

The Turnkey Facility of the Future  
Here Today

Are You  Ready

### Faster Time to First Product Run



- Enables delayed capital investment decisions
- Allows rapid capacity build up, while lowering inventory needs
- Generates revenue streams faster

### Scalability without Interrupting Existing Processes



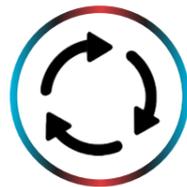
- Scaling up or out to fulfill increasing demand
- Capacity flexing to avoid underutilization of the facility or processes

### Multi-Product/ Multi-Purpose Facilities



- Required to gain full facility and process utilization
- Enables the supply of multi-therapy demands in specific locations
- Facility can be utilized for multiple product platforms or tenants
- Reduces COGS due to full utilization and shared costs

### Facility Flexibility



- The facility can be modified to fulfill demands of different drug development stages
- Manufacturing capacities can be adjusted rapidly
- The facility accommodates multiple product lifecycles

### Reduced Cost



- Achieved by process intensification and smaller facility footprints
- Lack of complex HVAC and duct systems reduces energy utilization
- Defining optimal facility designs utilizing total cost ownership analysis
- Cloning of infrastructures reduces design and qualification costs

The iCON™ facility platform, the collective efforts of IPS and G-CON Manufacturing, Inc., 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. An iCON facility can be built in less than 12 months which defers capital investments and advances revenue from production. iCON facilities allow for development capacity simultaneous to clinical production and ultimately commercial production for small or large volume products. iCON's modularity allows for movement and redeployment if product demand increases or decreases, in other words, true capacity flexing. In the event that a product reaches the end of its life-cycle, the iCON facility can be re-purposed for new product candidates or markets. With this capability, iCON's flexibility is unparalleled.

iCON's five choices of operation are unique from any other available facility option. The five choices allow development capacity parallel to producing clinical materials all the way to commercial scale. When the time is right, the development suites are easily converted into additional clinical capacity or small volume to full commercial production. This modular conversion approach avoids additional capital investments up to commercial phase production while allowing efficient development stage transfer without knowledge loss as progress is made. iCON represents a quantum leap in manufacturing flexibility, deployability and repurposability.

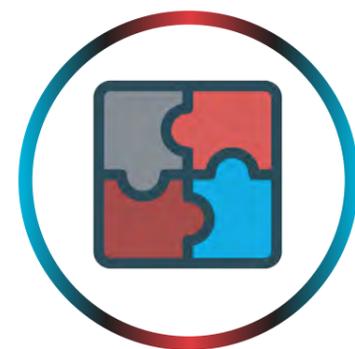
# Are You **iCON** Ready



## Who We Are

IPS-Integrated Project Services, LLC (IPS), a leading global provider of engineering, architecture, project controls, construction management, commissioning and qualification services, and G-CON Manufacturing, Inc., the leading supplier of prefabricated cleanrooms, have partnered to create iCON™, a turnkey modular facility platform solution for the biomanufacturing industry. The collaboration provides the most flexible and rapidly deployable facility platform, meeting the modular and mobile demands of the industry. The iCON team's broad range of technical capabilities and services along with prefabricated cleanroom PODs provides a true turnkey solution to biopharmaceutical manufacturers and CMOs with needs for production agility and capacity flexing.

## Platform Benefits



Prefabricated Process Cleanrooms (PODs®)



Collaboration with Key Bioprocess & Single-Use Vendors



Structure & Sub-Structure Platform Based on Cost Effective Pre-Engineered Building Delivery

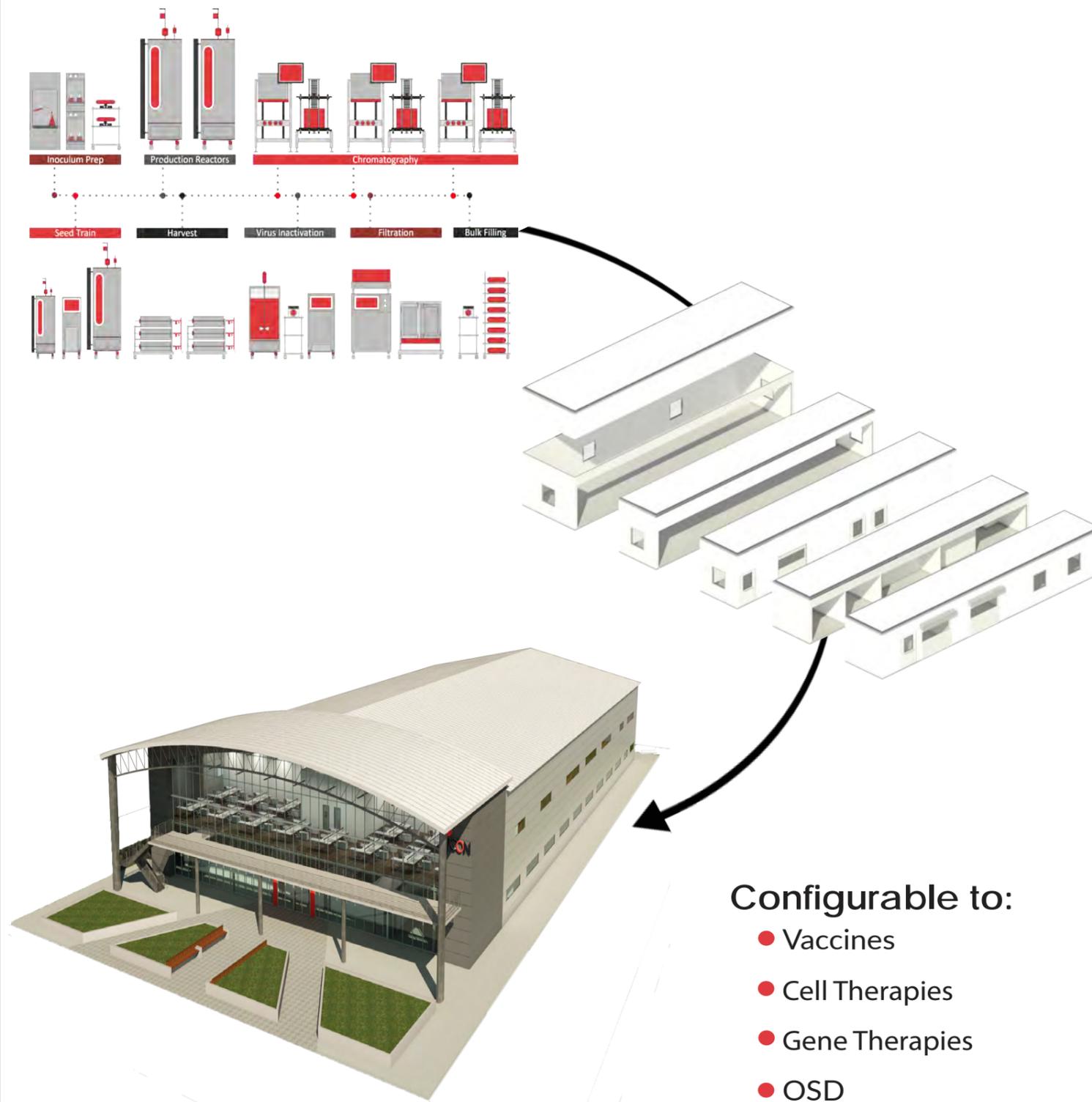


Turnkey Facility that Provides Fast-Track Design and Fabrication to Deploy Globally

The iCON team addresses the industry's manufacturing paradigm shift to smaller, separated, and clonable facilities. iCON™ is a true turnkey facility solution.



## A Closer Look



### Configurable to:

- Vaccines
- Cell Therapies
- Gene Therapies
- OSD

### Fulfilling Current Industry Demands

- Rapid deployment due to pre-design, pre-fabrication and pre-qualification
- Capacity flexing due to uninterrupted scaling-up, scaling-down and scaling-out
- High flexibility of possible 4 x 2,000L process streams for multi-product campaigns
- High quality, with robust designs and materials for long lifecycle value
- Reduced total cost ownership due to design, construction and qualification efficiencies
- Repurposable for next generation product lifecycles



...the Biomanufacturing Turnkey Solution

## 2000L Scale Hybrid Modular Facility



### Key Benefits:

- Über Flexible
- Turnkey Design Speed
- Predictable Cost and Timeline
- Modular Scalability and Tech Transfer
- High Lifecycle Value
- Robust Containment
- Segregatable – Sanitizable
- Repurposable –Relocatable

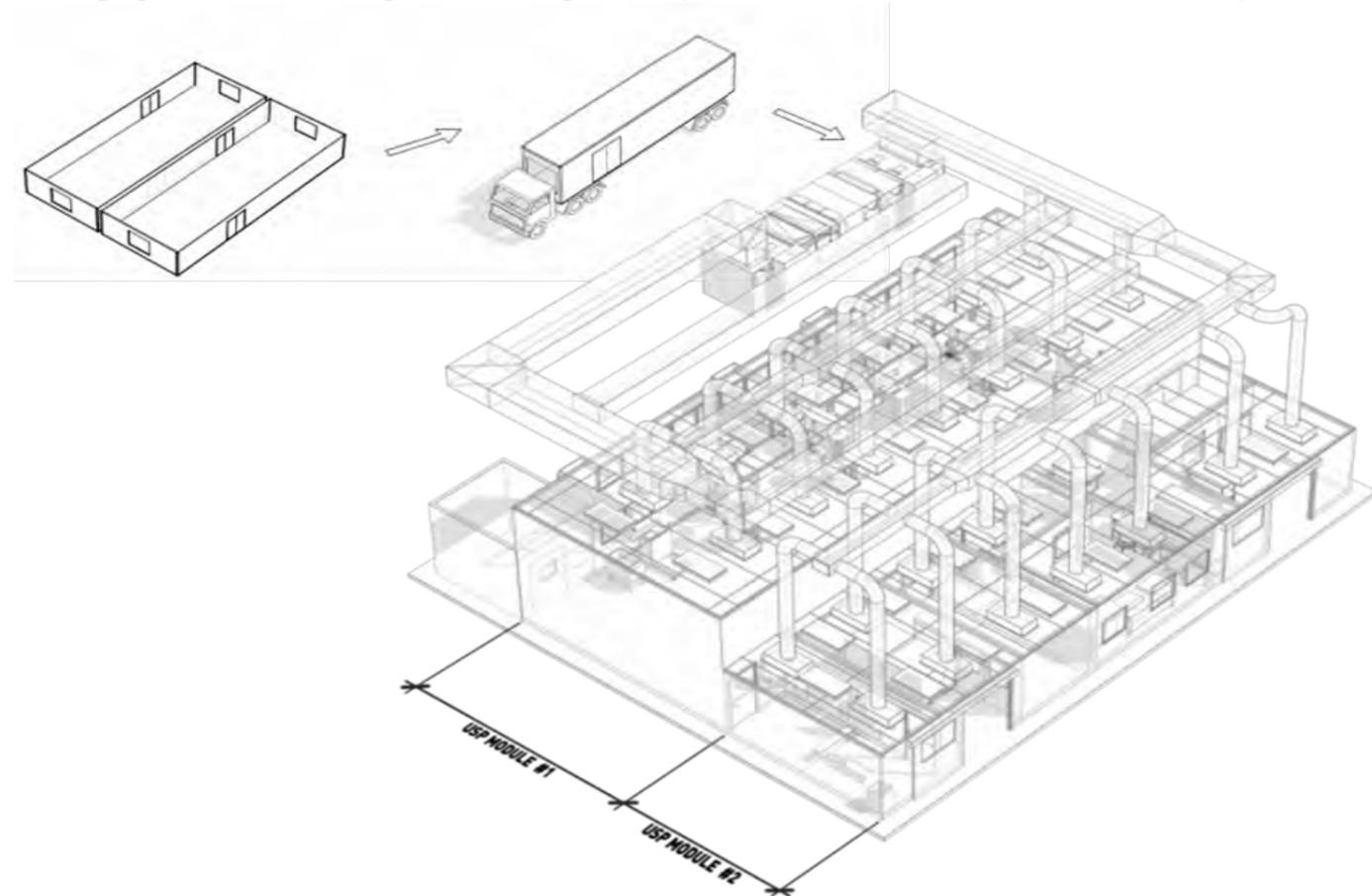
## Deep Bioprocessing Facility Experience

IPS is a leading provider of pharmaceutical architecture and engineering services in the world with over 1,000 architects, engineers, construction managers and compliance professionals delivering end-to-end solutions for small and large pharmaceutical operating and CMO companies. Over 60% of IPS revenue come from its biotechnology and vaccine portfolio of projects. G-CON, an innovator and industry leader in prefabricated podular systems, brings an in-depth experience in the design, manufacture, delivery and commissioning of its POD based systems. G-CON is the only company with comprehensive experience in designing and building flexible, prefabricated and prequalified cleanroom units. The combined iCON team can deploy engineering support that transcends the capabilities of most standalone AE, CM and manufacturing companies.

Our bench strength and broad range of technical capabilities can be bolted on as needed for additional services such as 3D walk-throughs and process modeling (REVIT, SuperPro, Biosolve, etc.) to improve the overall design and implementation experience far beyond any competitor, delivering a level of certainty that inspires investment.

## Expedited Delivery

The iCON team's high quality, flexible facility can be provided globally and faster than any other solution. We achieve this by simultaneously starting URS alignment, local permitting, shop drawing development, procurement and POD fabrication within weeks of each other. By running these activities in parallel and leveraging our standard designs, we can significantly shorten the schedule to validation start-up.



## Details of an iCON™ ÜBERbioFLEX Facility

Quantity	POD Product	Functional Description
2	ÜBERbioFLEX	Upstream inclusive of Inoculum Prep, Seed Expansion Trains, Production Bioreactors, Harvest Depth & Final Filtration System and Harvest Mixing Vessel (All Single-Use)
2	ÜBERbioFLEX	Downstream inclusive of Chromatography Skids/Columns, Portable CIP Skid, Packing Equipment, Ultrafiltration Step, Viral Inactivation Step, Viral Filtration Step and Intermediate SU Process Mixing Vessels
1	ÜBERwashFLEX	Washer, Sterilizer, Pass-Throughs, Laminar Flow Modules (Wrap Areas) and Storage Capabilities for small parts and assemblies
1	ÜBERprepFLEX	Buffer Preparation inclusive of 2kL Mixers, 1kL Mixers, Small Scale Mixing Systems, Mobile Bag Holders, Fixed Bag Holders (All Single-Use)
1	ÜBERprepFLEX	Media Preparation inclusive of 2kL Mixers, 1kL Mixers, Small Scale Mixing Systems, Mobile Bag Holders, Fixed Bag Holders (All Single-Use)
1	ÜBERprepFLEX	Weigh/Dispense and Sampling inclusive Laminar Flow Modules, Scales and Miscellaneous Equipment/Furniture

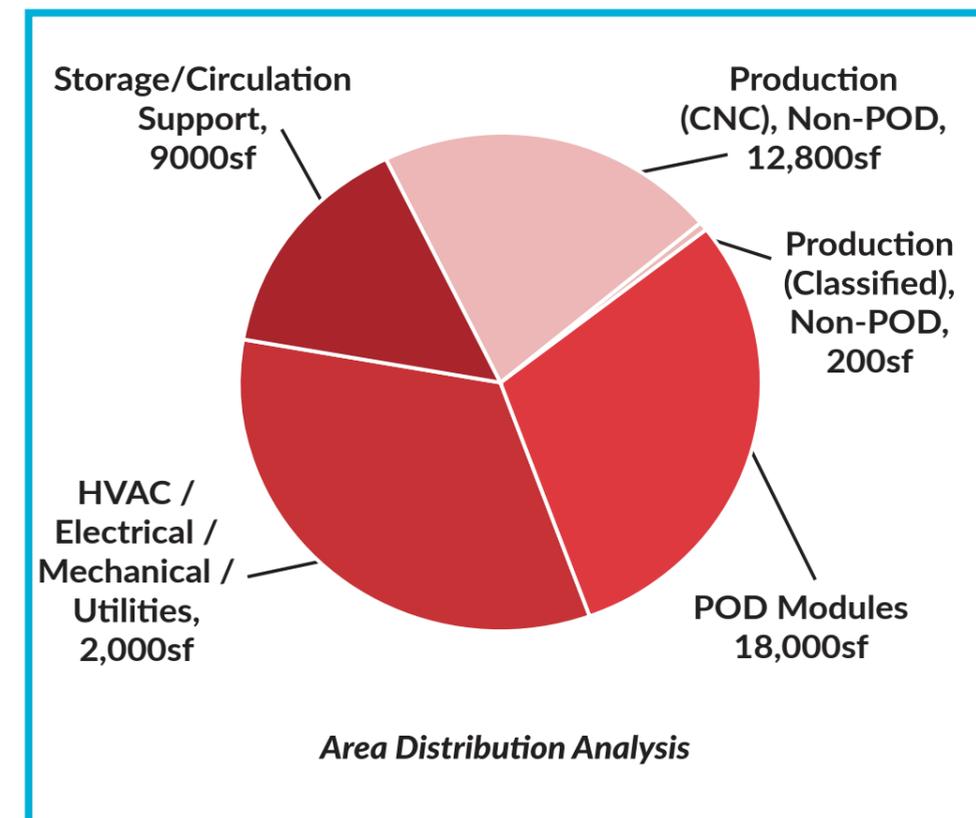
The facility is a standard 4x2000L facility that is expandable. The 4x2000L program includes the processing elements detailed above. These areas would occupy approximately 40% of the facility footprint.

The remaining areas would house the following functions:

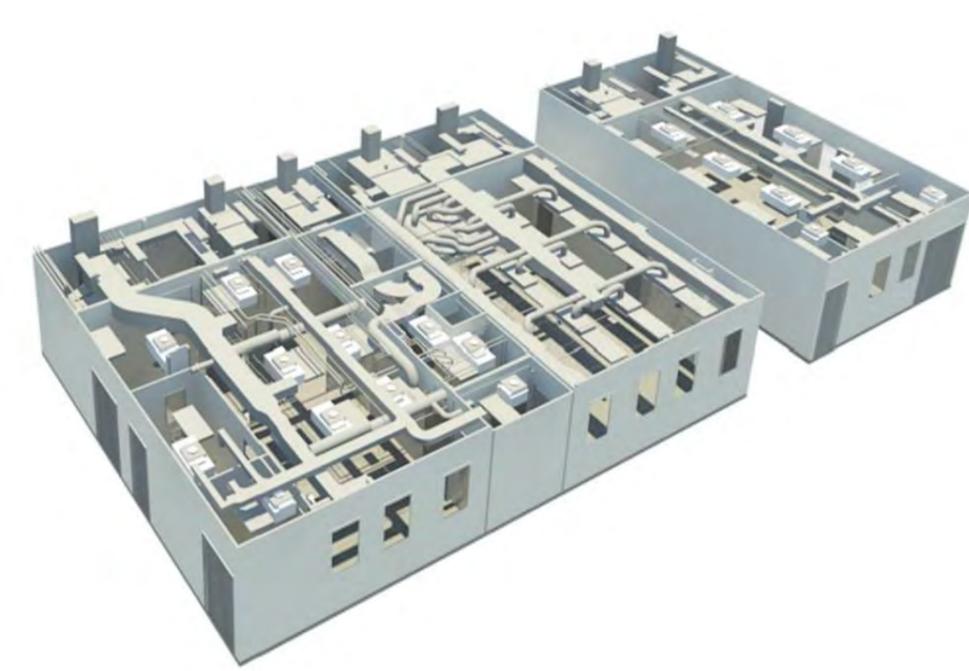
- Non-Classified Circulation, Receiving, Waste Storage & Staging Areas
- Non-Classified Lockers & Wash Areas
- Non-Classified Laboratory
- Classified Circulation & Media/Buffer Logistics Corridors
- Mechanical, Utilities & Electrical Support Accelerated Depreciation of Assets

While the ÜBERbioFLEX facility is a standard platform facility, the accessory use spaces identified above can be "Optionalized" to fit any application.

Given the high volume of single-use equipment and consumables required to support a 4x2000L production engine, our design utilizes an overall footprint of approximately 60,000 square feet (5,575 sq.m) that includes material handling and interim staging. A facility under-designed for material handling will be quickly overwhelmed with bag holders, raw material, and waste, reducing the output of the facility and impacting the quality and likelihood of approval by the regulatory agencies.



Assumptions - approximately 40,000 square feet of process space and an additional 20,000 square feet of mechanical support and staging space. An "Optionalization" analysis may reduce or increase the footprint.



## Cost Basis

Based on the iCON™ team's experience, we can provide an order of magnitude estimate at the initial phase of the project for a minimal investment. We do this through our Inceptioneering™ process, where we engage a client for a 2-4 week period to understand their User Requirement Specification and align the iCON offering with the customers goals, production requirements and their process platform (if different from the iCON standard).

## Financial and Operational Benefits

Producing 20 batches per year with an average downstream yield of 66%, our 4x2000L facility is capable of producing 215 kg per year (at 3 g/L). With this amount of production, all major financial performance indicators, e.g., ROI, ROA, and NPV, favor the ÜBERbioFLEX facility and will be even more compelling as titers increase and batch schedules are optimized. By choosing PODs over the traditional stick built approach, the assets are fully depreciated in 7-8 years versus 35-40 years, a major tax advantage.

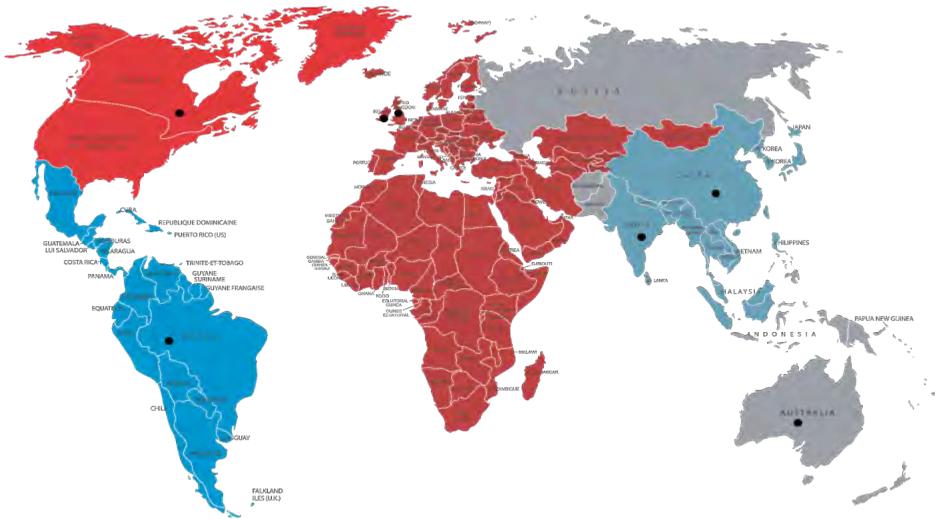
**inceptioneering™**  
*where projects begin*

Additionally, clients will benefit from a design that is vetted by internationally known experts in the following ways:

- “Optionalization” of a Standard Design
- Speed to Market & Delayed Capital Outlay
- Regionalization of 40% or more of the Facility Cost (advantageous in varying economic structures)
- High-Quality Materials of Construction
- World-Class Equipment Vendors Integrated by World-Class EPCMV Service Providers
- Process Flexibility
- Sophisticated Business Case Support through IPS Inceptioneering™ Process



# International Network



# US Network



## Contact Information

IPS-Integrated Project Services, LLC

721 Arbor Way, Suite 100

Blue Bell, PA 19422

P: 484.344.9234

E: [ips@ipsdb.com](mailto:ips@ipsdb.com)

[www.ipsdb.com](http://www.ipsdb.com)

G-CON Manufacturing Inc.

6161 Imperial Loop Drive

College Station, TX 77845

P: 979.431.0700

E: [sales@gconbio.com](mailto:sales@gconbio.com)

[www.gconbio.com](http://www.gconbio.com)



Tom Piombino (IPS)  
Biotechnology Process Architect & Sr. Director  
Contact: [TPiombino@ipsdb.com](mailto:TPiombino@ipsdb.com)



Dennis Powers (G-CON Manufacturing)  
Director of Sales Engineering  
Contact: [DPowers@gconbio.com](mailto:DPowers@gconbio.com)

Contact us to learn more.

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