



**Gene & Cell Therapy
Biotechnology
Viral Vector Facility**



AGUADILLA PUERTO RICO

Gene and Cell Therapy – THE PROMISE

- Potential to Treat both Liquid and Solid Tumors
- Promising results in difficult to treat diseases (Alzheimer...)
- Potential to treat viral infections such as HIV, Influenza
- Extension of people's lives even with late-stage complications
- Promise of rapid vaccine development (COVID Vaccine)
- Extend current people's longevity

Gene Therapy – Financially Biased

- Very Expensive
- Small Scale
- Not present in most
Second/Third World Countries
- Minimal exposure to global
populations across the world

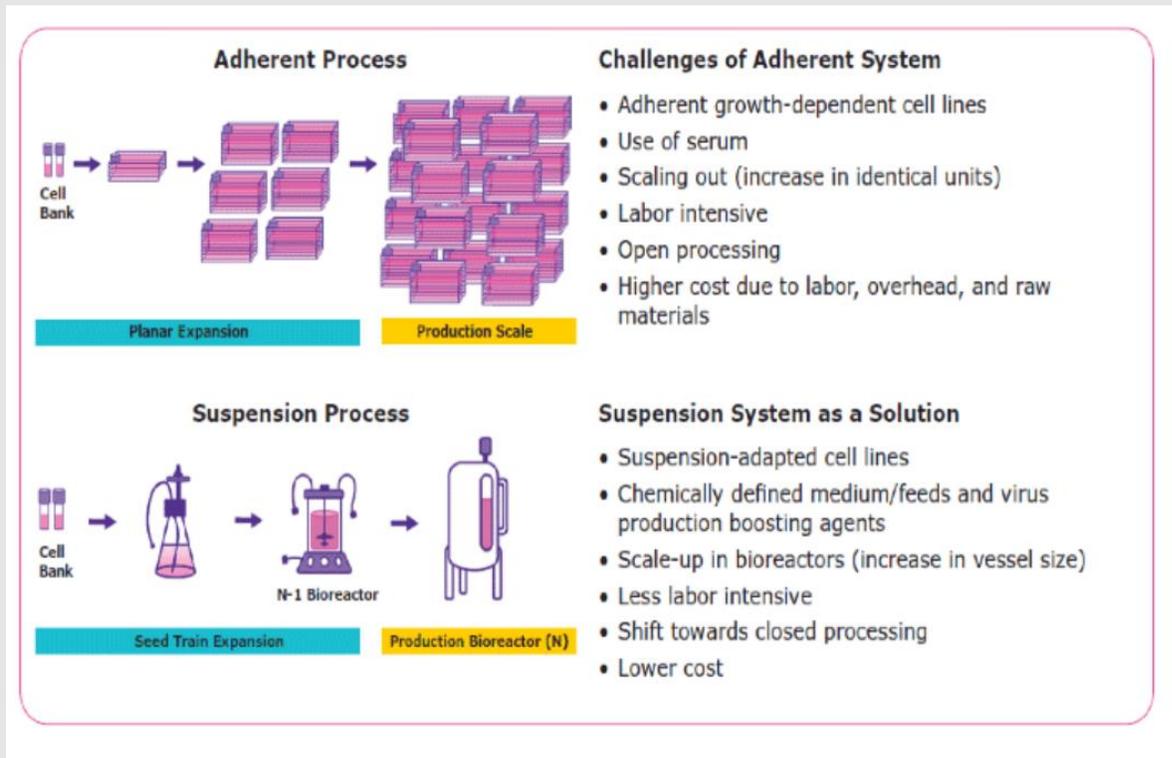
Elements to Solve for Access and Costs

- Sharing of IP and Technologies across countries
- Financial Incentives to existing company to accelerate distribution
- New Insurance paradigm for highly expensive companies
- Scale Out manufacturing
- Scale-up manufacturing
- New manufacturing paradigm

What BSC offers?

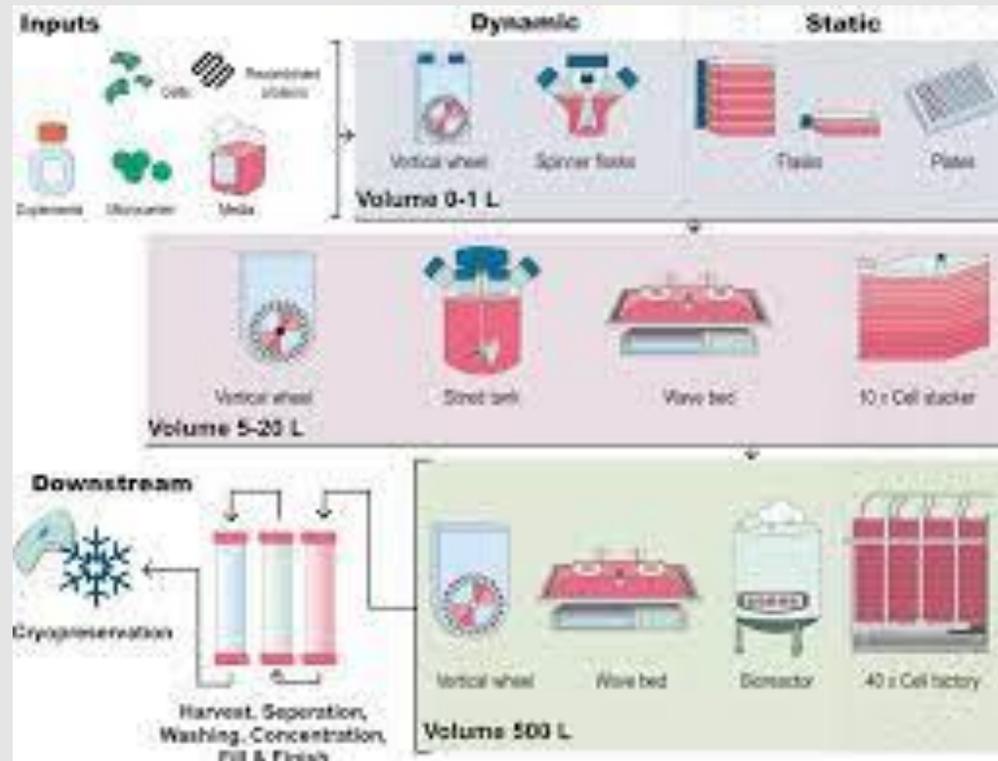
- We can provide lab and manufacturing space for early-stage companies in the US
- We can support contract manufacturing for companies based outside the US
- We can assess your clinical candidates and help with the Clinical Trials and Commercial Scale ups
- Technical transfer of BSC in-licensed technology to India and third world

Scale Out Manufacturing – Challenges?



- Taking existing scale and duplicating it
- Use for Autologous manufacturing
1 patient = 1 lot
- Large scale not yet developed
- Manufacturing equipment not available

Scale Up Manufacturing - Challenges



- Difficult to match operational parameters
- Process equipment designed for antibodies
- Cells very sensitive to minor changes
- Harvest impact cell viability
- Purification too harsh for cells
- Limited resource(s) and capacities

Lack of
Integrated
Manufacturing

Lack of Single
ECOSYSTEM

Multiple
CDMO

Lack of
Virus
Capability

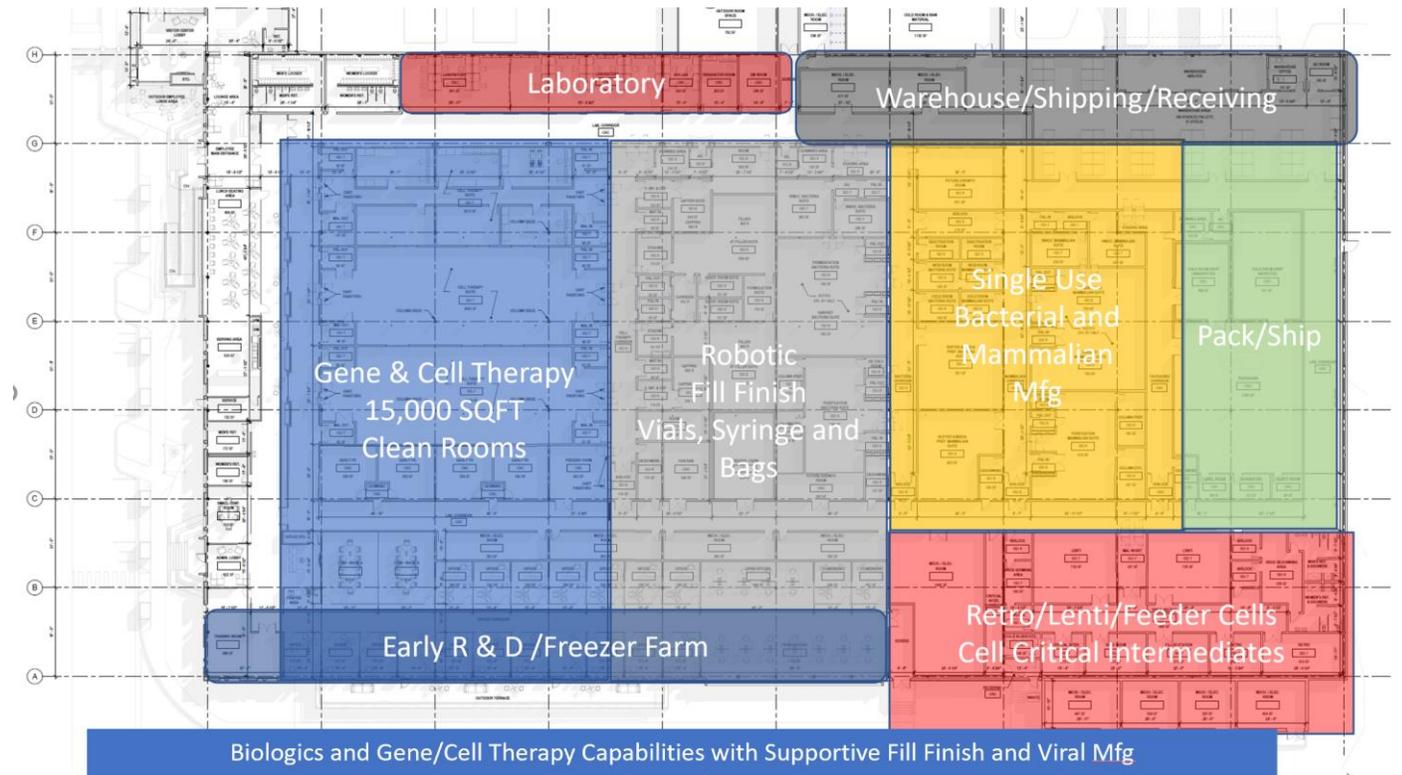
- Cell Therapy Capability
- Viral Manufacturing
- Cell Expansion
- Biologics for Bio specifics

Feeder
Cells

Blood
Sources

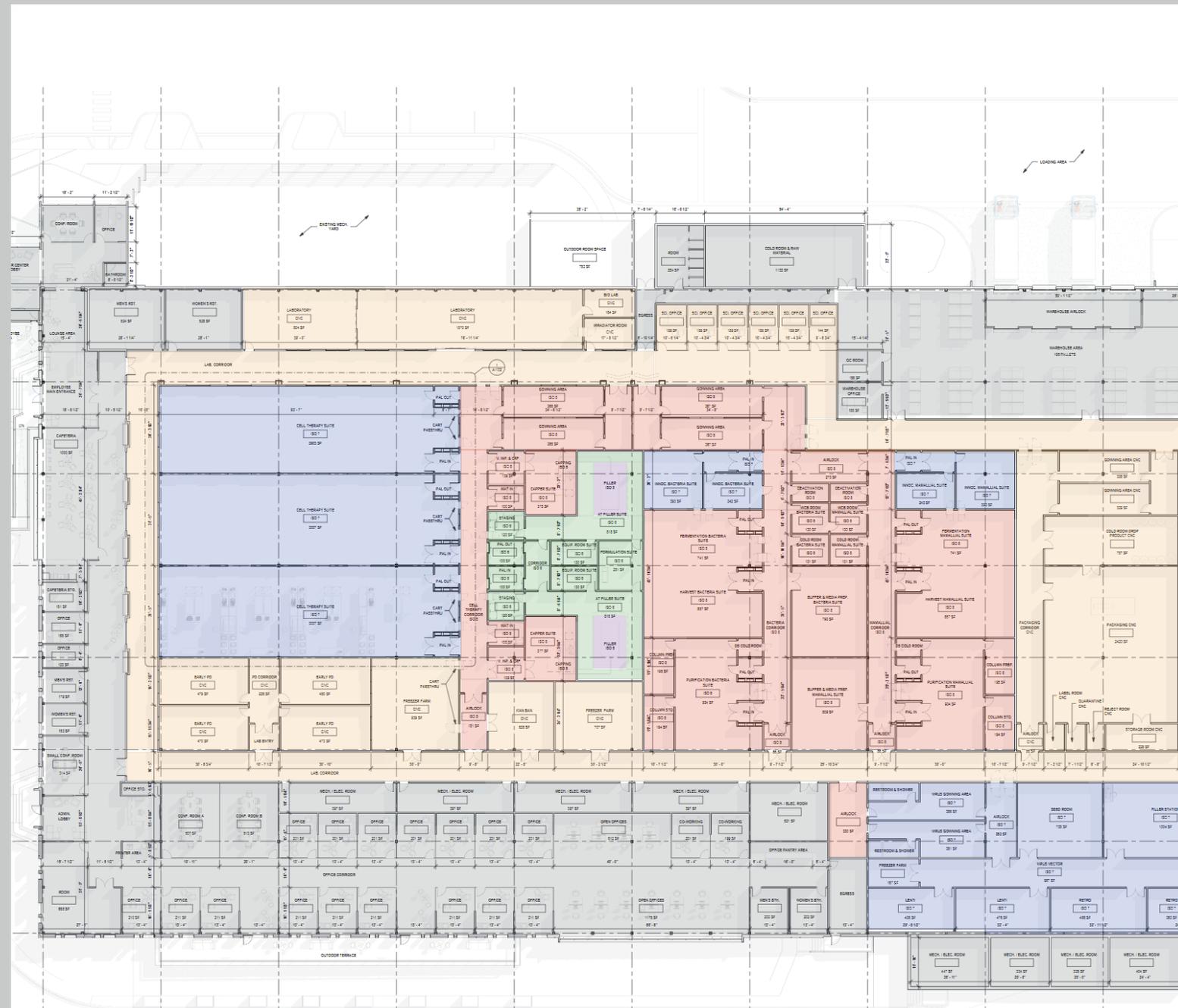
Integrated ECOSYSTEM

- 20,000 sqm facility with 7,500 sqm of ISO 8/7 rooms being converted to support clinical and commercial manufacturing
- Capabilities
 - Gene and Cell Therapy
 - Viral Vector Manufacturing
 - NK primary and NK562 feeder cells
 - Bacterial DS and DP
 - Mammalian DS and DP
 - Robotic fill finish for Biologics and Gene & Cell Therapy
 - QC laboratory
 - Located in Aguadilla Puerto Rico

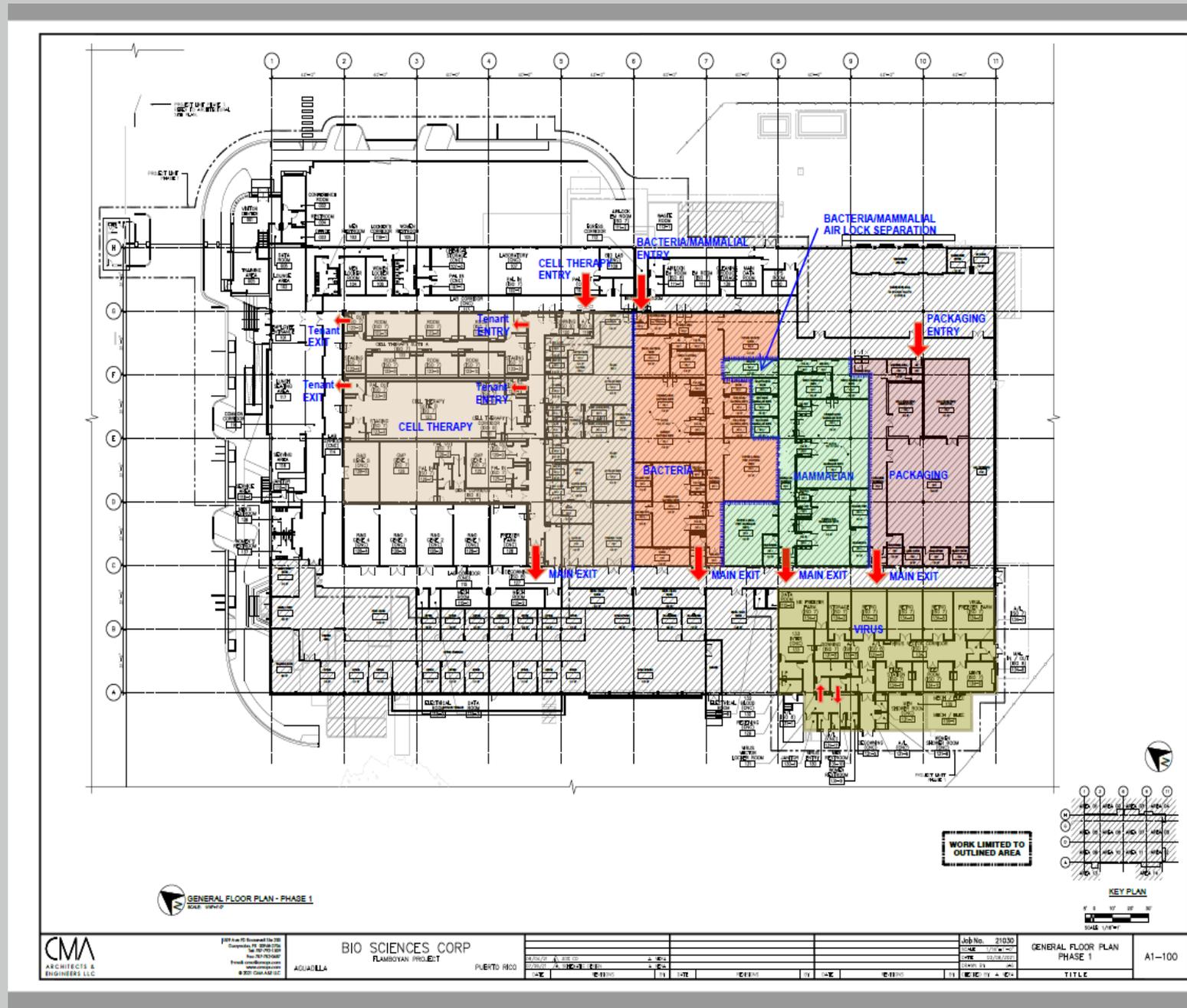


Overall Design

- Facility Design with Unidirectional Flow for People, Materials and Waste
- Contamination is controlled via Three level gowning, supported by central CNC corridor
- Facility is entered using a common gowning locker room where captive shoes and uniform are kept for employee. Visitors will wear disposable garments
- Second level gowning required to enter manufacturing ISO 8 corridor
- Third level gowning required to enter the suites where manufacturing process takes place
- Each suite is designed with independent HVAC to eliminate cross contamination
- Each room within a suite is pressurized and cascaded within the suite as well as airlock that acts as sinks to ensure air, particles are maintained within the suite

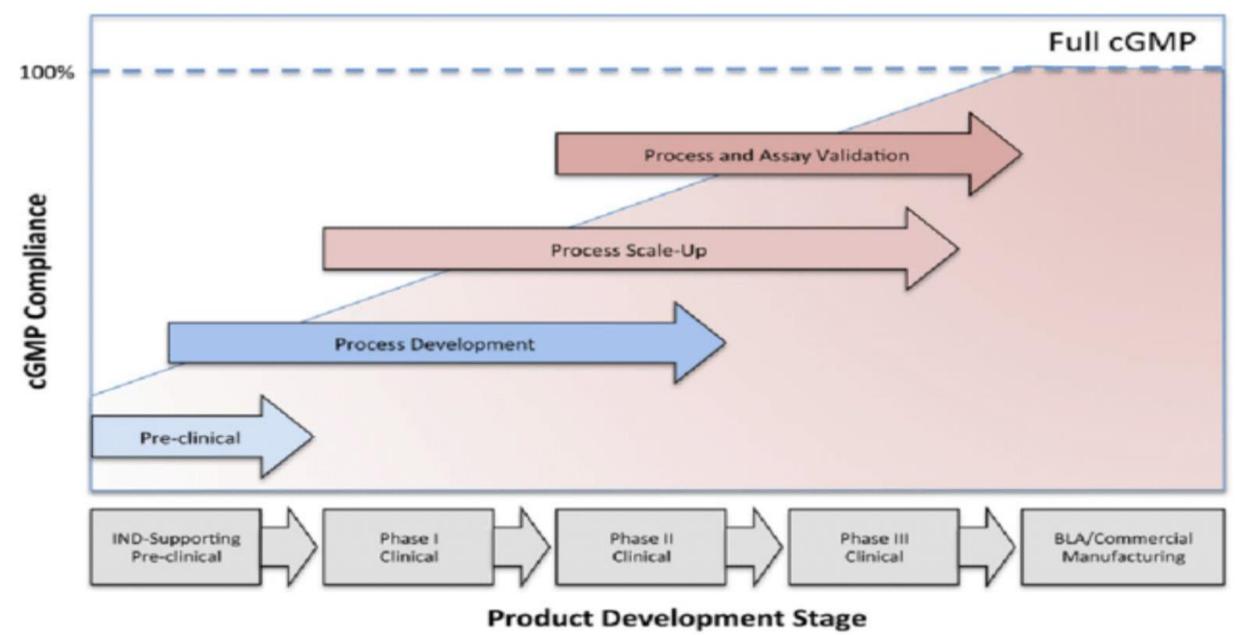
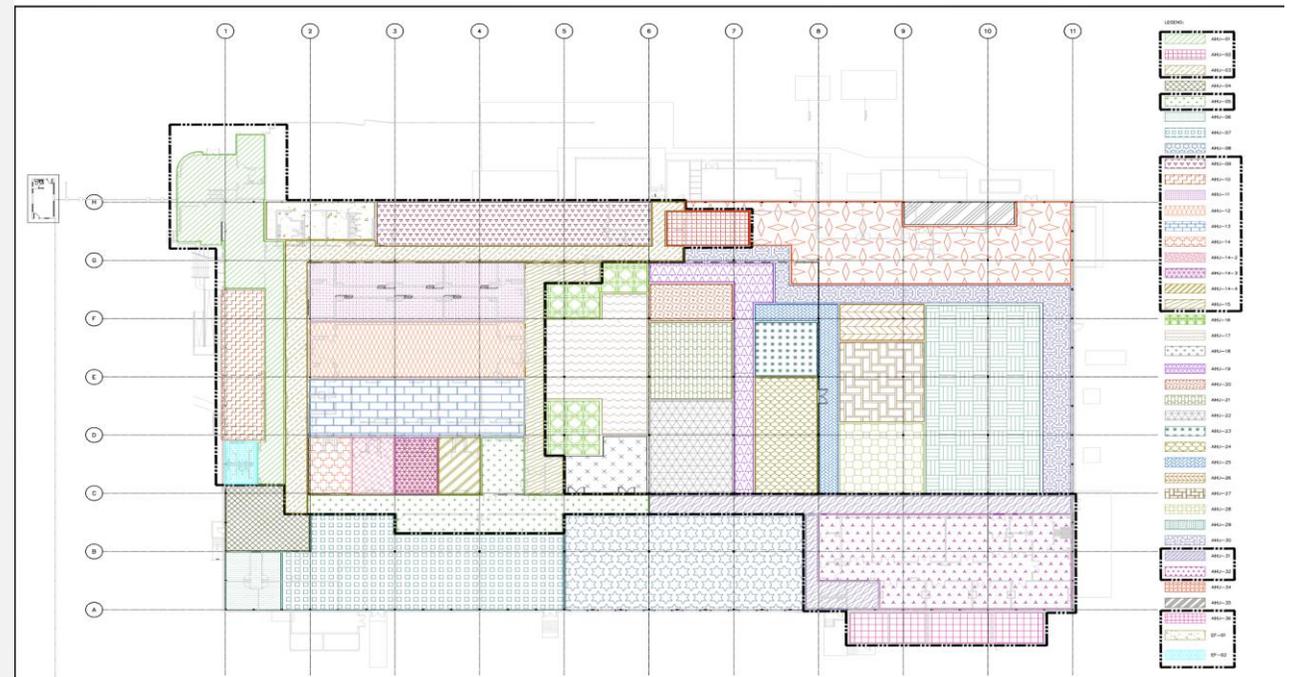


- Global Compliant
- Unidirectional flows for
 - People
 - Materials
 - Waste
- Modular constructed
- Ballroom
- Suite based



Dedicated HVAC to Reduce Cross Contamination Risks

- Dedicated HVAC per suite
- Plant Uniform and Captive shoes required to enter facility
- CNC corridor designed to protect individual suite
- Three-level gowning operating suite entrance
 - Lockers->entry into common corridor → entry into manufacturing spaces
- Unidirectional flow of people, material and Waste
- Phased appropriate Controls implementation based on product development stage(s)



Facility Entrance and Welcoming Center

- Facility is controlled and secured through welcoming center
- Visitors & Employees enter the facility after full registration or via batch access
- Welcoming center houses conference rooms, offices and training center; allowing it to support different types of visitors



- Interior Courtyard design for Collaboration
- Façade designed allowing natural light in common spaces & offices
- Cafeteria Isolated from the manufacturing entrance
- Lobby space designed to accommodate multiple client visitors



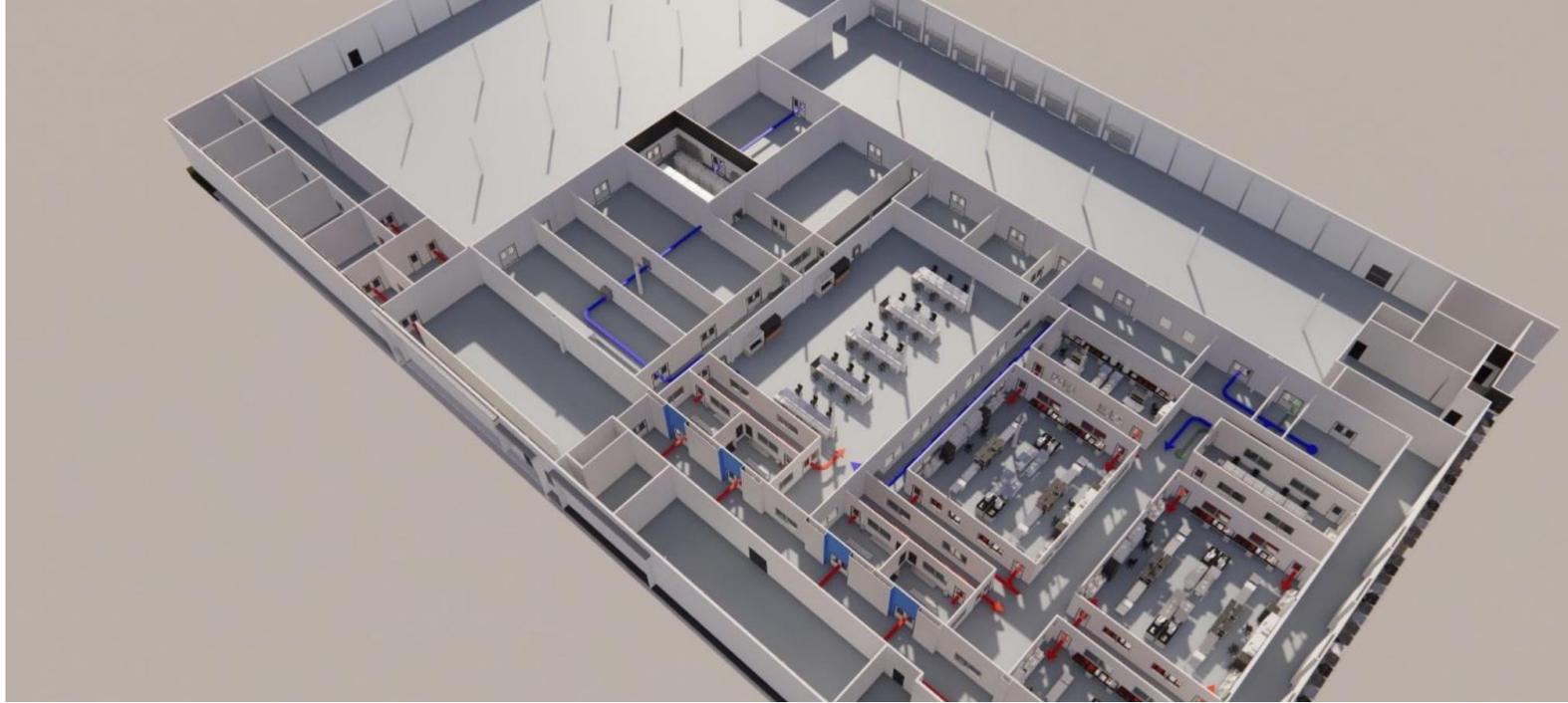
Open Space for Collaborating



CNC Interior Corridor

Multi-Tiered ISO driven Gowning

- Three-tiered gowning from common lockers to ISO 8 and ISO 7 to sequentially reduce contamination risks
- Common gowning area for first level gowning to enter CNC for both lab and manufacturing spaces
 - Captive plant uniform and shoes
 - Disposable gowning for visitor
- Interior controlled corridor (CNC) accessing the gowning entrances to manufacturing areas
- Uni-directional flow for People, Material, and Waste
- Critical material protected using controlled carts
 - HEPA Cart
 - Temp controlled Cart
 - Standard covered cart
- All process material assigned and transported in dedicated carts



- Suite arranged out based on clients' requirements and process flows
- Gases, Utilities and Data via utility ceiling panels
- Stainless steel chairs & racks designed for ISO 7 environment
- Ballroom and individual suite can be accommodated
- Large common laboratory to house both common and dedicated instrumentation

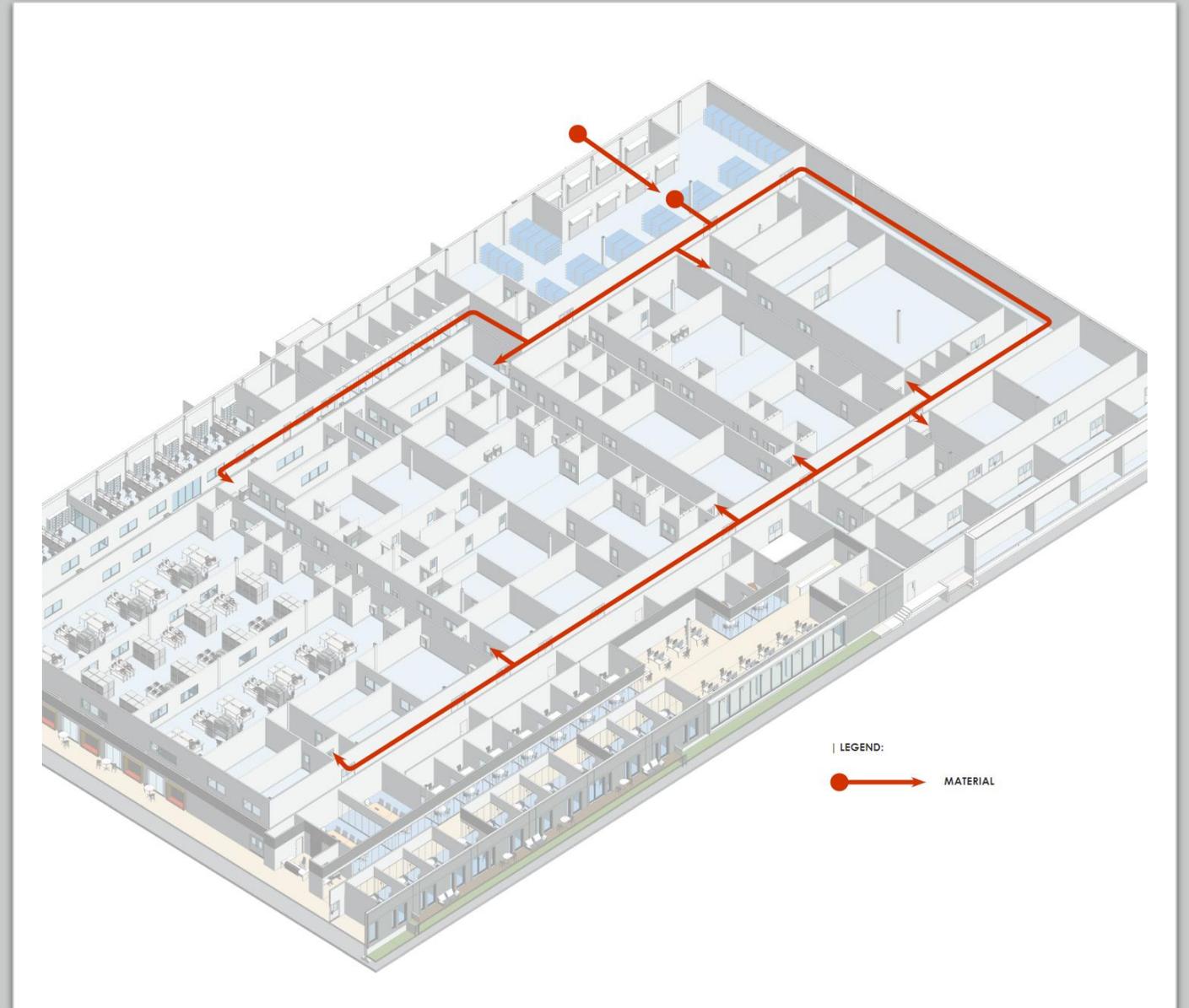


Equipment Layout for Lab and Typical Gene & Cell Therapy Suite



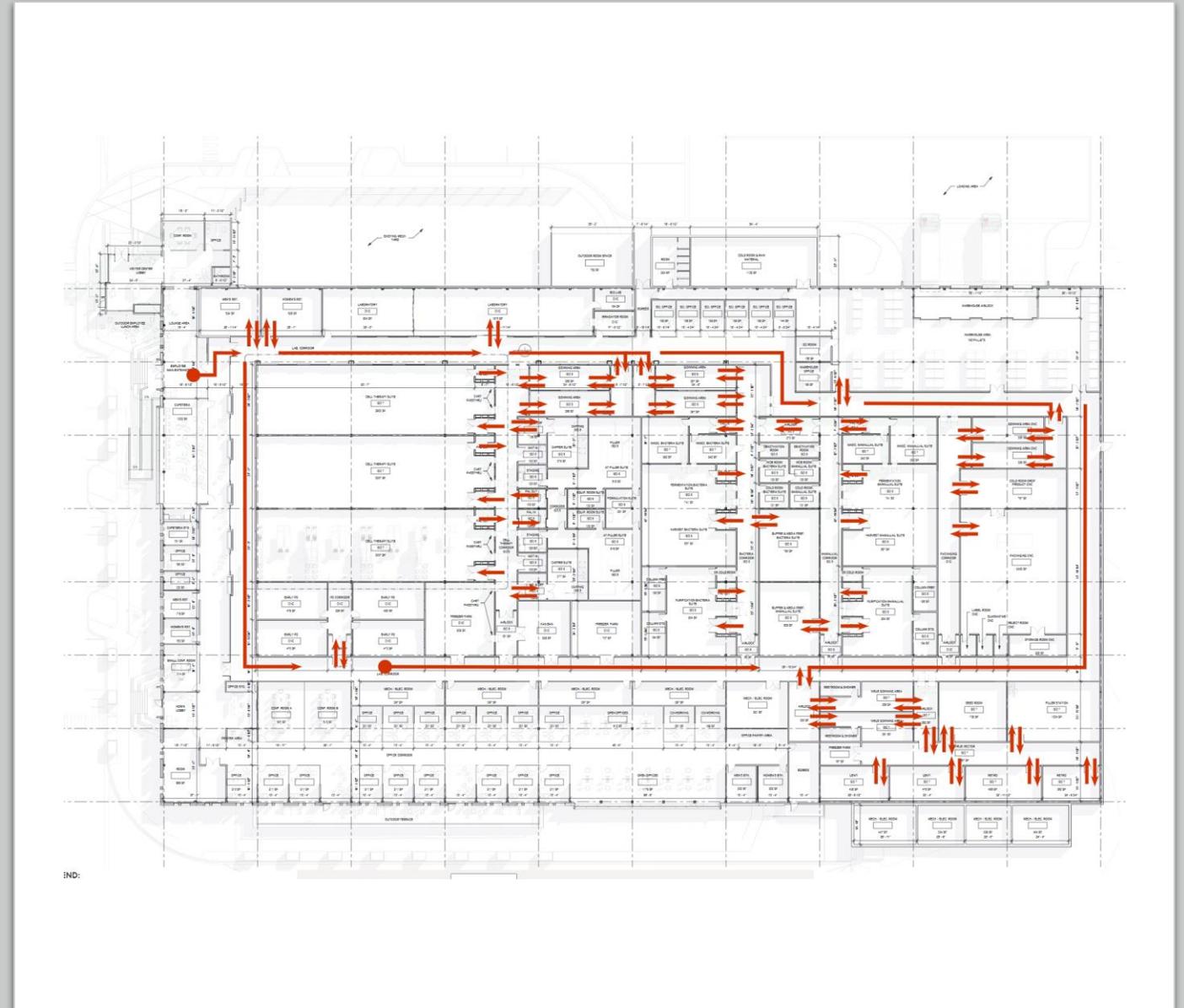
Interior CNC corridor – Material Movement

- CNC corridor designed to allow material to flow through a controlled environment
- Material enters the individual suites through an environmentally controlled pass-through with a HEPA Ionizer to improve cleanliness
- Pass-through are interlocked and classified to ensure appropriate airflow direction
- Materials entering a customer suite also enter through a secondary pass-through that has an HEPA ionizer and that is classified and interlocked
- Material and People travel unidirectional within the facility and within the clean room or suite



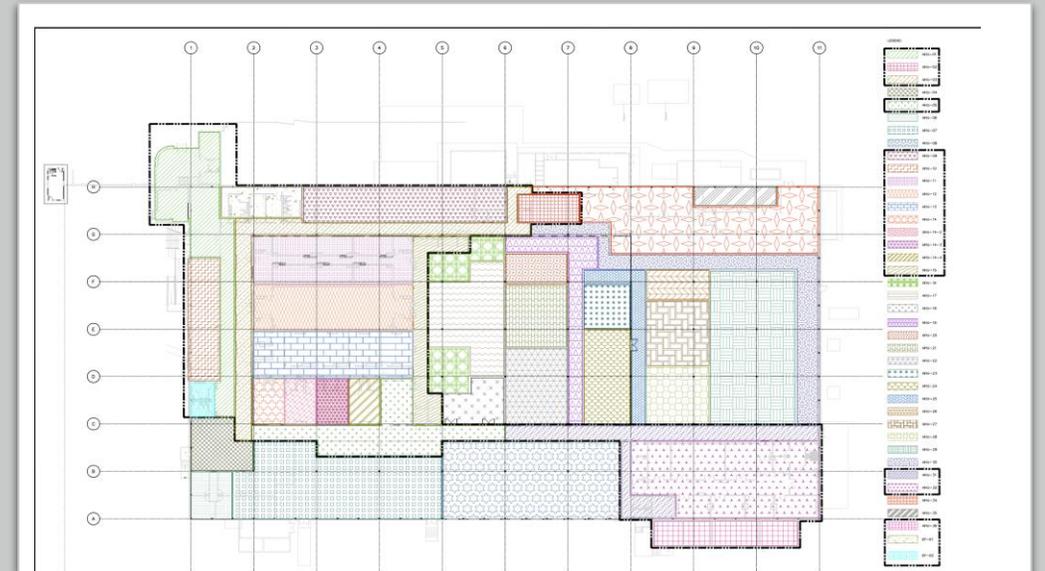
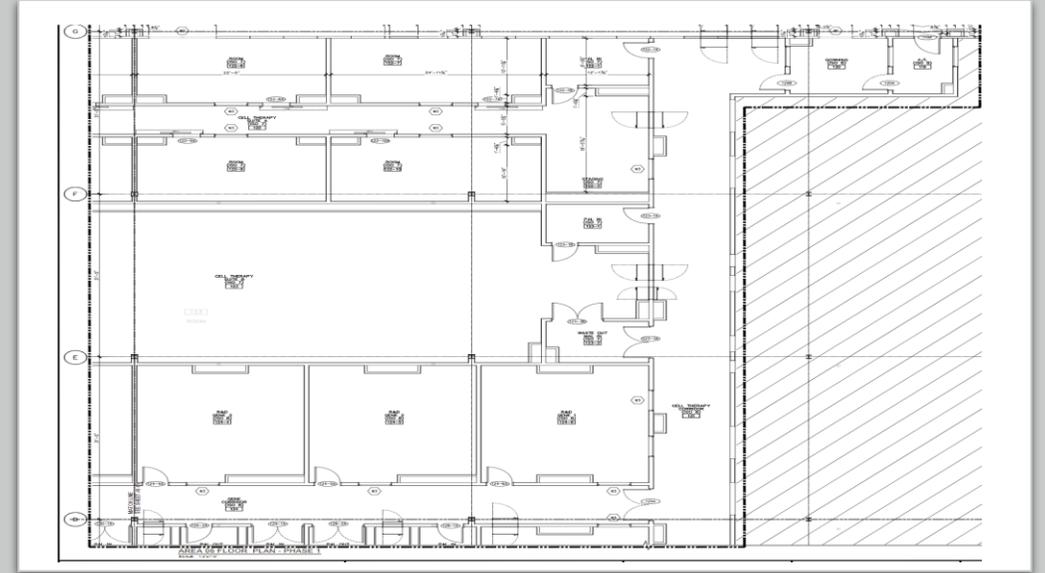
Unidirectional Material Movement Within each operational Suite

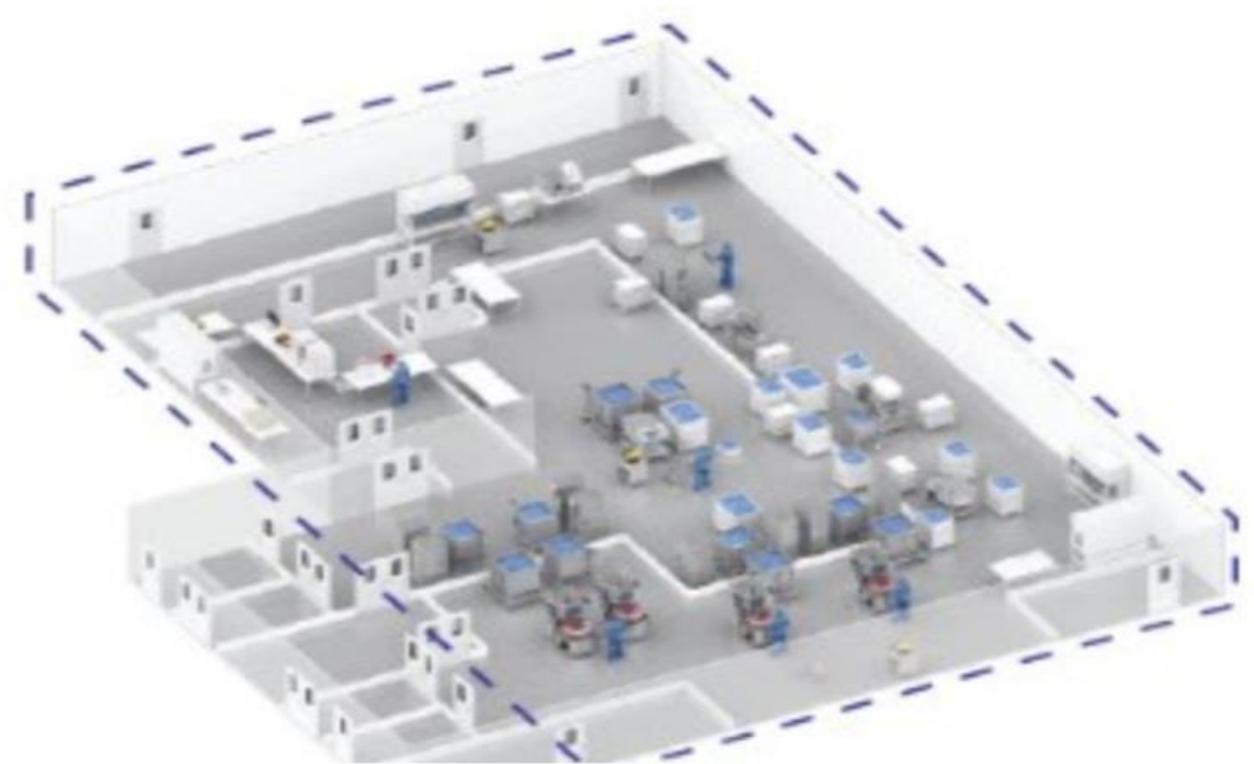
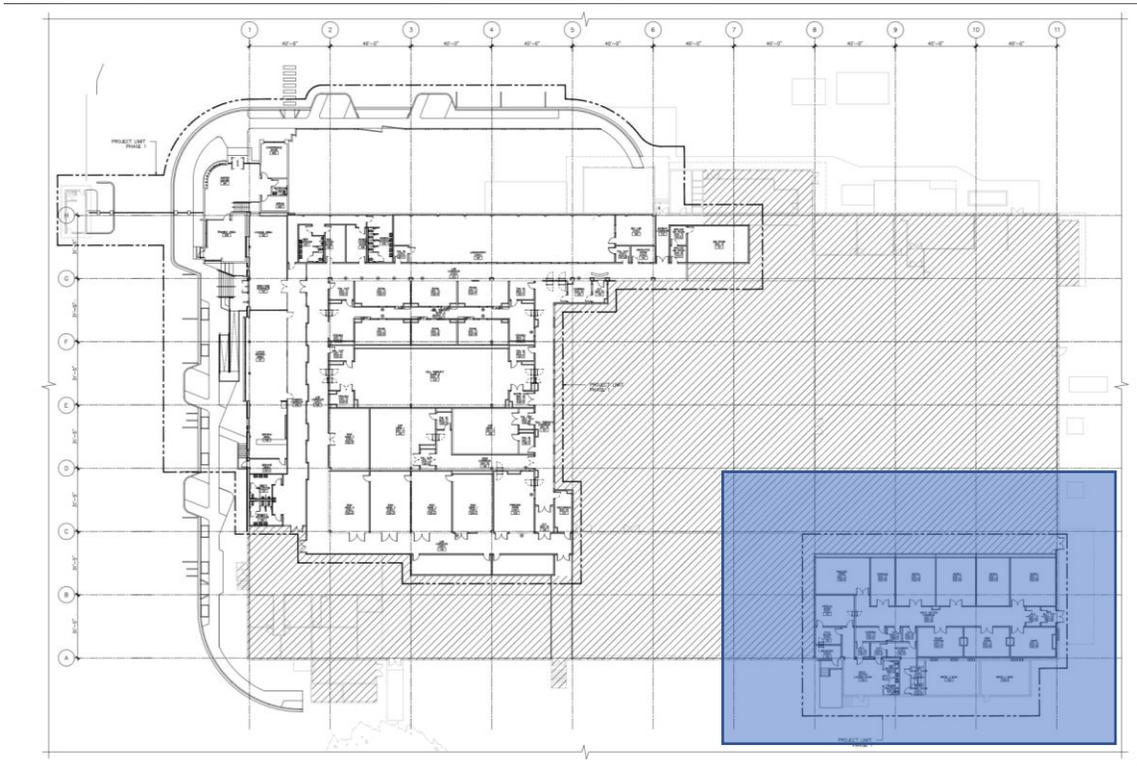
- Material entry is controlled by Individual SOPs for each suite
- Entrance of material to a suite is done via an ionize pass-through which is controlled and classified
- In process samples are collected and submitted to lab via sample pass-through
- All materials traveling through the corridor are housed in dedicated carts which, if required, are temperature controlled and classified
- Frozen material is moved using a HEPA Cart with Dry Ice or conditioned as needed
- Material are tracked using barcode and are kitted to ensure no mishaps.



Dedicated HVAC for Each Suite

- Each work center (Gene and Cell Therapy) has dedicated secondary gowning which is located at the entrance to ISO 8 common corridor
- Each suite has dedicated air conditioned with airflows synched and controlled within the rooms
- Material and People are unidirectional with dedicated entrance
- Each suite is validated and controlled using dedicated EMS and BMS that controlled temperature, humidity and pressure cascade





Dedicated Viral Vector Production

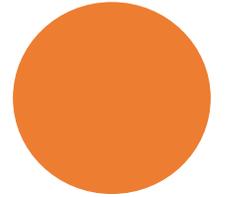
Robotic Fill Finish

- Fill Finish Suite will comprise ISO 8, ISO7 and ISO5 spaces to support fully automated manufacturing
- The filling process is conducted through single use system for any product contacting parts. This includes surge tanks, needle manifolds and filling needles.
- Pre-sterilized vials/syringes/bags are utilized to ensure no cross contamination can occur
- Vanrx robotic filling line with Class A Isolator
- AT filler M-1 filler to support the filling of small batches of Gene and Cell Therapy vials
- Bag filling system to support DP product in IV format
- Dedicated HVAC with ISO 5 classification for filling equipment and ISO 7 background
- Dedicated gowning entrance to common ISO 8 corridor, followed by dedicated gowning for each of the filing rooms



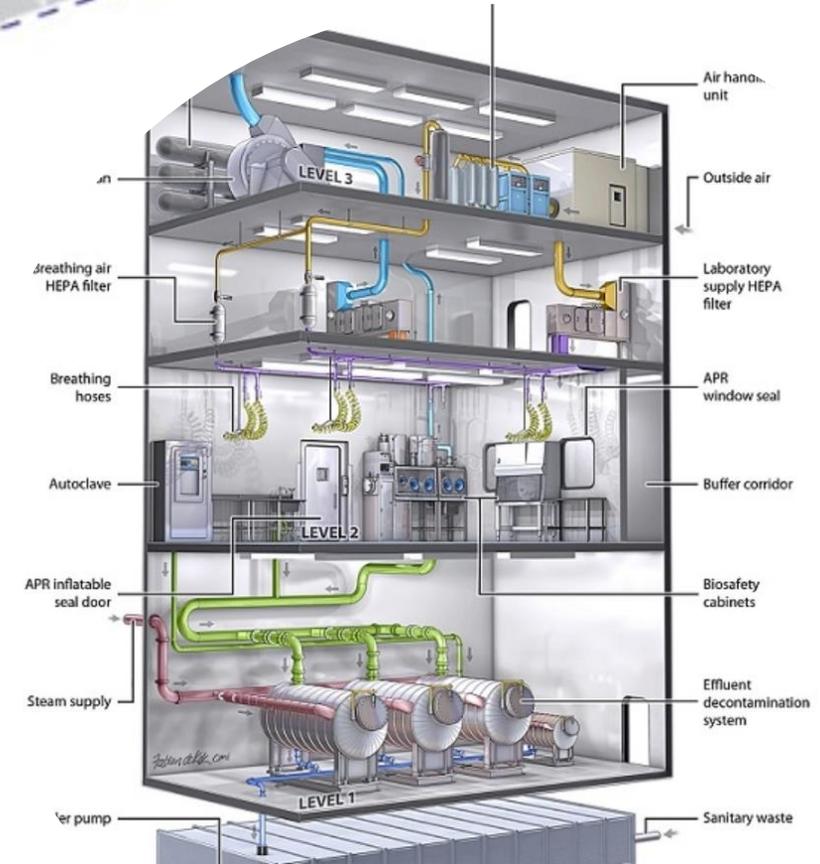
Bacterial and Mammalian Suite

- 100% single-use Pall bioreactors
- Single-use 250-1000L bioreactor
- Dedicated ISO 7 purification suite
- Automatic DS fill and freeze/thaw units
- Dedicated entrance to common ISO 8 corridor for each suite
- Dedicated secondary gowning designed for entry into classified space
- Separated by ISO-8 controlled and interlocked airlock
- Pressurization cascade design for air to not escape to other suites
- Doors, pressures and temperature monitored and controlled by BMS



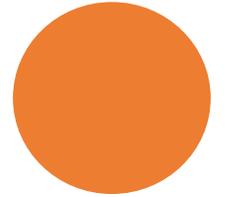
Viral Vector Suites

- Viral vector suite is **isolated** and has its own independent entrance and designed to meet BSL2 levels
- Viral suite has independent utilities and HVAC and does not interact with main manufacturing space
- Dedicated independent gowning and showers at the exit of the suite
- The rooms for Viral vectors are designed to be ISO 7 with ISO 5 BSC
- Independent filler to support vial filling for final viral construct
- Viral Freezer farm has been designed to support frozen vials
- Viral vectors are transported via a secured HEPA and Temperature controlled cart

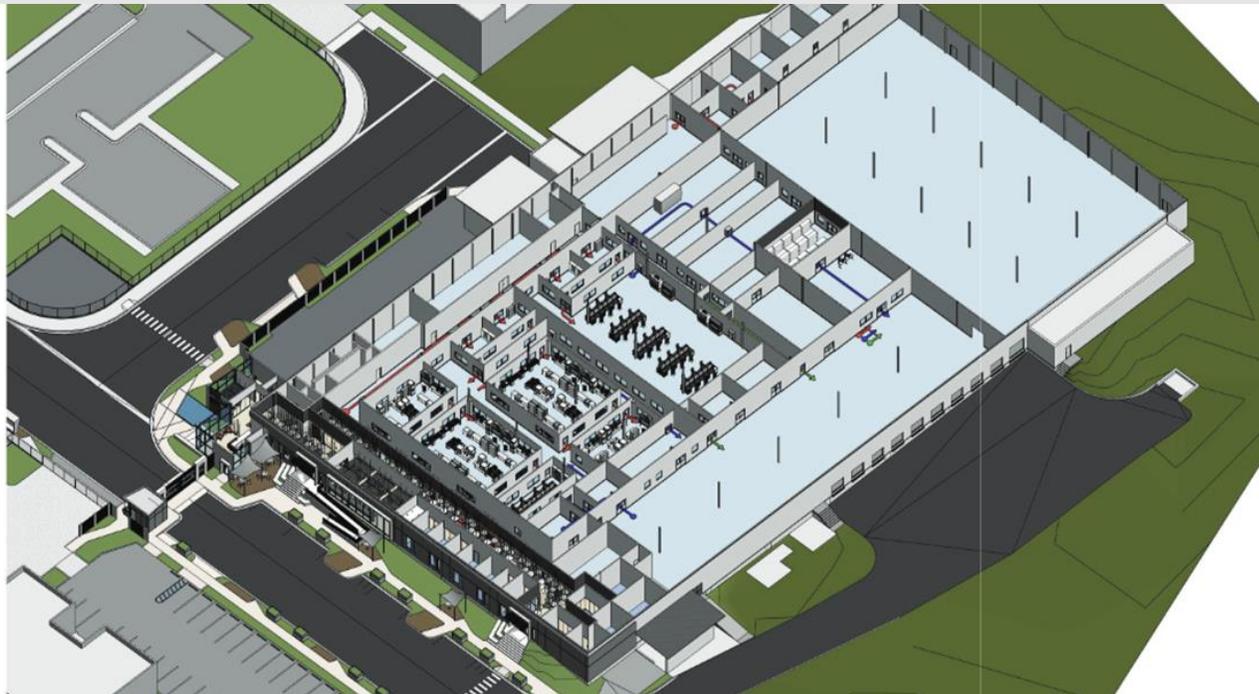


Warehouse

- Warehouse is controlled and validated
- A variety of bins can be selected to support client storage requirements
- Full automation with barcode and RFID (when required)
- Mini containers are used to segregate and manage dedicated inventory for each client
- The combination of barcode and warehousing system allow for materials to be picked and send to customer suites
- Inventory can be tracked with a combination of warehouse and MES system until material is consumed

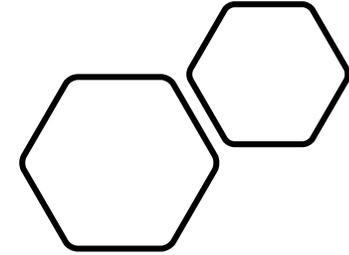


PDMO – Partnership Development Manufacturing Organization



- Ability to construct custom client facility
- Scale up and Scale out capabilities
- All capabilities in one place
- Located in Puerto Rico – Pharmaceutical Hub
- Full Global Compliant and FDA Inspection Ready

Global Reach Contact Us



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Questions