

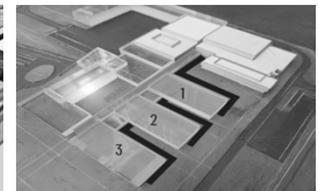
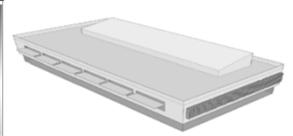


## PLATFORM DESIGNS FOR TODAY'S NEW DRUG PRODUCTION FACILITIES

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.



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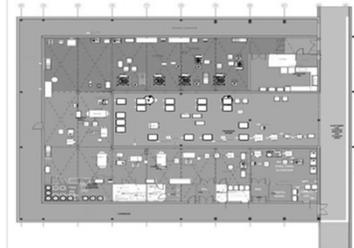
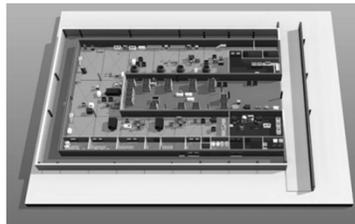
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## Success Factors: What we will deliver ...

- Scalable and Flexible
- Lowest Cost per Unit Output
- Leverage Product Technology
- Leverage Skidded and Pre-Engineered Components
- Platform Approach with Multi-Site Capability
- Procurement Strategy that Reduces Project Delivery Risk & Lower Cost.
- Cost and Schedule Certainty
- Keeps Simple and Low Cost Spaces Simple and Low Cost



Concept Model



Can be built just about anywhere ... with cost and schedule certainty.



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## Competition in the "House in House" Modular Market

GCon iCon



iCON

The iCON™ facility platform redefines the turnkey concept that the industry requires. iCON is the most flexible and rapidly deployable facility platform available. iCON meets the production agility demands of the industry due to new production module designs and the use of prefabricated cleanroom PODs.

iCON™ PRODUCT PORTFOLIO ESTABLISHES SECOND MANUFACTURING SITE IN KILKENNY, IRELAND



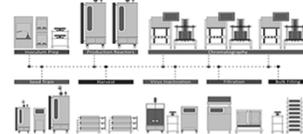
Our Company Why PODs Product Offerings iCON™ News and...

How Do You Create the Ultimate Solution for Speed, Flexibility and Efficiency in Facility and Process Designs?

PROCESS FLEXIBILITY



INTEGRATED PROCESS TRAIN  
(Optimized for your preferred equipment)



SCALABLE 4x2000L mAb PROCESSING FACILITY

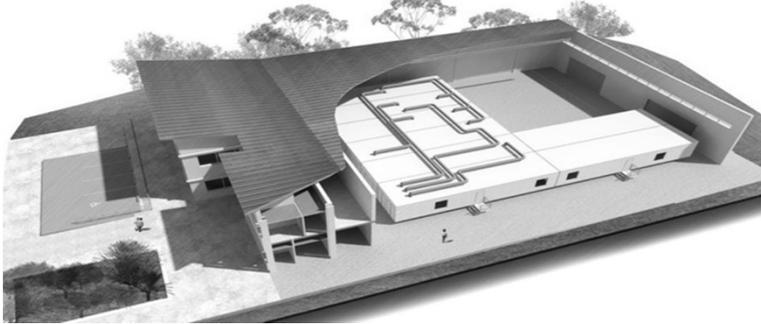


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# Competition in the “House in House” Modular Market

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



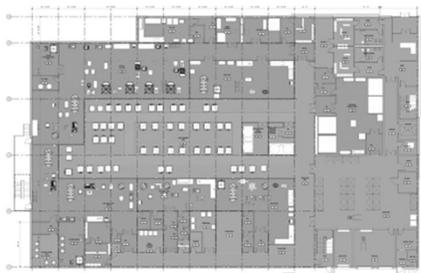
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# Layout Evolution: Reduced Footprints Options

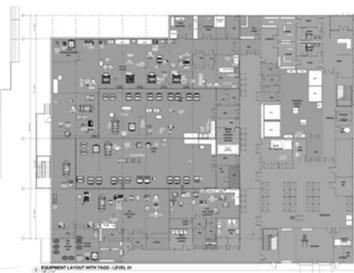
Modular Concept Studies

U Shape Concept: Option A



• Unclassified Transfer Area

Compact Concept: Option B



• Fixed Totes Inside Media and Buffer Prep

Ultra-Compact Concept: Option C



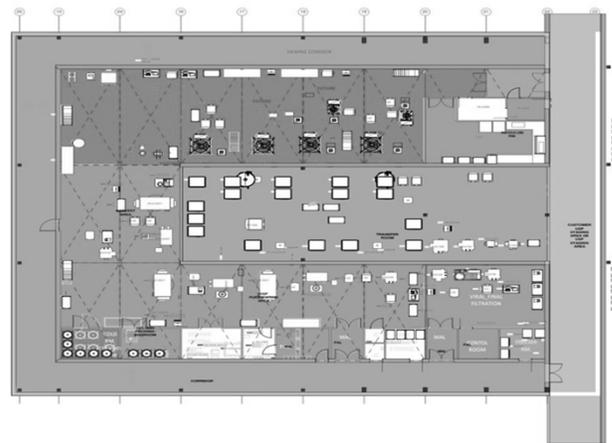
• Lonza Prototype



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# “BOX IN BOX” MODULAR: Case Study: 18 Modules, The Smaller the Bester



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

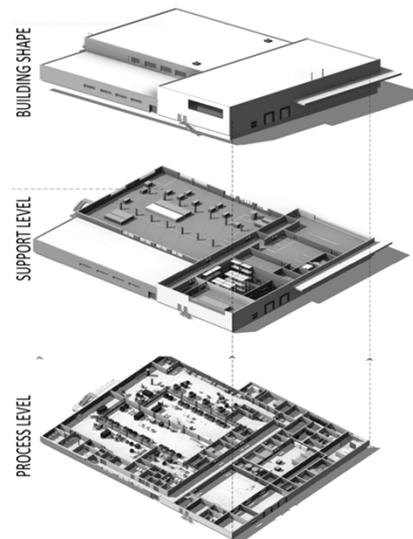
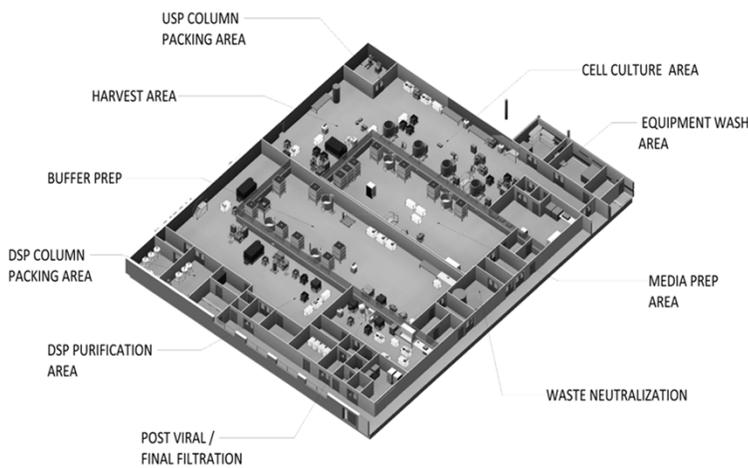


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# MODULAR BUILDING WITH CLEANROOM SYSTEM

Building Shell is Modular



Not a “House in House” Design

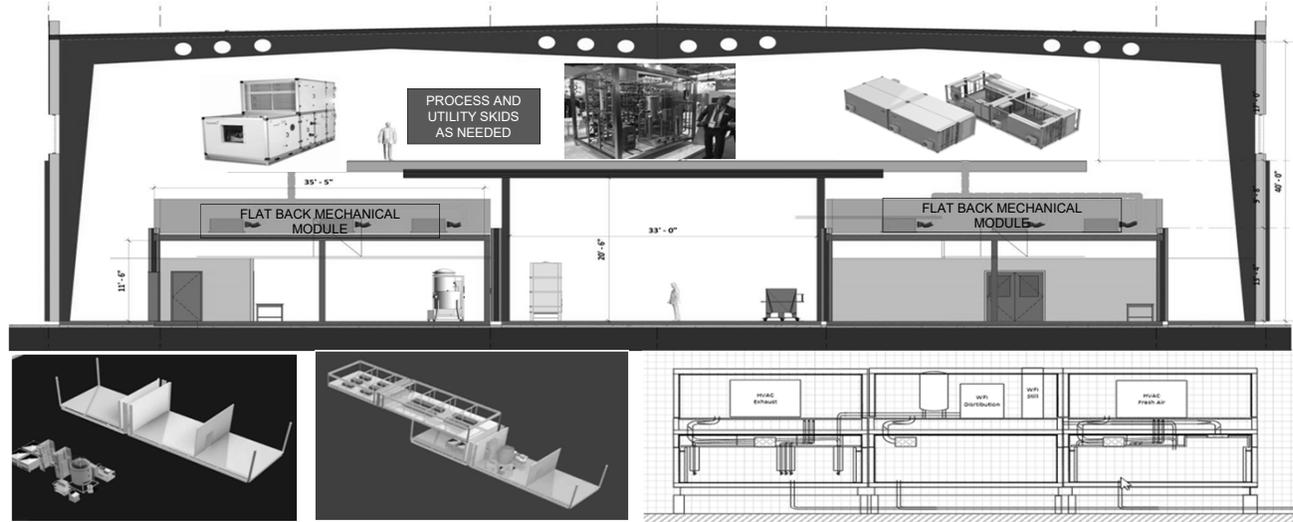


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# “BOX IN BOX” MODULAR:: EQUIPMENT LAYOUT

Portal Frame Building with Modular Cleanrooms



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## Module Design

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



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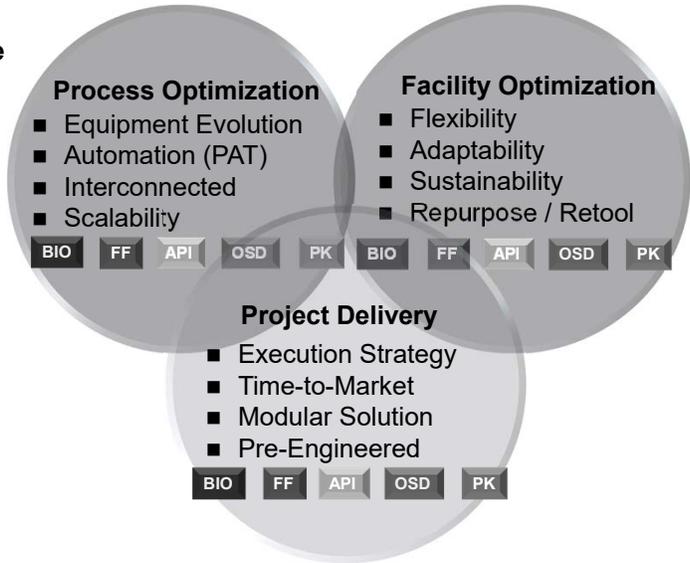
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# Process Architect as Technology Integrator

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**

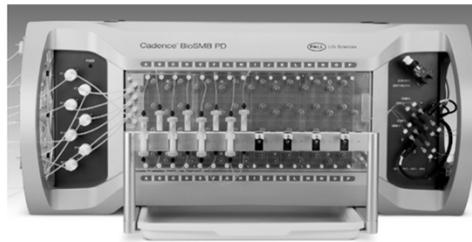
- machine learning
- algorithms
- big & smart data
- Cloud
- Simulators

**Connected Things**

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

**Advanced robotics**

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



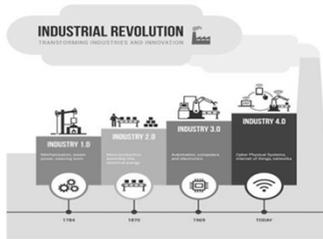
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# Changing Traditional Manufacturing

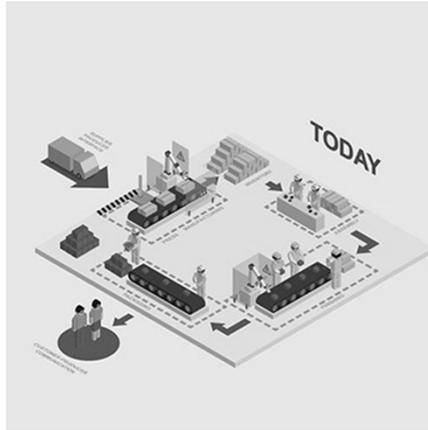
## Technology Trends:

- From Isolated to Interconnected Process Technologies
- Advanced Instruments & PAT
- Advanced Computer System, AI
- Use of Big Data
- Robotic and Machine Learning Systems

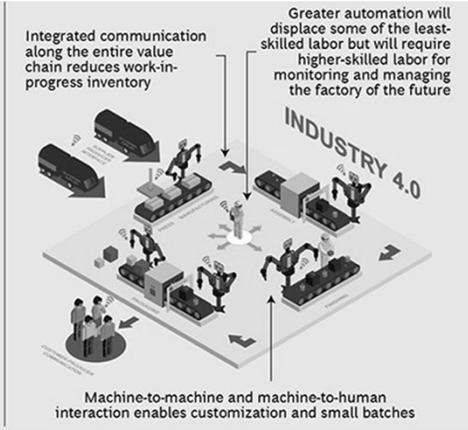


From Isolated, optimized cells

...



...to integrated data and products flows across manufacturing facility

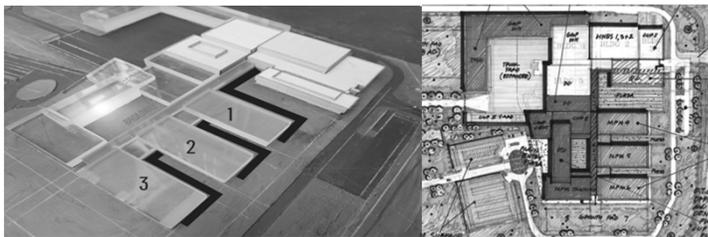


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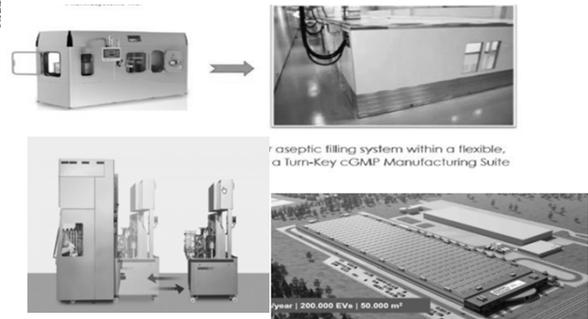
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# Multi-Product Modular Production Facility: MPM

Robotic & Multi Format Fillers inside POD's



- Flexibility - Multi Product / Multi Site Capable
- Uses Pre - Engineered Solutions to reduced risk:
- Platform Design can be built in multiple locations
- The ability to rapidly handle changes in production demands and format

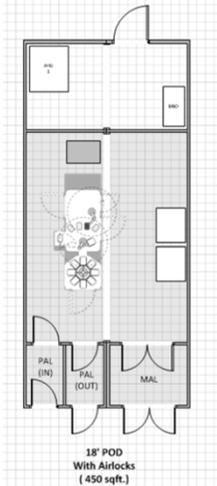


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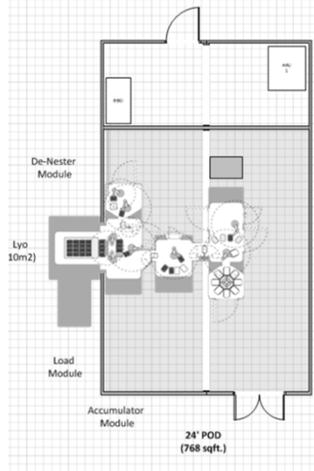
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# Use of Predefined Production Layouts

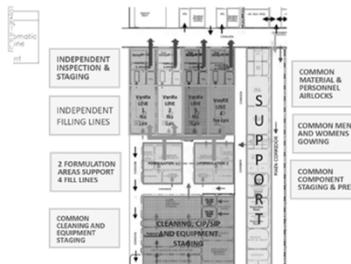
18' x 42' POD  
SA25



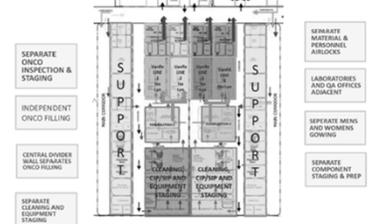
24' x 42' POD  
SA25 with Lyo



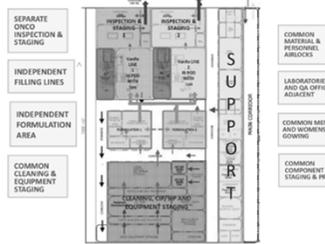
MPM OPTION 1: 4 VanRx FILL LINE S – NO LYO'S



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

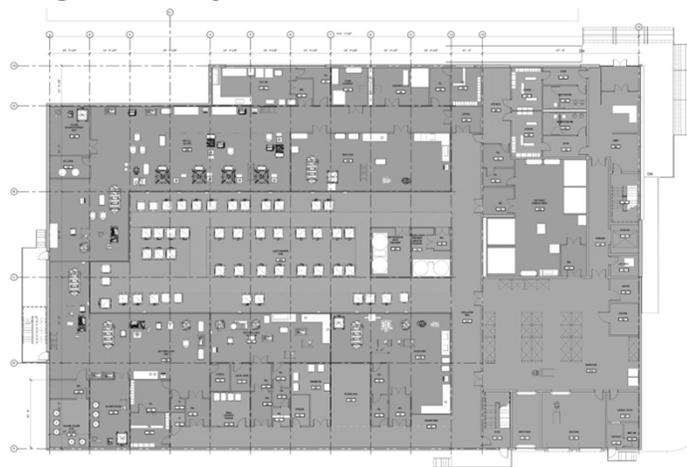
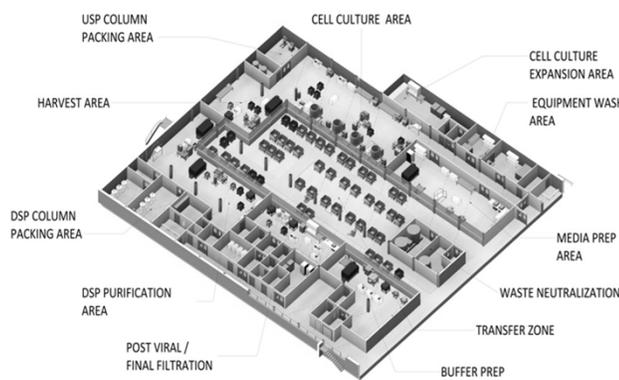


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# Modular SUMT Biomanufacturing Facility

Centralized CNC Liquid Management Hall



**Multiple Layouts and Project Delivery paths from a Single Platform Design**



March 20, 2018

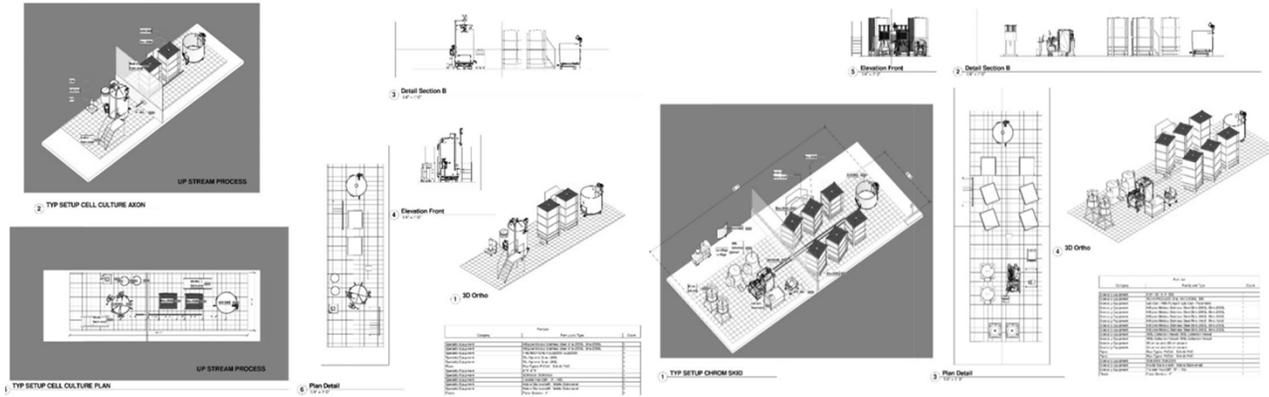
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# Modular SUMT Biomanufacturing Facility

Continuous Media & Buffer : Fixed Totes and Mixers



UP STREAM PROCESS CELL

DOWN STREAM PROCESS CELL

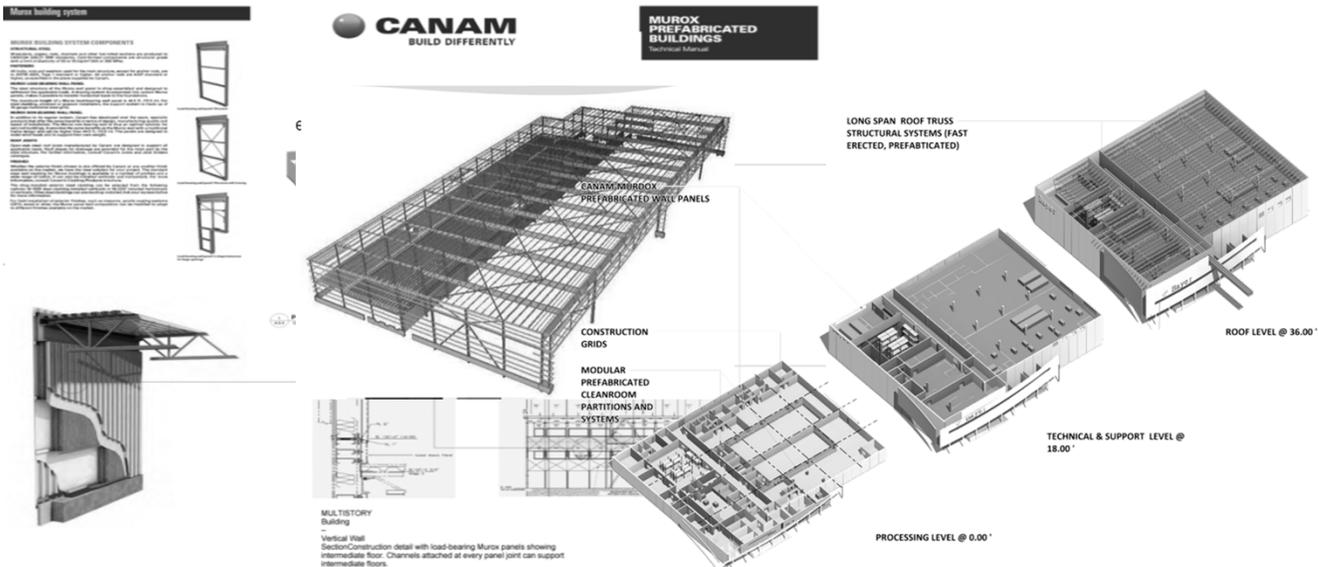


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# Modular Exterior Shell Opportunities

Prefabricated Modular Wall Panels:

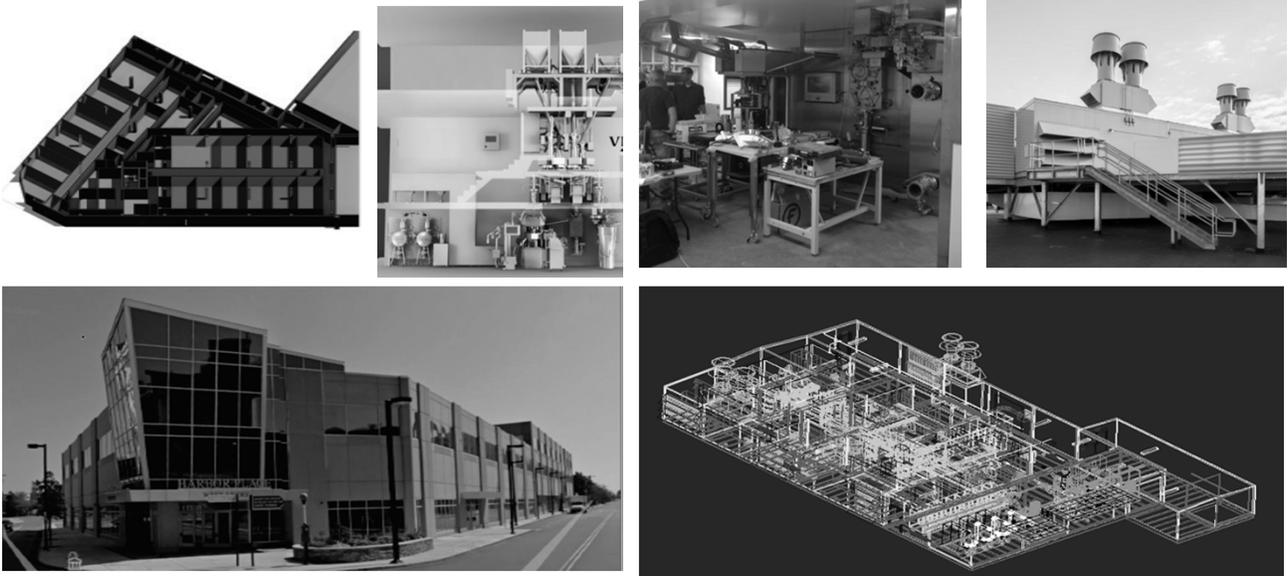


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# Combining Modular Facility and Process Systems

Taking Advantage of Modular Marketplace to Deliver Project



Connecting

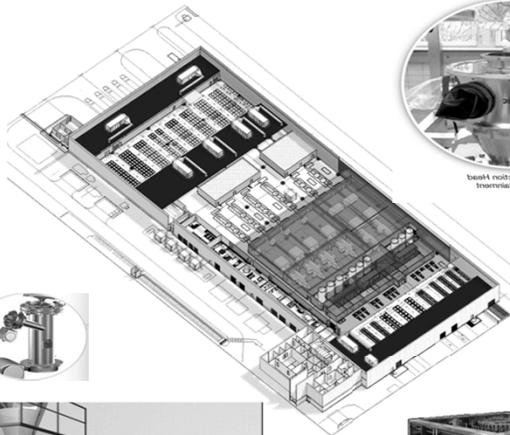
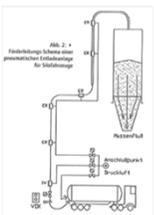
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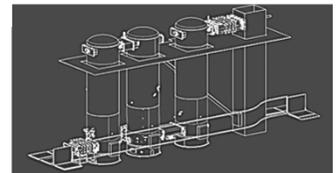
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# Modular Design— Each cell makes approx. 200 L solution / minute

Optimization from Raw Material Receipt through Finished Goods Inspection



Rapid testing



Continuous Sterilization



Formulation & Mixing concept



Optical inspection machine



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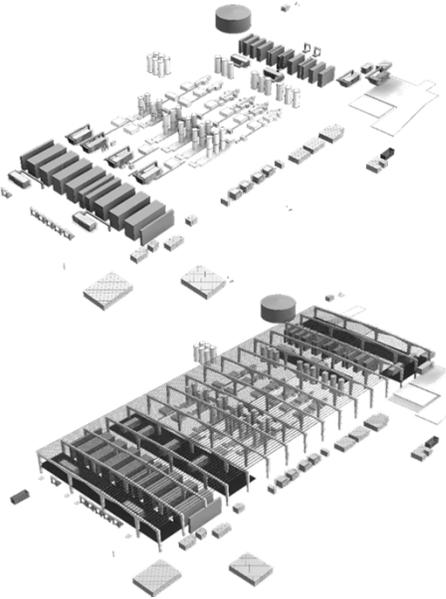
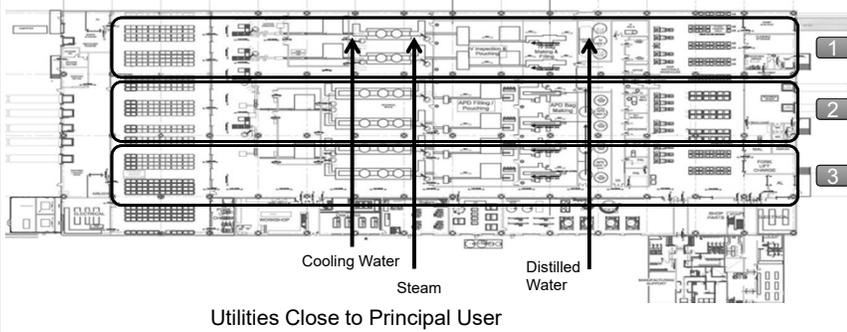
# Case Study: Future Factory

IV Bag Filling Facility: 200MM units/year

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



Modular Expandability with minimum interruption



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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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