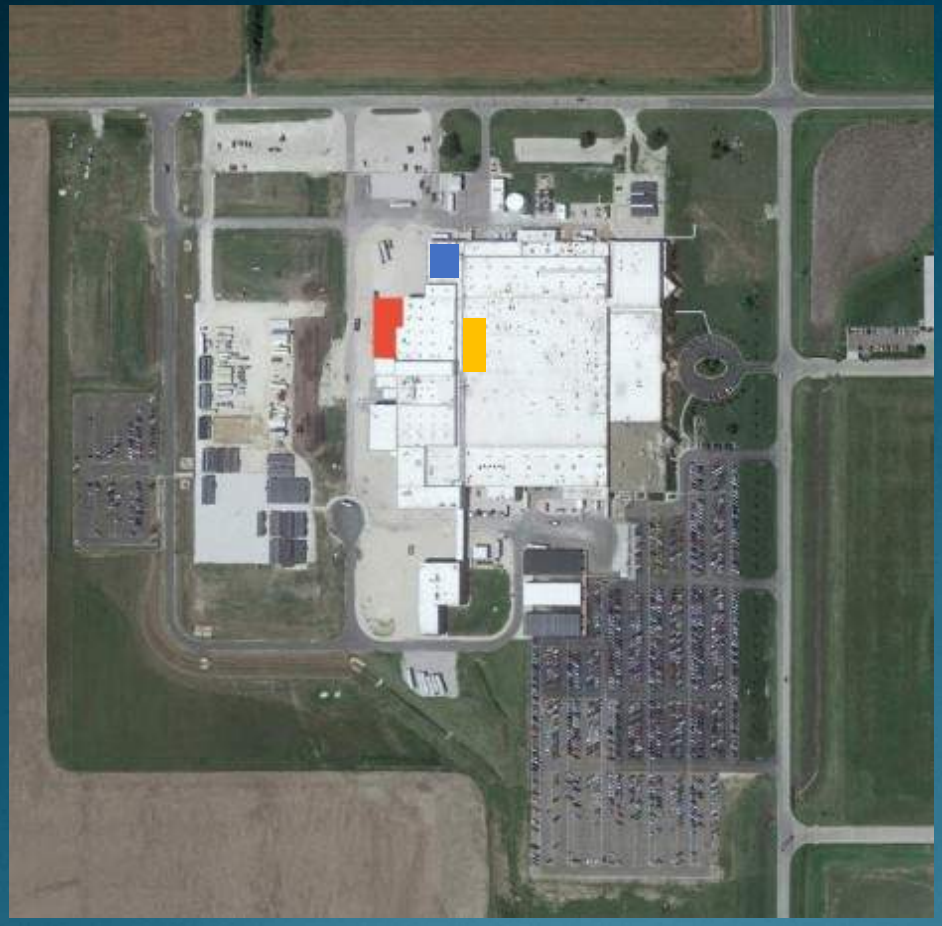
		Schedule			Host Facility				$	Scope	
		Bandwidth	Greenfield v. Renovation	FAT	**Operational Facility**	Laydown Area	Construction Access	Own, Lease, Move	Cost	Program Definition	**Process Flow**
	Stick Built	X	R		-	X	X		X	X	-
	Modular 1	-	R				X				
	PreFab 1	-	R		X	X	X	X	-	X	
	Stick Built	X	R		-	-			X		-
	Modular 1	-	R		X	X	X		X	-	
	PreFab 1	-	R				-		-		



FEASIBILITY EVALUATION

- WAREHOUSE
- INTERIOR RENOVATION
- EXPANSION

		Schedule			Host Facility				$	Scope	
		Bandwidth	Greenfield v. Renovation	FAT	**Operational Facility**	Laydown Area	Construction Access	Own, Lease, Move	Cost	Program Definition	**Process Flow**
	Stick Built	X	R		-	X	X		X	X	
	Modular 1	-	R				X				-
	PreFab 1	-	R		X	X	X	X	-	X	
	Stick Built	X	R		-	-			X		
	Modular 1	-	R		X	X	X		X	-	-
	PreFab 1	-	R				-		-		
	Stick Built	X	G		X	X	X		X	X	
	Modular 1	-	G		X	X	X		X	-	X
	PreFab 1	-	G		X	X	X		-	-	



DECISION

EXPANSION

Adherence to site master plan

METHOD

Stick built

DECISION CRITERIA

- Evolving program
- Minimize disruption to ongoing manufacturing
- Balance between construction and operational function
- Access to utilities

BUILDING

HYBRID SOULTION

Modular wall panels were used in several areas to accommodate long lead equipment, valve changes, utility panels, HMI and point of use cabinets

In Conclusion

IT DEPENDS

How well defined is the program and process needs?

What sort of flexibility do I need for future expansions or modifications?

Is cost to be evaluated as initial cost or life cycle costs?

Does the initial investment justify a faster speed-to-market?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