

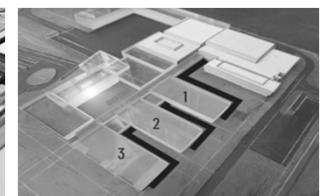
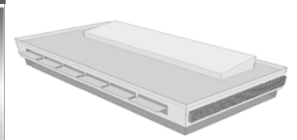


PLATFORM DESIGNS FOR TODAY'S NEW DRUG PRODUCTION FACILITIES

Peter Cramer, AIA
ISPE Product Show
Track 2, Session 4
September 26, 2018



Peter Cramer, AIA, NCARB, LEED AP, is the VP of Life Science Facility Design at M+W U.S., Inc. with more than 25 years of industry-leading experience in preparing conceptual and basis of design documents for pharmaceutical and biologics clients.



Connecting

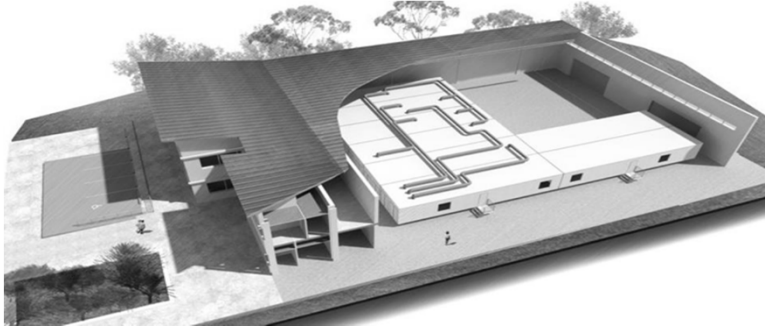
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Competition in the “House in House” Modular Market

Germ Free “bioGO and GCon Cell Therapy Pods



Cell and Gene Therapy
Prefabricated Cleanroom PODs

G-CON's Cell Therapy PODs® provide the most comprehensive and flexible processing solutions for the personalized and regenerative healthcare industries.

Cell and Gene Therapy Prefabricated Cleanroom PODs (2.30 MB)
03/28/2018



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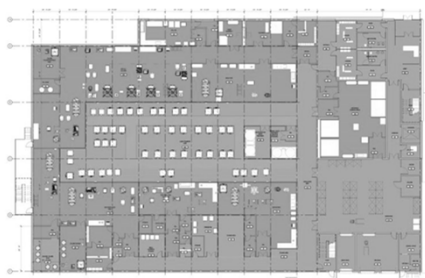
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Layout Evolution: Reduced Footprints Options

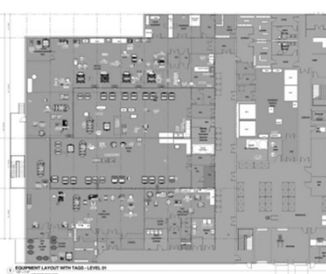
Modular Concept Studies

U Shape Concept: Option A



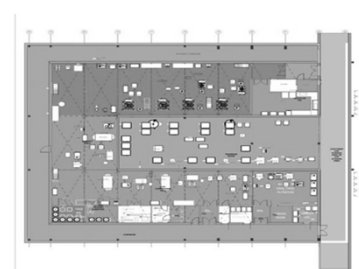
- Unclassified Transfer Area

Compact Concept: Option B



- Fixed Totes Inside Media and Buffer Prep

Ultra-Compact Concept: Option C



- Lonza Prototype



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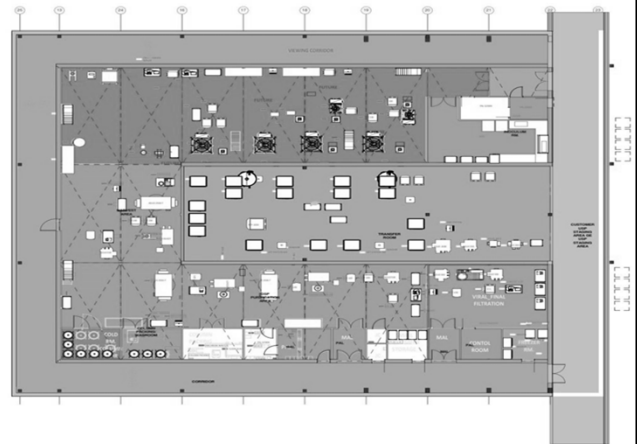
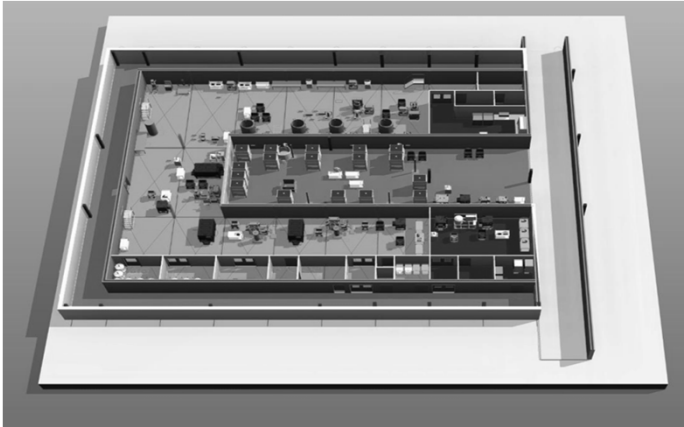
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“BOX IN BOX” MODULAR:

Case Study: 18 Modules, The Smaller the Bester



Central Zone Could become Classified Common Media and Buffer Prep & Staging



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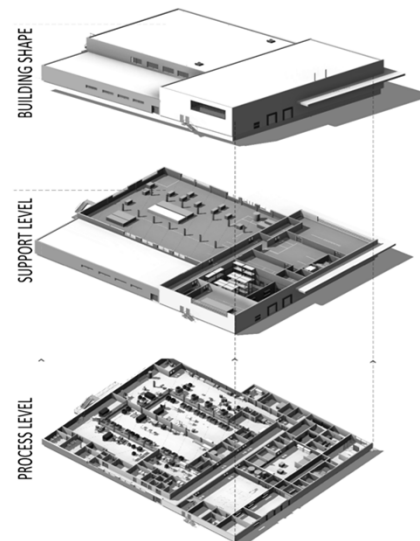
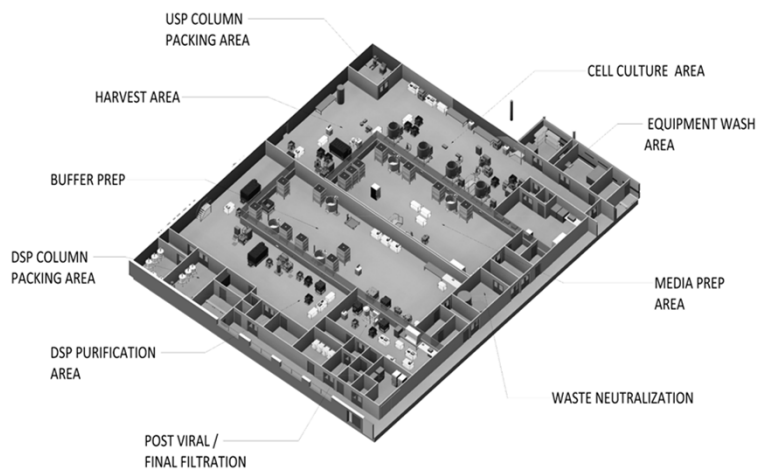
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MODULAR BUILDING WITH CLEANROOM SYSTEM

Building Shell is Modular



Not a “House in House” Design



Connecting

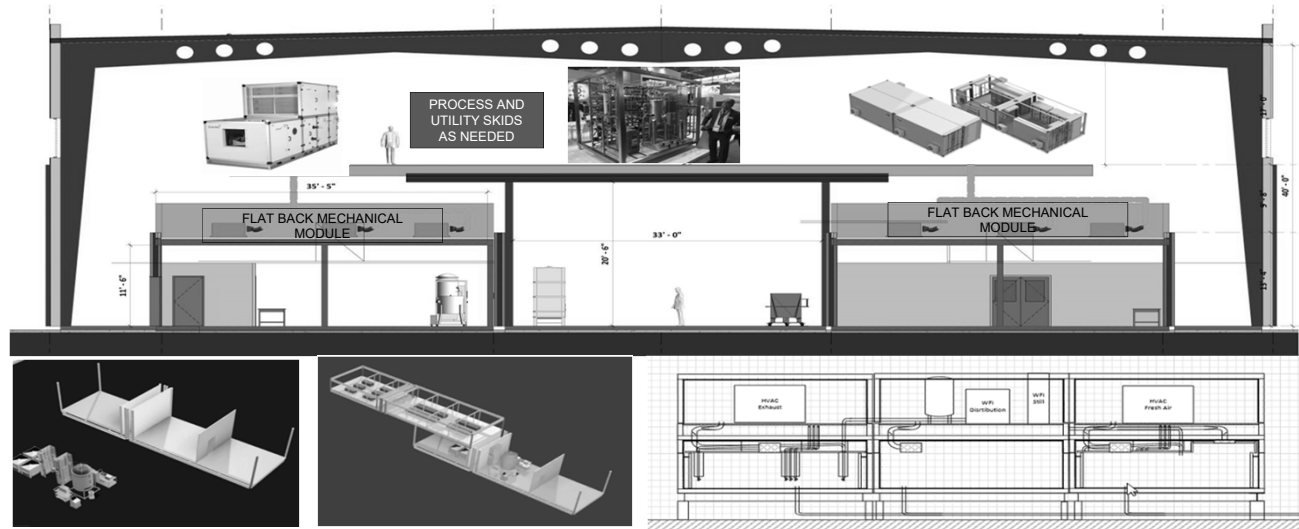
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“BOX IN BOX” MODULAR:: EQUIPMENT LAYOUT

Portal Frame Building with Modular Cleanrooms



Connecting

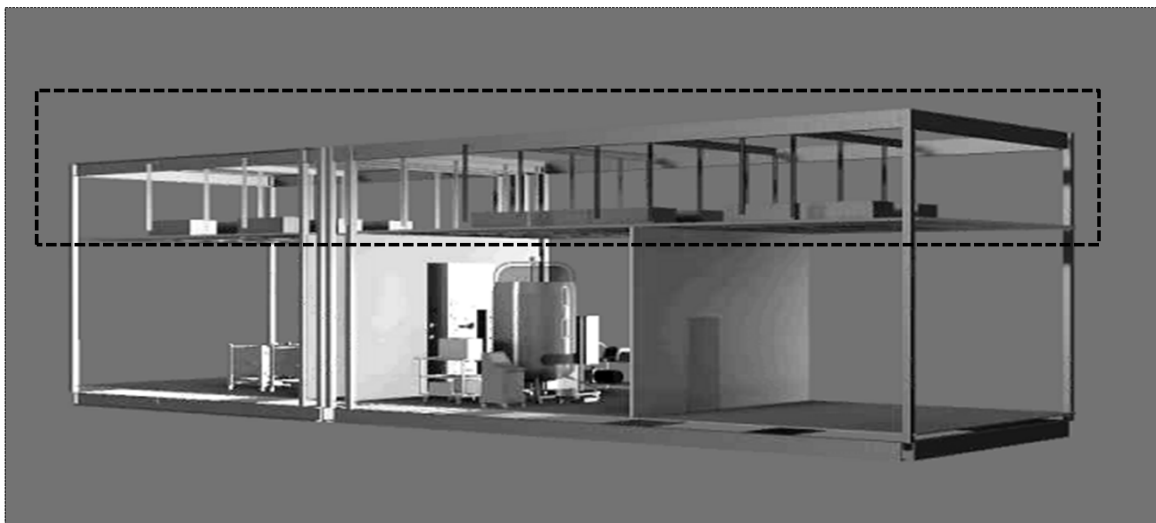
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Module Design

Flat Pack Mechanical Module (PAM): A Home for new Technology Products



Connecting

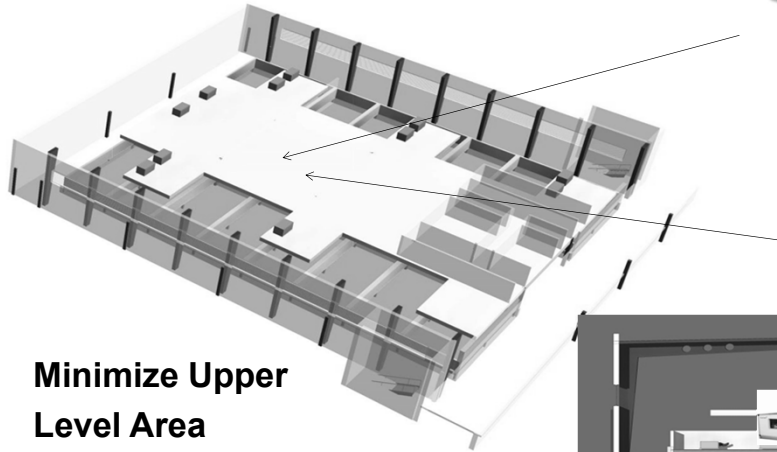
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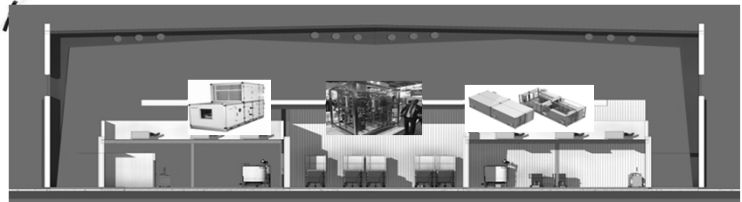
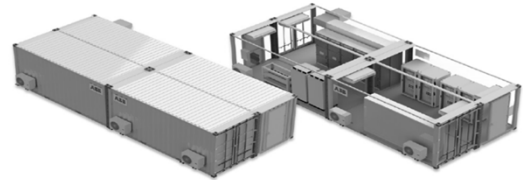
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Mezzanine and Interstitial Platform

A Place for Skidded and Pre-Engineered Solutions



Minimize Upper Level Area



Connecting

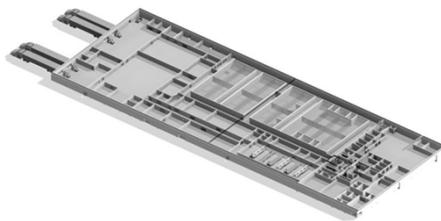
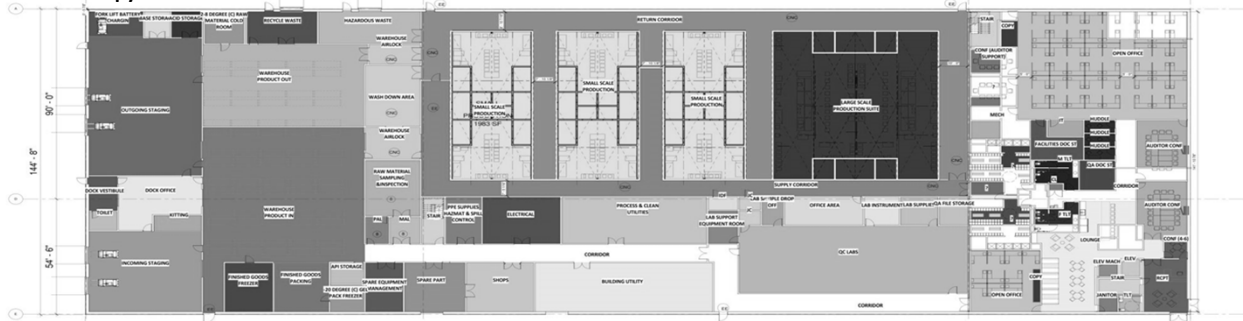
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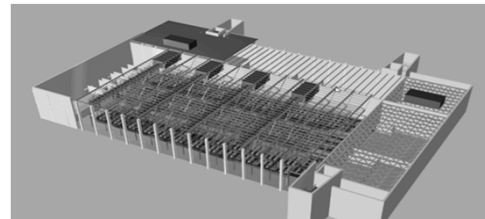
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“HOUSE IN HOUSE” FOR CELL THERAPY FACILITIES

Cell Therapy Modules inside Ballroom



AMP= Advance Manufacturing Platform



Open Ballroom Hold Modular Process



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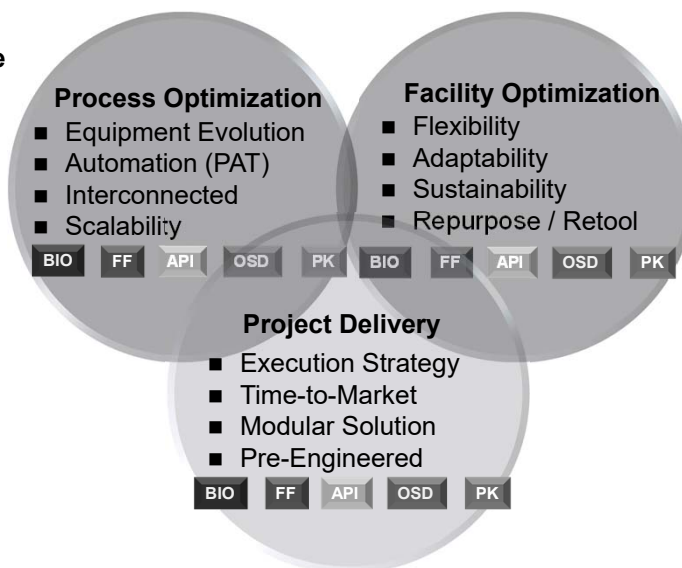
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Process Architect as Technology Integrator

STAYING RELEVANT IN THE DIGITAL ERA

- **Process Architects** are focused on finding creative ways to leverage and deliver new technologies in order to streamline the way Life Science Company deliver their products.
- **Mantra:** Provide value to our customers by designing something **NEW** and **BETTER** to support their business goals.
- **Focused on Today's Big Design Drivers:**
 - **Fast, Flexibility, multiproduct production**
 - **Reduced Risk Project Delivery**
 - **Seamless GMP**
 - **Sustainability through smaller more efficient production facilities**



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ARE YOU READY FOR NEW INDUSTRIAL REVOLUTION 4.0?

DIGITAL ERA OF DESIGNING INDUSTRIAL PROJECT

Industry 4.0 : technological building blocks are available



Decision-making computing

- machine learning
- algorithms
- big & smart data
- Cloud
- Simulators

Connected Things

- Physical and digital objects
- IoT
- Reliable wireless
- Data acquisition

Advanced robotics

- Cyber Physical Systems
- Cobots
- Intelligent machines
- Autonomous vehicles
- Additive Technologies



Connecting

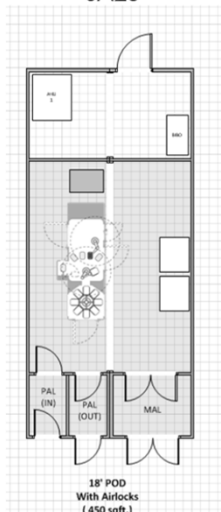
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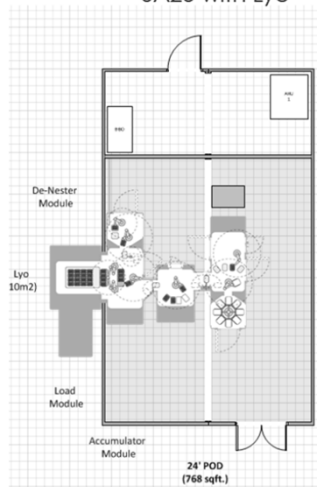
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Use of Predefined Production Layouts

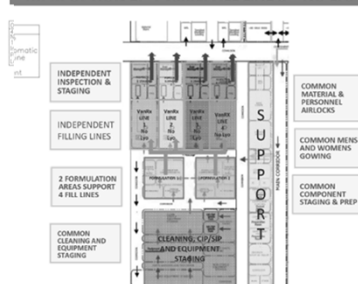
18' x 42' POD
SA25



24' x 42' POD
SA25 with Lyo



MPM OPTION 1: 4 VanRx FILL LINE S – NO LYO'S



MPM OPTION 2: 2 ONCO, 2 NON-ONCO FILL LINE – NO LYO'S



MPM OPTION 5: 2 VanRx FILL LINES W/LYO'S IN PO



MPM OPTION 6: 1 HIGH SPEED FILLING LINE W/LYO

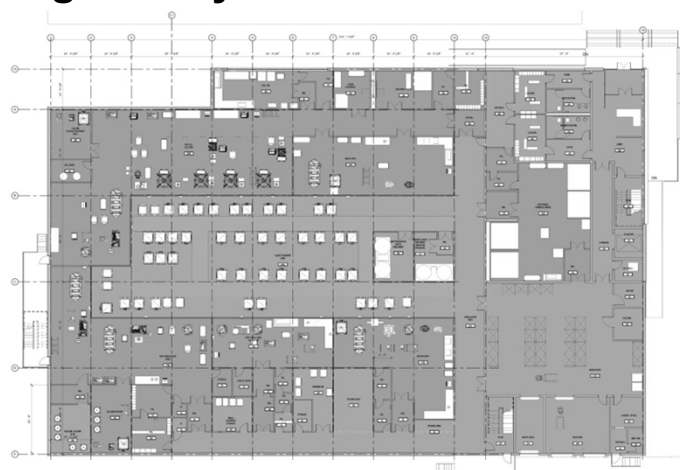
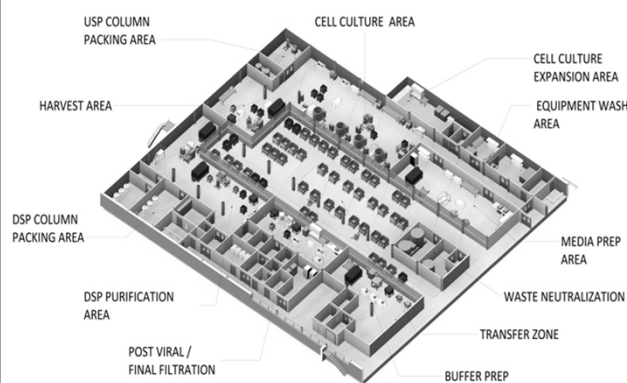


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Modular SUMT Biomanufacturing Facility

Centralized CNC Liquid Management Hall



Multiple Layouts and Project Delivery paths from a Single Platform Design



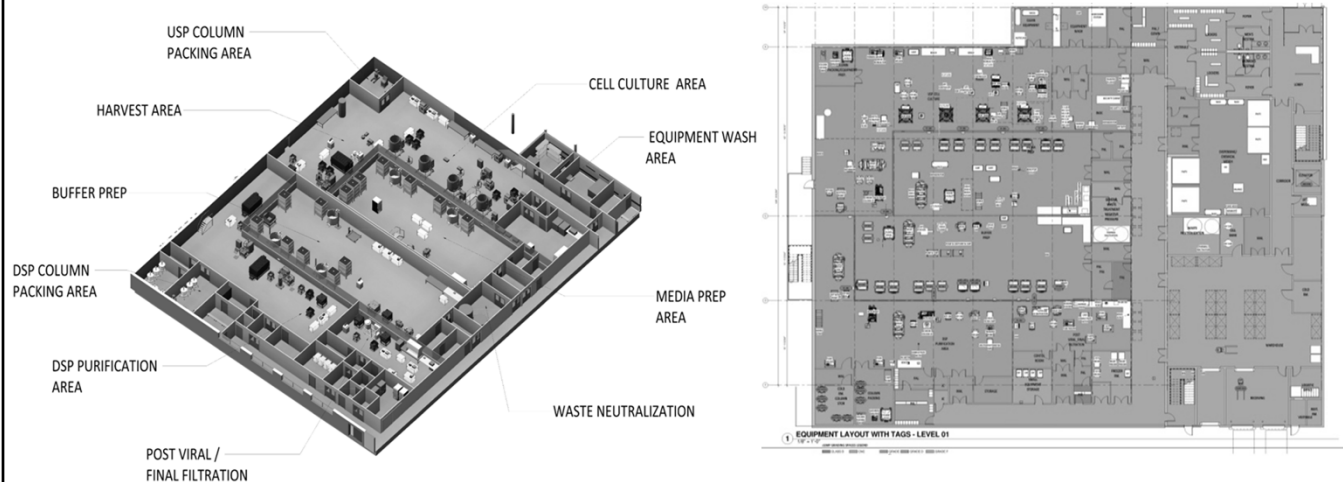
March 20, 2018

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Modular SUMT Biomanufacturing Facility

Centralized Media & Buffer : Fixed Totes

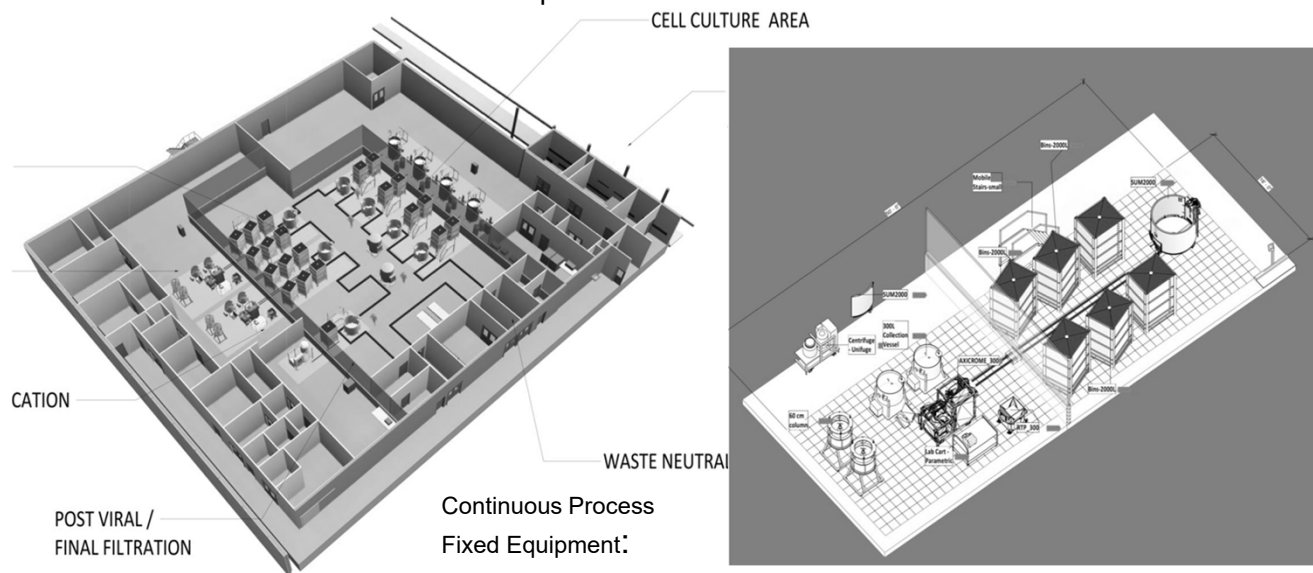


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Modular SUMT Biomanufacturing Facility

Centralized Common Media & Buffer Prep & Hold:

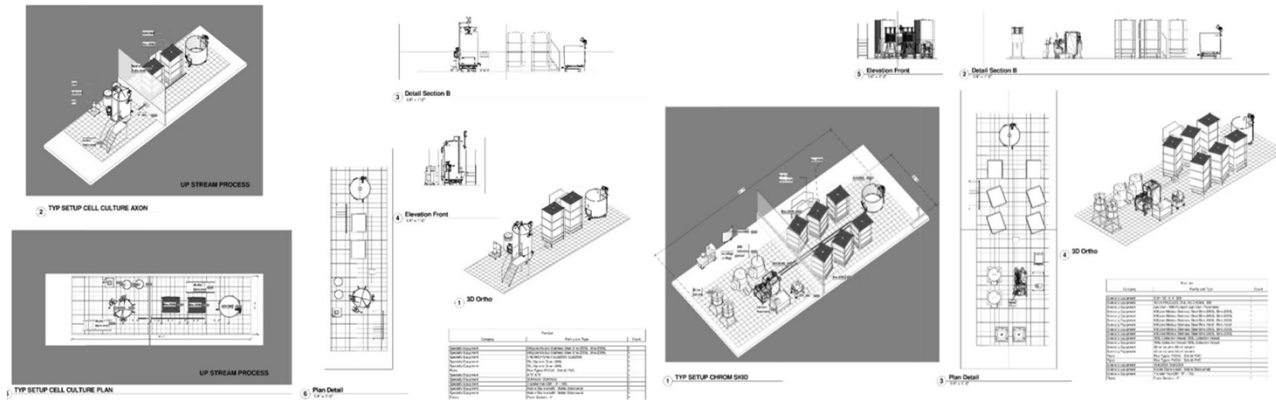


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Modular SUMT Biomanufacturing Facility

Continuous Media & Buffer : Fixed Totes and Mixers



UP STREAM PROCESS CELL

DOWN STREAM PROCESS CELL



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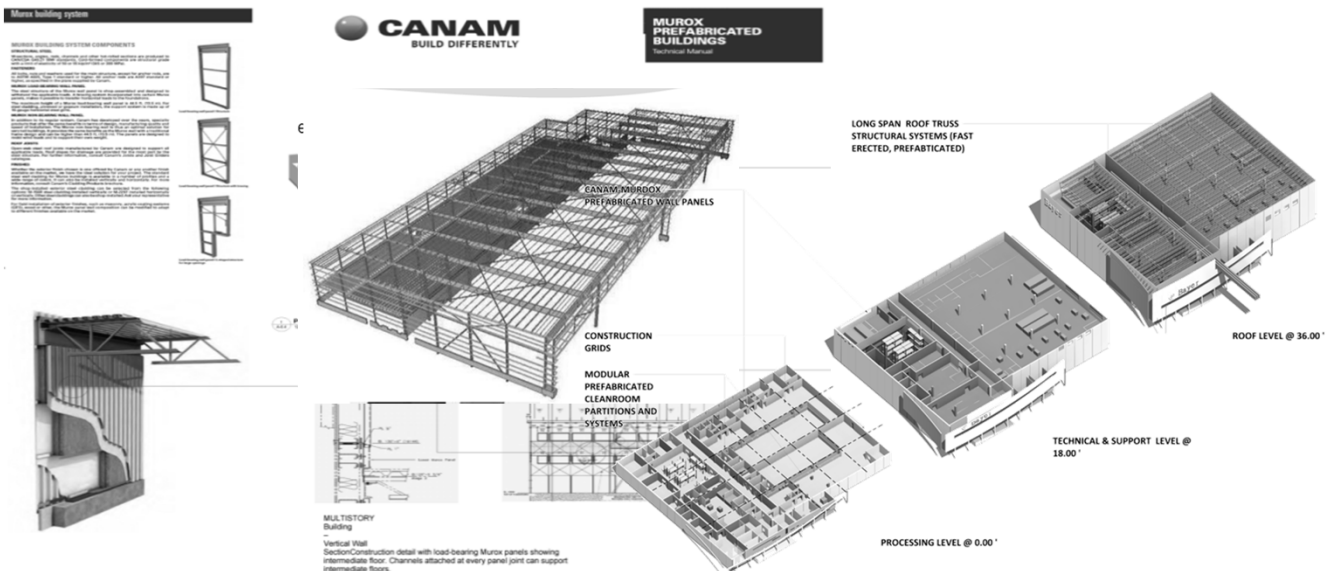
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Modular Exterior Shell Opportunities

Prefabricated Modular Wall Panels:



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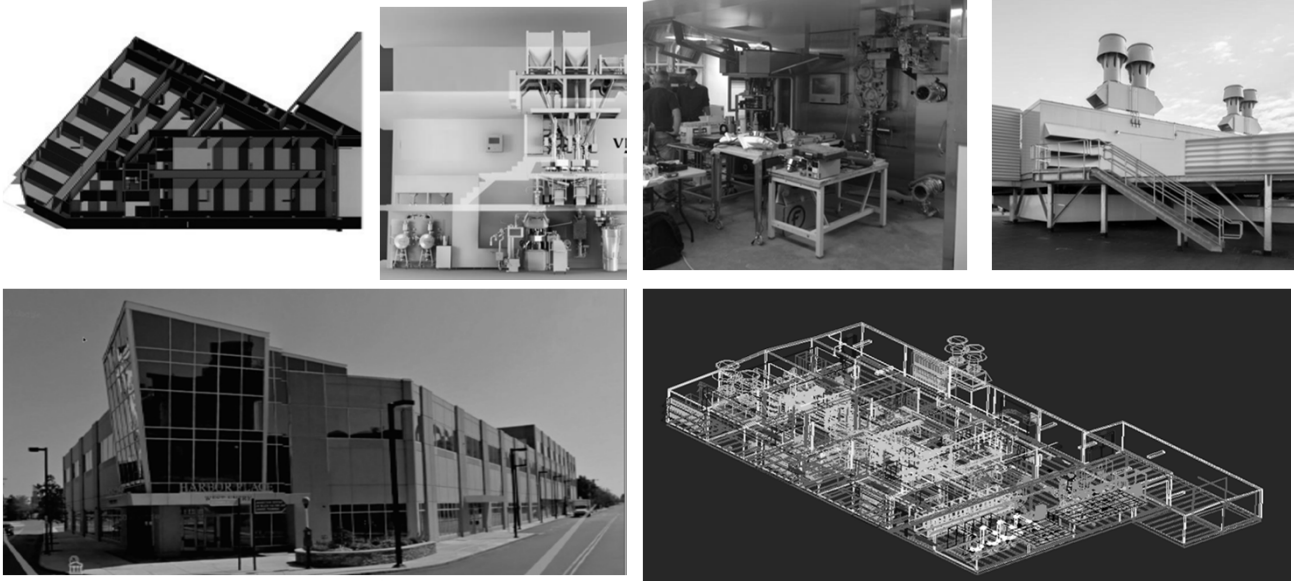
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Combining Modular Facility and Process Systems

Taking Advantage of Modular Marketplace to Deliver Project



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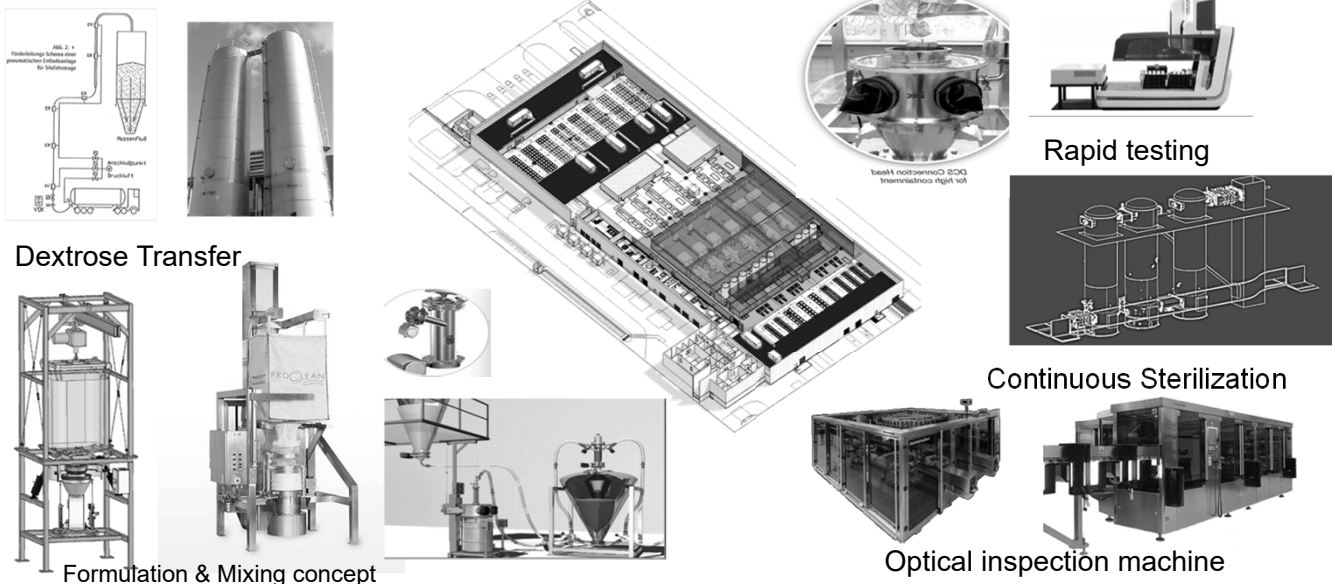
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Modular Design– Each cell makes approx. 200 L solution / minute

Optimization from Raw Material Receipt through Finished Goods Inspection



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Case Study: Future Factory

IV Bag Filling Facility: 200MM units/year

Each Cell is complete from Raw Material to Finished Goods: 200L/min.

OUTGOING
WHISING

STERILE
PRODUCT

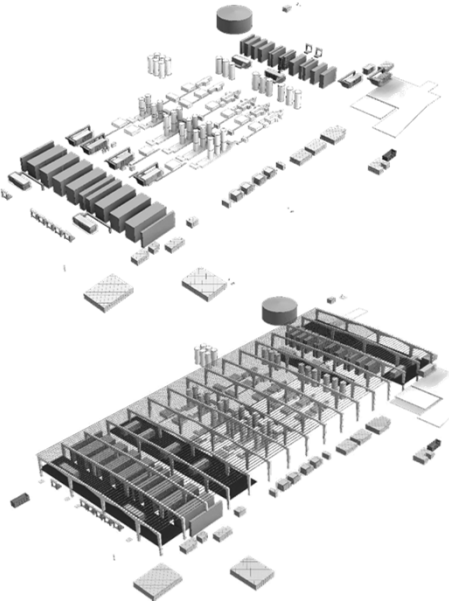
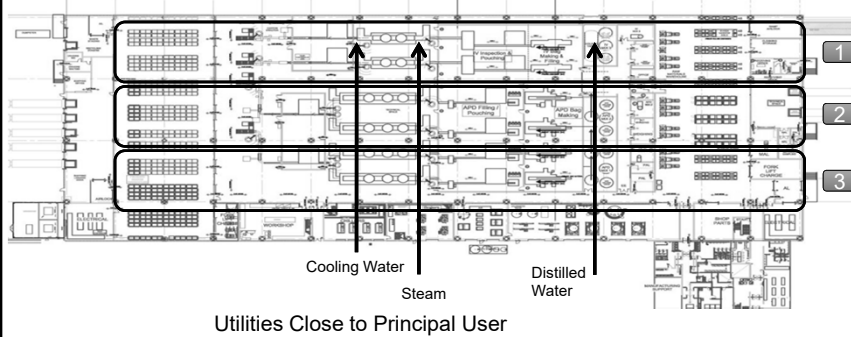
NON-
STERILE
PRODUCT

PRIMARY
CONTAINER

MATERIAL
ENTRY
TO
CLEAN
ROOM

RAW MATERIALS
& COMPONENT
INCOMING
WHISING

Modular Expandability with minimum interruption



Connecting

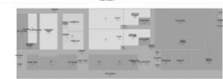
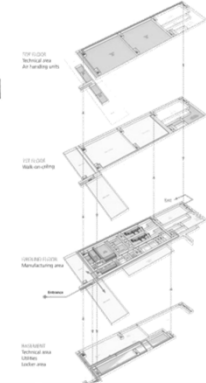
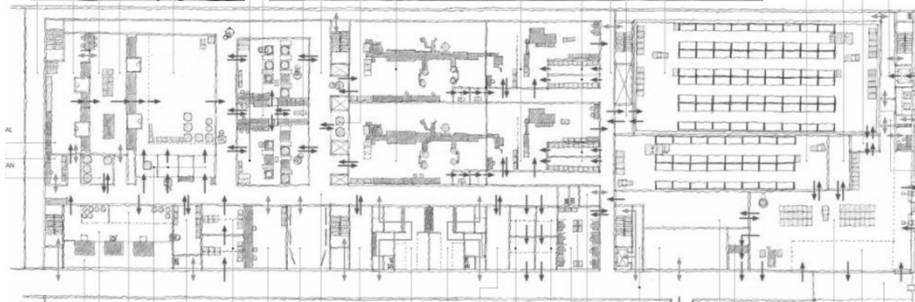
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Fill Finish Facility Concepts: Cartridge Filling

Single Story Process Floor Simplifies Facility Design



- Flexible Formulation: 2000L Mobil Product Vessels
- Automated Component Processing & Inline Inspection
- Linear Design Supports Expansion with two future filling line



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