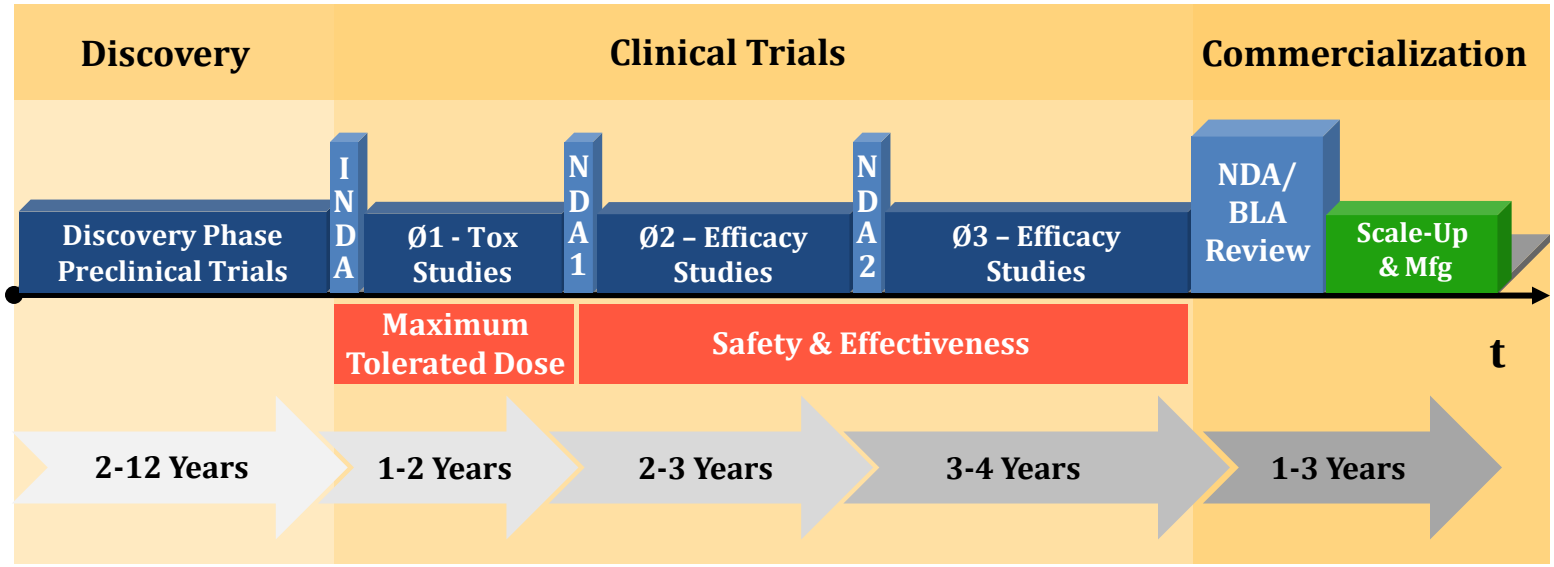
Biologics Modular

Enabling Biotechnology Development Through Cost Efficient Modular Laboratory Solutions

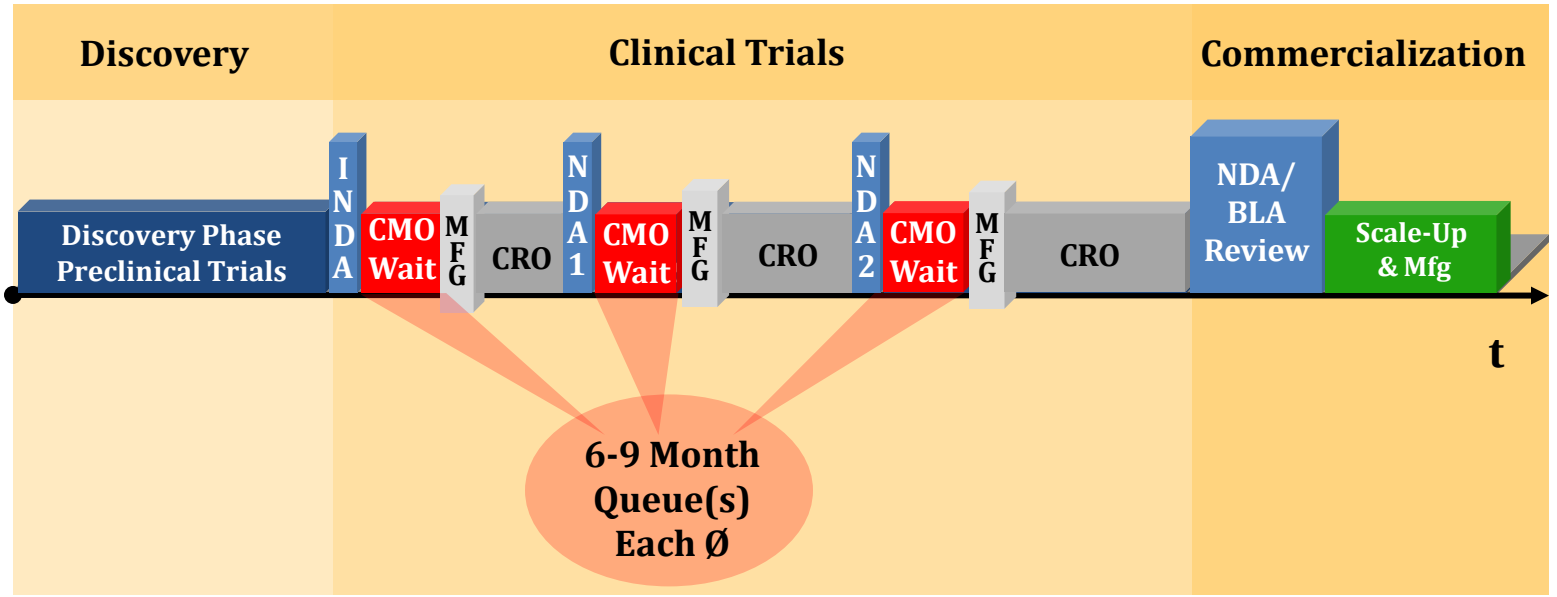
Time ✹ Risk ✹ $$$$



Old: BioPharmaceutical Discovery Business Model

- 10-15 Year Development Horizon
- $1.2 Billion Average Cost to Achieve Commercialization
- 8 of 10 Molecules to Enter Clinical Trials Fail

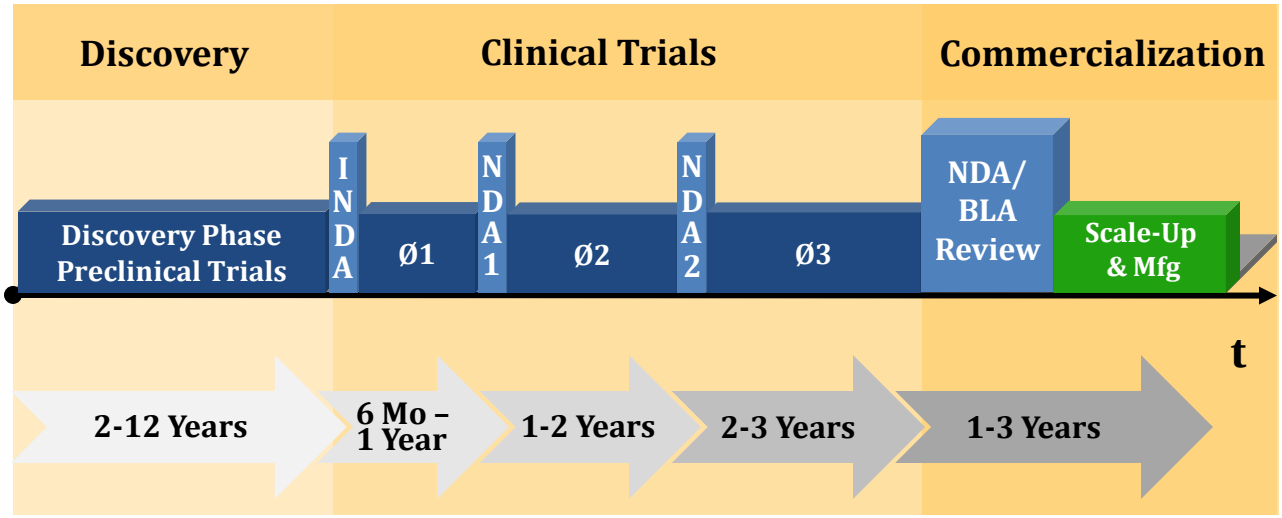
Time ✹ Risk ✹ $$$$



Old: BioPharmaceutical Discovery Business Model D

- Development Highly Dependent on Constraints of External Resources
  CMO (Contract Mfg), CRO (Contract Clinical Trials), FDA
- Resource Underutilization Due to "Hurry Up & Wait" w FDA
- Contract Manufacturing (CMO) Capacity is Typically Expensive
- CMO Cannot be Reserved Due to Uncertainty of Response from the FDA
  – 6+ Month Delay Waiting on Mfg Slot
- "Bricks & Mortar" Alternative Consumes Too Much Time and Capital.

Time ✹ Risk ✹ $$$$



New: BioPharmaceutical Discovery Business Model

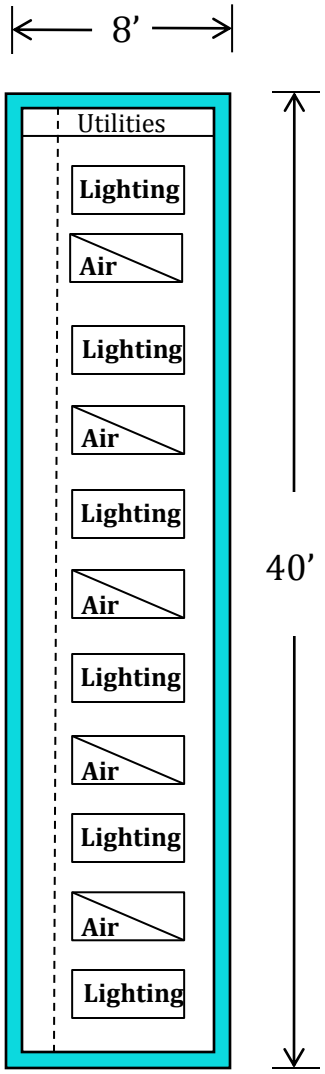
- Eliminate the CMO Bottleneck
- Clear Path To Success – Biologics Modular Enables Biotech Company to take Control of their Process and GMP Manufacturing
- Company Resources Can Focus on Product Effectiveness and Process Optimization
- Capital is Conserved (Fast Failure)
- Competitive Risk is Reduced
- Commercialization Time Under Patent is Increased

Biologics
Modular

Modular Solution

Patent Pending

Modular Design Features



Module Design Features

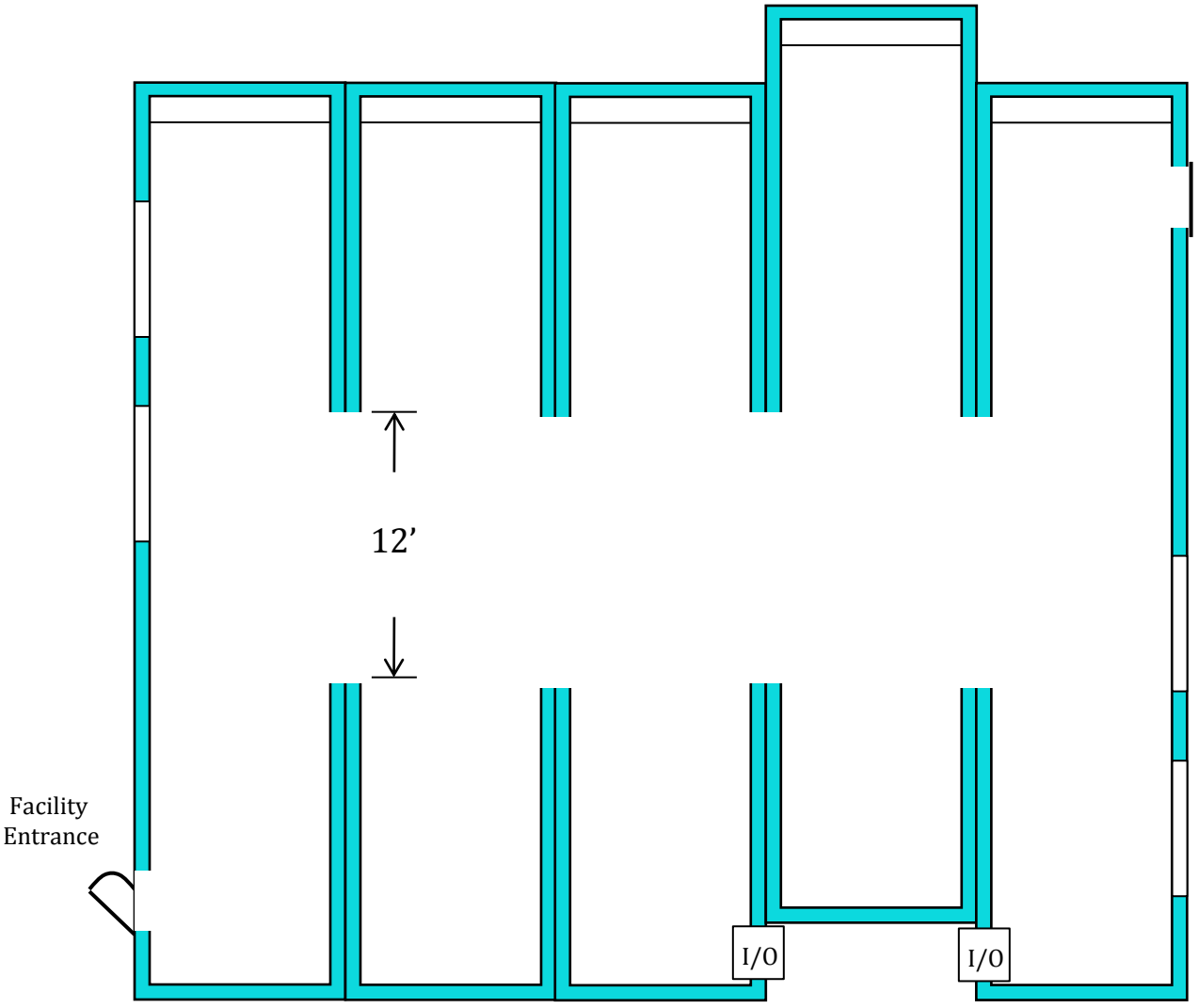
- Start w/ Used Overseas (8’ x 9.5’ x 40’) Shipping Container
  - Environmentally Green
  - Made in the U.S.A.
- Fixed Ceiling Air Plenum and Utility Chase
- Utility Cabinet Built at Container End
- Universal Design: Lighting, HVAC, and Air Quality System Optimized for 300 Square Foot Clean Room Space

Establishes Fixed Structural, Scalable Design

Cost Analysis – Biologics Modular Facility

- "Ideal Hosting Facility" - $1.1 million plus lease
  - Clean Room (900 ft^2)
  - Analytical Lab (600 ft^2)
  - Warehouse w/ Shipping / Receiving
  - Office
  - $5000 per month lease

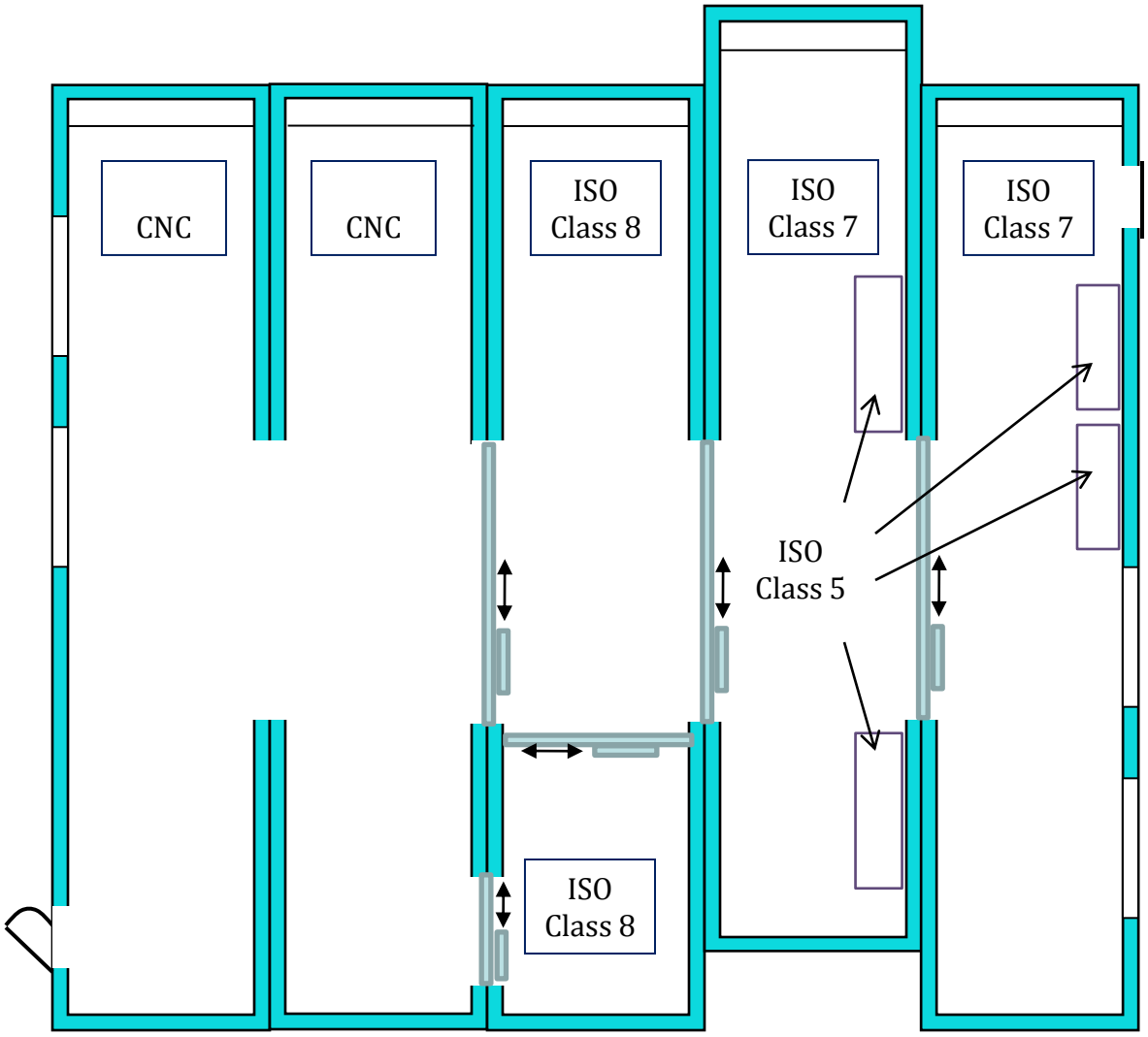
Modular Design Features



Module Design Features

- Innovative Coupling Technology to Join Multiple Containers
- Twelve Foot Transition Between Each Container
- Exterior Container Design w/ (2) Windows / Exits
- Additional Containers Can Be Added As Needed to Expand Space
- Container Shifted to Allow For Material Transfer In and Out of Classified Work Areas

Modular Design Features

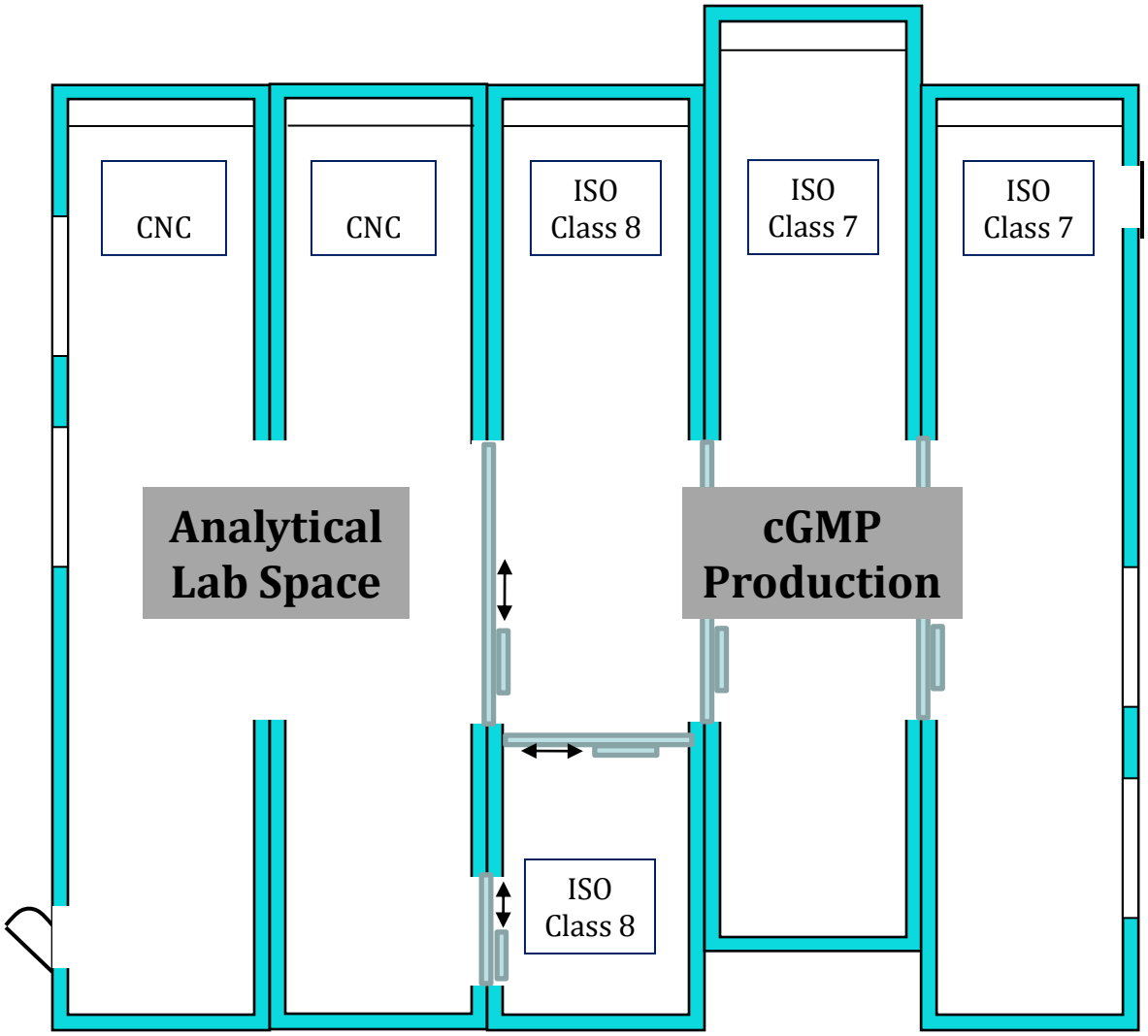


Module Design Features

- Antimicrobial Materials of Construction
- Soft Wall Technology Allows Configurable ISO Cleanroom Classification
- Coved seams at ceilings, walls, floors to ISPE
- Container Technology Optimized for Cascade of ISO Class 8, 7, & 5 Work Areas

CNC – Controlled, Non-Classified

Modular Design Features



Module Design Features

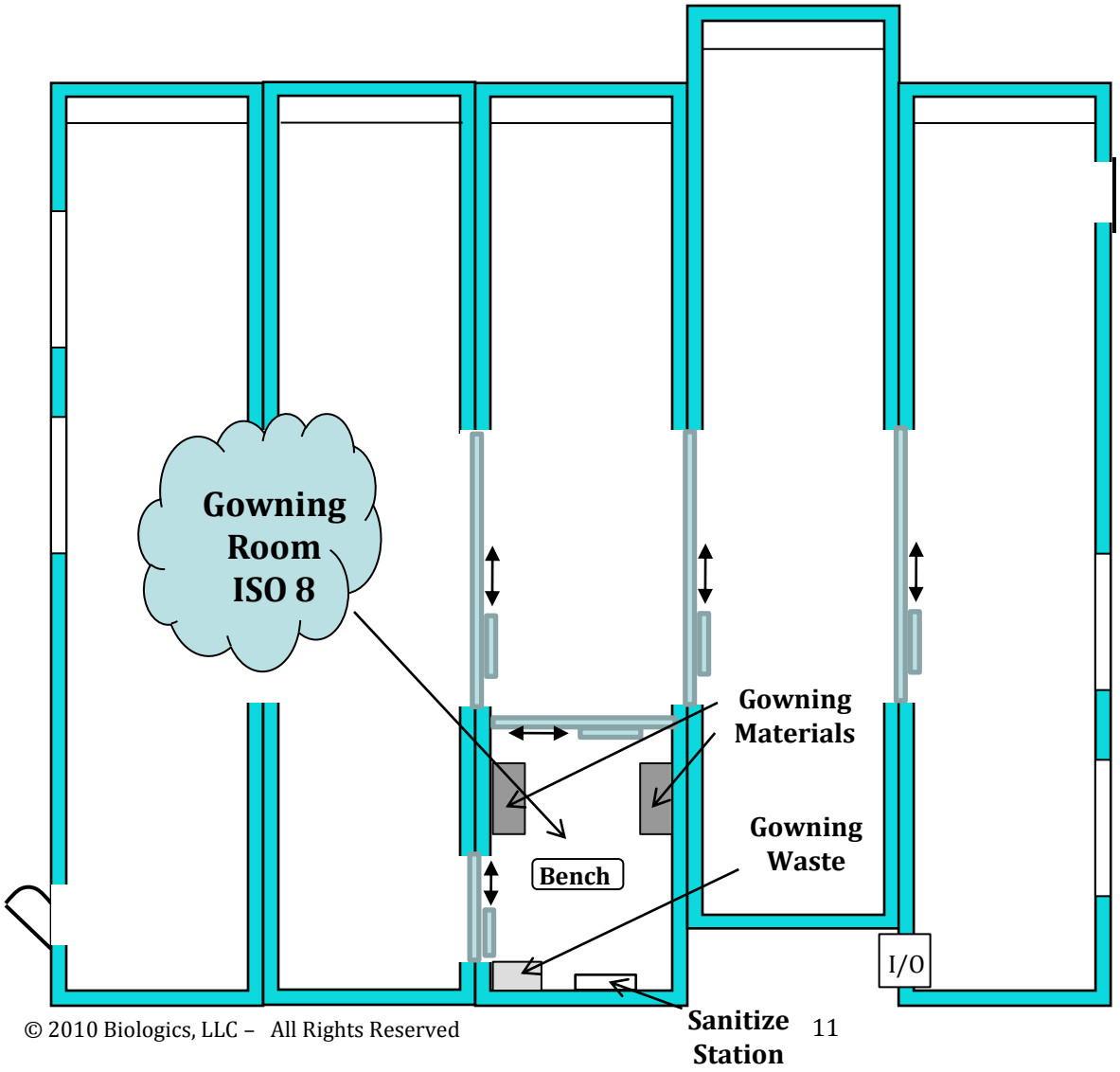
These Variations in Work Space Classifications Allow for:

- Collaborative R&D non-classified work spaces

Coupled with:

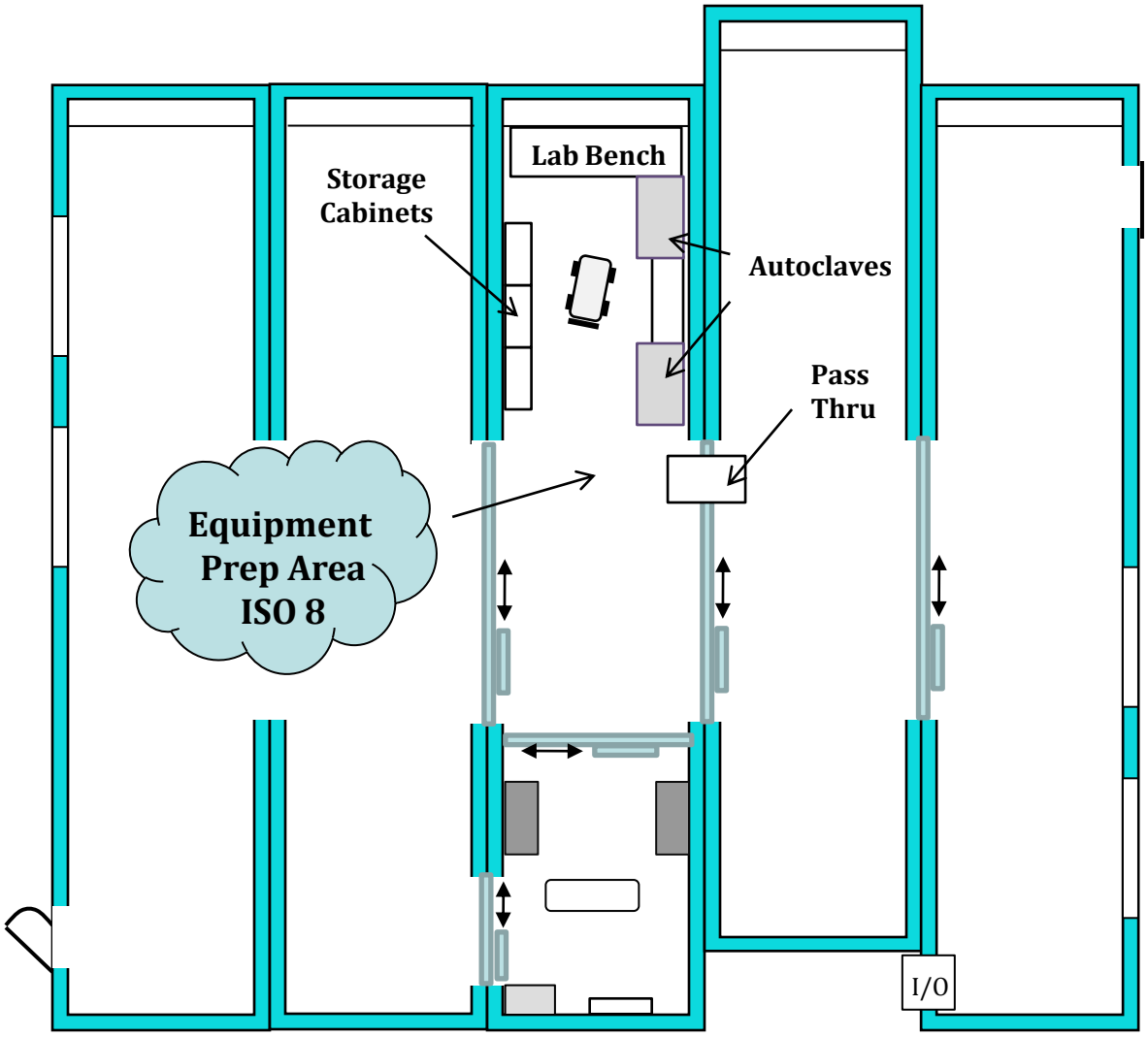
- Biological processing in controlled and classified work spaces

Modular Design Features



Workspace Functionality
cGMP Production • IPad Human Machine Interface (HMI): – Phone – Internet – Communications – Electronic SOP's – Intercom – Music • ISO Class 8 Gowning Room

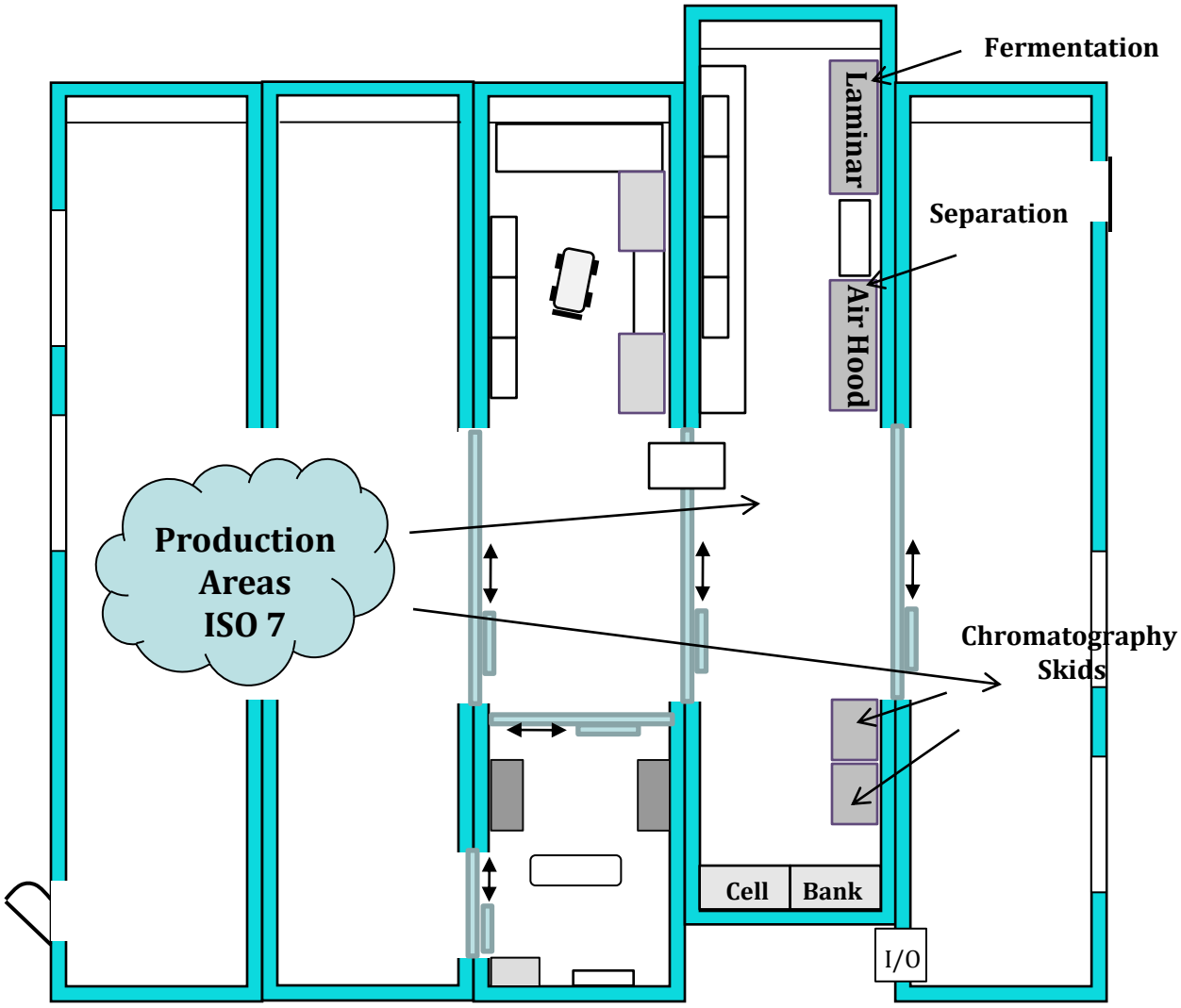
Modular Design Features



Workspace Functionality

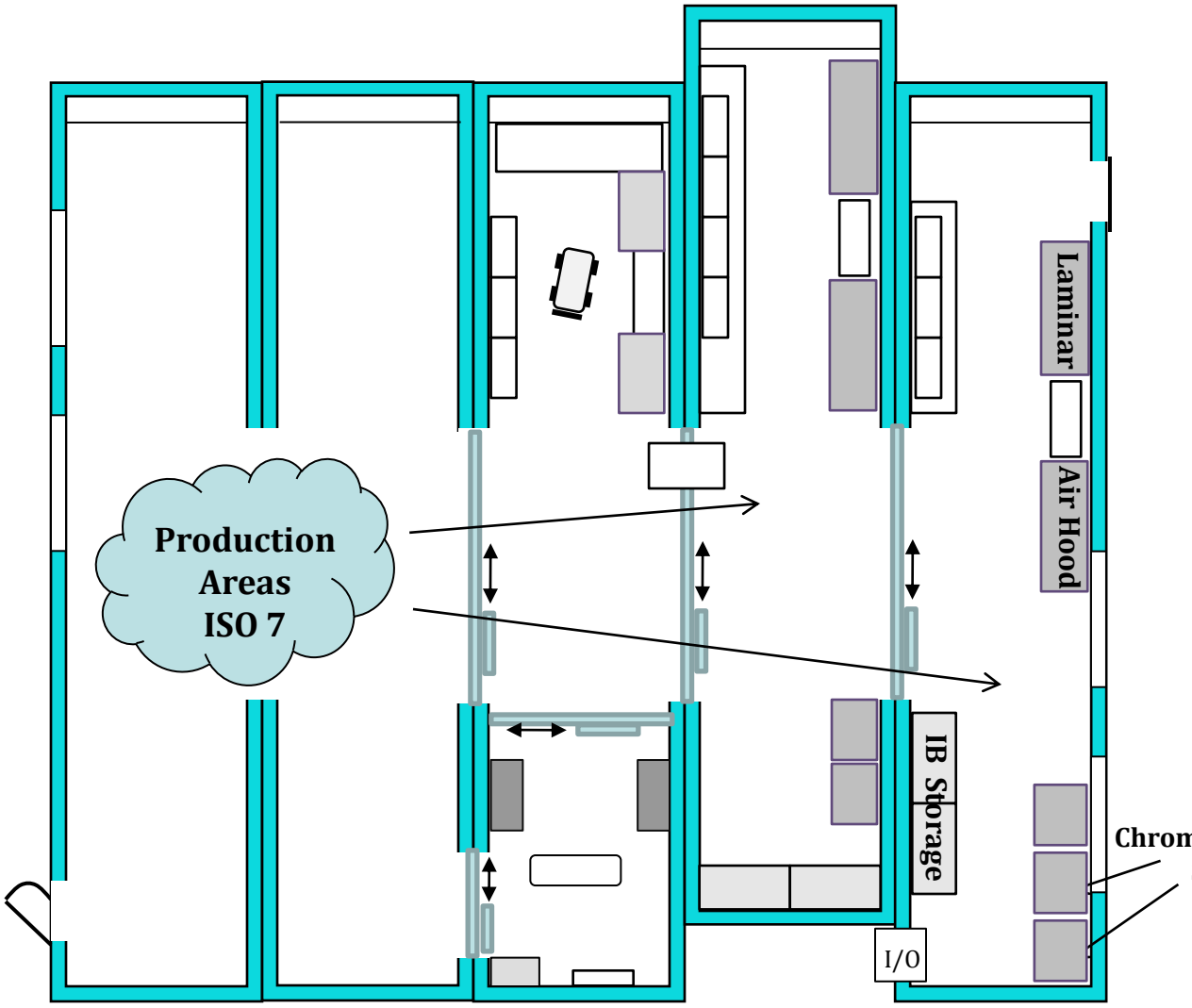
cGMP Production
• ISO Class 8 Gowning Room
• ISO Class 8 Equipment Prep Area
  • Autoclaves
  • Pass Through
  • Storage Cabinets
  • Equipment Cart
  • Work Areas

Modular Design Features



Workspace Functionality
cGMP Production • ISO Class 8 Gowning Room • ISO Class 8 Equipment Prep Area •ISO Class 7 cGMP Production Area(s) - Laminar Air Hood(s) for : Fermentation & Separation - Chromatography Carts - Cell Bank Storage - Work Area - Storage Cabinets

Modular Design Features

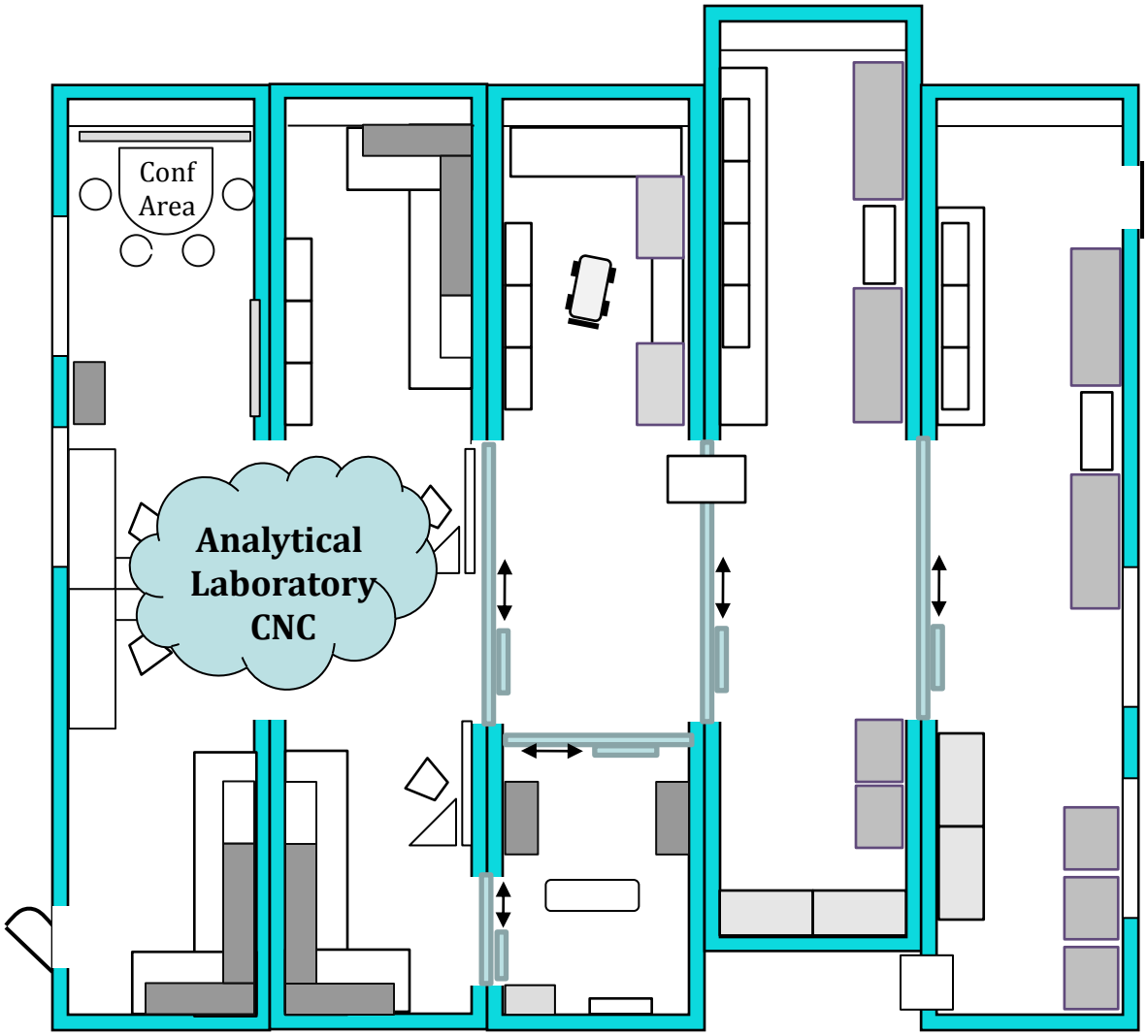


Workspace Functionality

cGMP Production

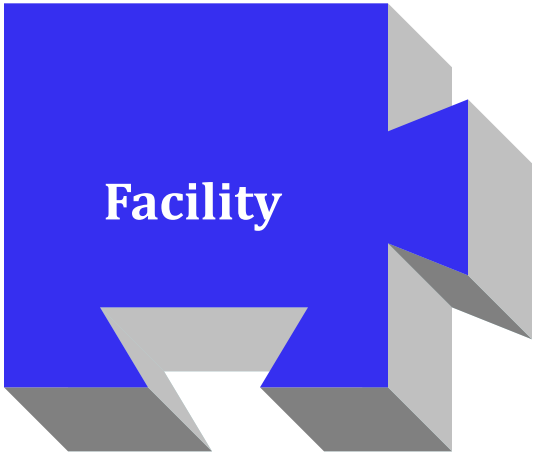
- ISO Class 8 Gowning Room
- ISO Class 8 Equipment Prep Area
- ISO Class 7 cGMP Production Area(s)
  - Laminar Air Hood(s) for : Fermentation & Separation
  - Chromatography Carts
  - Cell Bank Storage
  - Storage Cabinets
  - Work Area

Modular Design Features



Workspace Functionality
Analytical Laboratory Controlled, Non-Classified (CNC) • Wet Lab Benches • Fume Hoods • Work Stations • Emergency Wash Stations • Conference Area

Clear Path To Success ™



Facility

Repeatable, Scalable Design & Construction

- Fixed “Lego” Building Block Structure
- Lighting, Electrical, HVAC, Air Filtration , Surfaces and Finishes, SCADA, and Communications ALL based on Standardized Design
- Interior Equipment Selection and Placement such as Work Benches, Fume Hoods, Laminar Air Flow Hoods, and Storage Cabinetry are Standardized with Limited Options

Standardized Documentation and Controls

- cGMP Compliance
- Cleanroom Facility Certification to ISO 8,7, and/or 5
- Facility SOPs

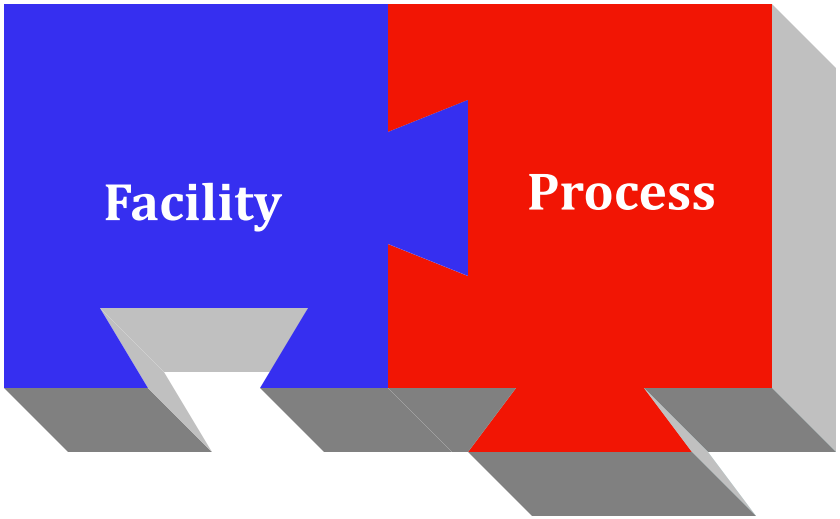
Validation

- Factory Acceptance Testing
- Equipment and System Installation Inspections: IQ, OQ, PQ

Biologics Team

✓ **$500 Million+ in Capital Project Experience**

Clear Path To Success ™



Process

Process Design

- Process Design & Engineering
- Equipment Specifications
- Equipment SOPs

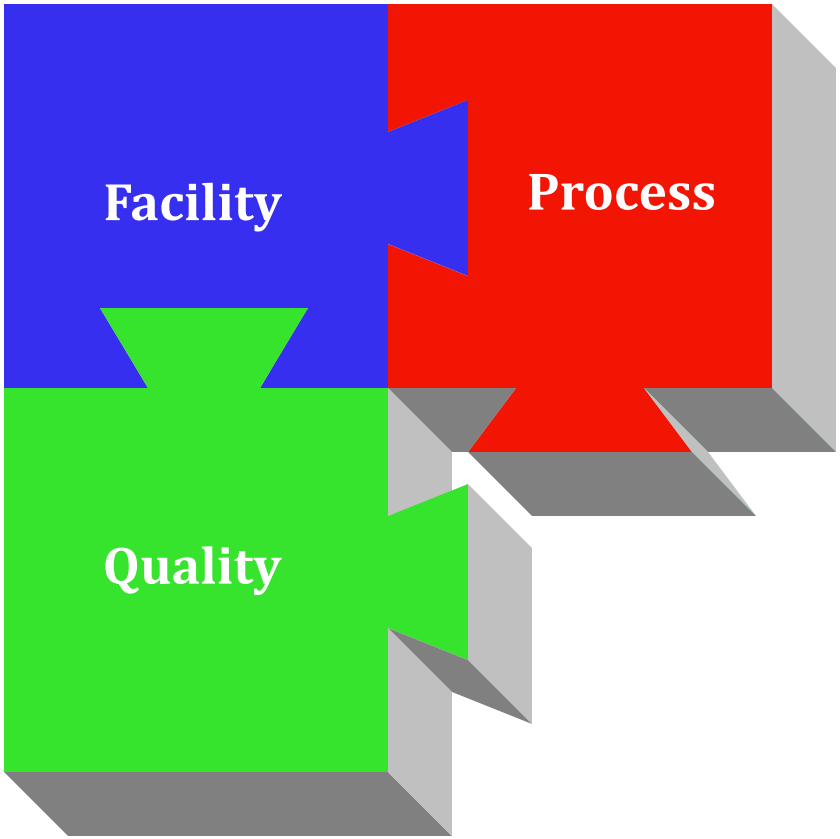
Implementation

- Commissioning
- Factory Acceptance Testing
- Equipment and System Installation Inspections: IQ, OQ, PQ
- Process Validation
- FDA Certification

Biologics Team

✓ **15+ years Process Design and Engineering Experience in the largest biotech manufacturing operation worldwide.**

Clear Path To Success ™



Corporate Quality System

Quality Control

- Project Validation Master Plan
- Site Validation Master Plan
- SOP Development
- QA/QC Plan and Procedures
- Batch Ticket Creation

Manufacturing Operations

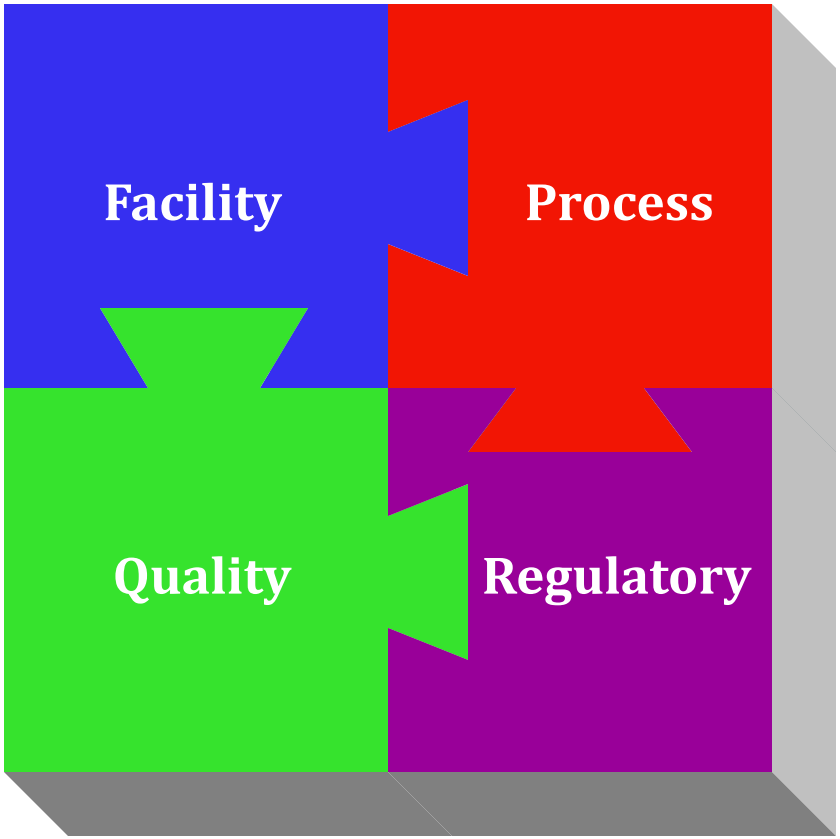
- Manufacturing SOPs
- Personnel Training
- In-Process Assays and Laboratory Controls
- Batch Records

Biologics Team

✓ **20+ Yrs Combined Experience in FDA Regulated Manufacturing**

✓ **50+ Yrs Combined Experience in Writing SOPs, Training Documents, Batch Records**

Clear Path To Success ™



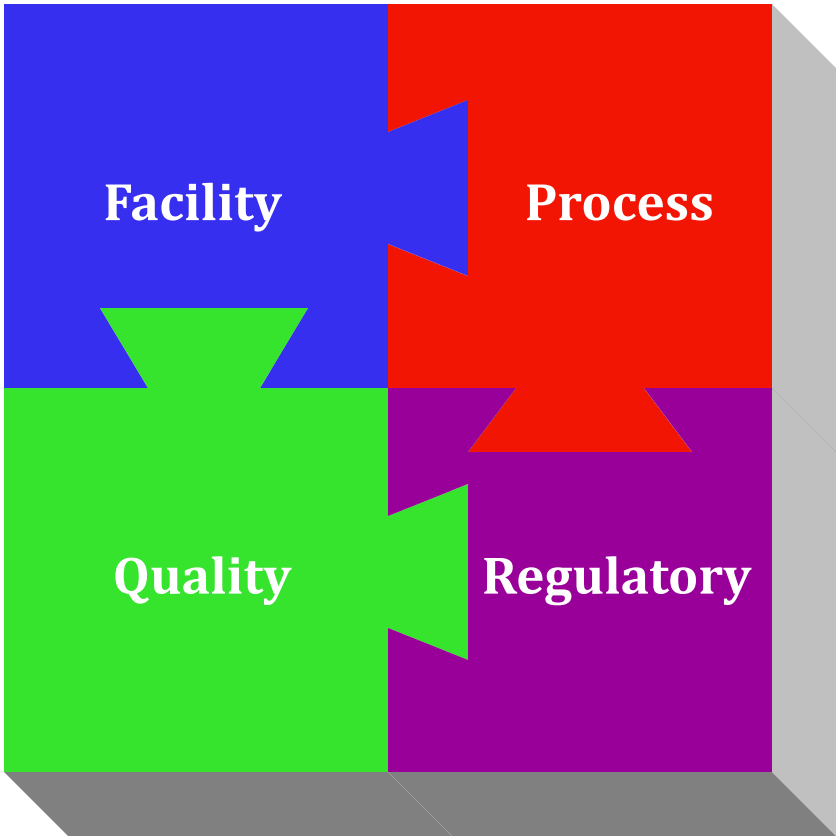
Regulatory Approvals

- Regulatory Strategy
- FDA Interface including Interpretation of FDA Policy and Guidelines
- NDA / ANDA Submission (New Drug Application, Amended)
  - Clinical
  - CMC

Biologics Team

✓ 20+ Yrs Combined FDA Project Mgmt
✓ Significant FDA Contacts and R'ships
✓ 9+ Successful NDA's
✓ 17 Successful ANDA's

Clear Path To Success ™



Biologics Clear Path To Success

The experience and know-how to support our customers' successful transition from the university research lab to the development and production of clinical material.

Biologics Value Proposition

Pain	Traditional Bricks and Mortar Design
	- $400ft^2$ Typical Cost Structure
	- Long planning, design, engineering, construction and validation horizon
	- Escalates the Risk of Investment; Slows Capital Formation
Value	Modular Design and Construction is Pre-Validated
	- Coverts Project Timeline From Months to Weeks
	- Significantly Reduces the Cost of Construction (50% to 80% less)
	- Directs the Focus on the Manufacturing Process, Including Quality and Regulatory
Pain	Differing Facility/ Capacity Requirements during Transitions of Clinical Trial Phases
Value	Modular Design Facilitates Mobility and Re-Useability
	- Function Specific Modules; "What you need, when you need it."
	- Lease Options Allow for Temporary Facility Utilization

Biologics Value Proposition

Pain	Dearth of FDA Compliant Lab Space for Research
	- Most University Research Labs are NOT FDA Validated
	- Cost to Build, Validate, and Maintain is Expensive (Same Cost Constraints as Biotech)
Value	Laboratory R&D Space is Pre-Validated
	Modularity Offers Significant Cost Reduction
Pain	Needs Change or End Leading to Capital Under-Utilization
Value	Flexibility/Mobility Allows for Scale Up as well as Scale Down Utilization
	- Ex: Phase 1&2 Clinical Trials have validated process but now require 3x capacity increase; Duplicate 3 more already validated module designs
Pain	Developer/Land Owner Left Holding Specialized Tenant Improvements
	Recycling: Biologics Will Decommission and Reclaim Containers At Their Expense