WHITE PAPER

Achieve commercialization quicker & with more certainty with GeneSuites

A new cGMP biomanufacturing solution to bring CGT and other advanced therapies to market quicker while mitigating risk and materially lowering upfront cost.

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GeneSuites™
where cures thrive

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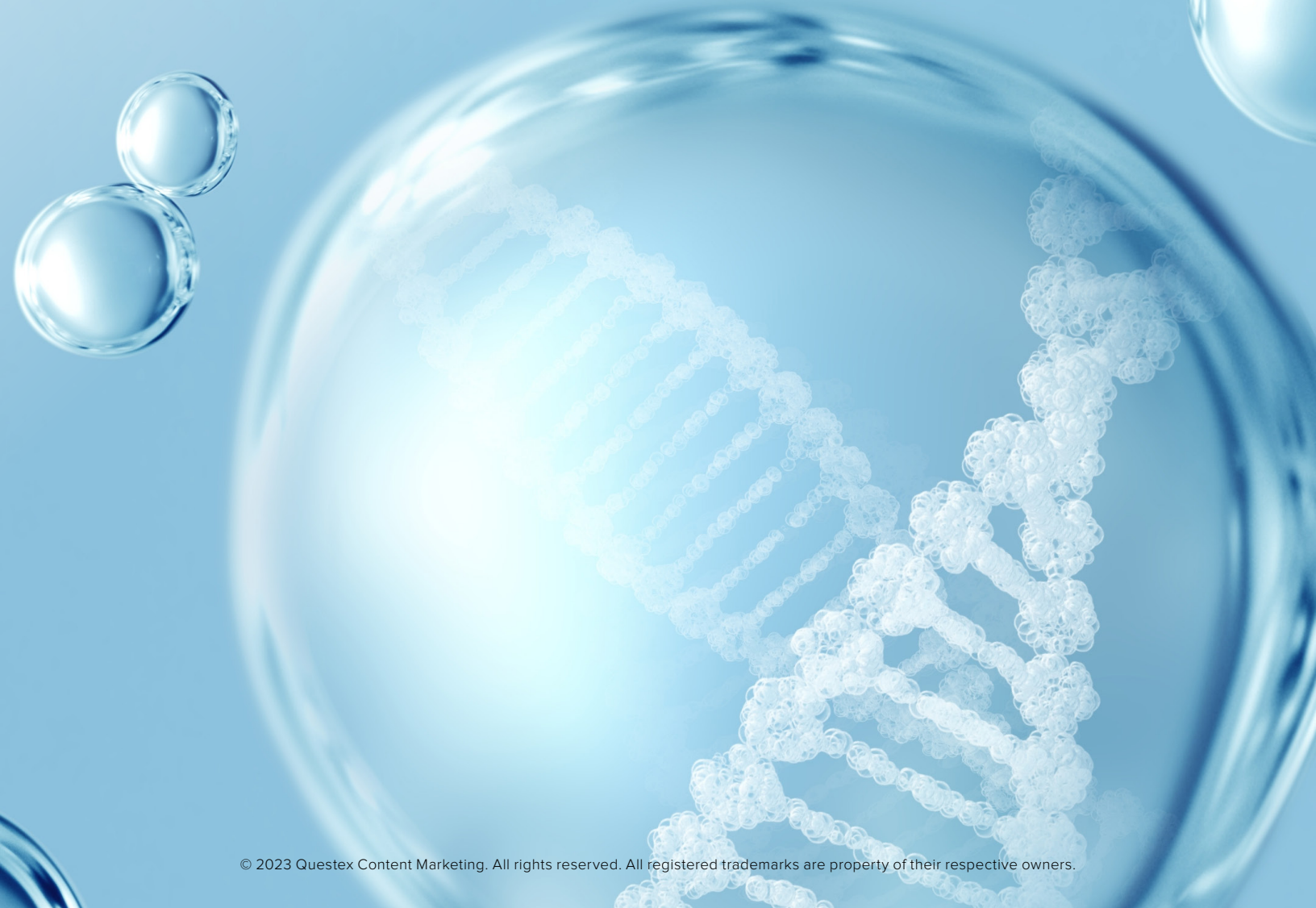

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GeneSuites forges a new path that lowers barriers for advanced therapy manufacturing through greater control of capital, intellectual property, and process while accelerating speed to market.

New advancements in scientific innovation present unprecedented opportunities through Cell and Gene Therapy (CGT) and advanced therapeutics. Projections for investigational new drug applications (INDs) grow rapidly each year while record numbers of clinical trials are initiated, signaling increased biomanufacturing demand on top of the already capacity-strained manufacturing landscape. While investments in the discovery of advanced therapies continue to increase, more can be done to create an environment for success through the development of new cGMP biomanufacturing facilities.

The technology, expertise and intellectual property contained in the manufacturing process can be a significant differentiator and competitive advantage for life science companies; whereby, maintaining control and minimizing risk around these processes is a critical component to the timely advancement of these novel therapeutics.

GeneSuites offers a new cost- and time-certain path for life science companies. Companies can enjoy the advantages of a purpose-built cGMP facility that retains manufacturing process and Intellectual Property (IP) control in-house with lower capital barriers to entry; thereby bringing life-saving therapies to commercialization quickly, safely and with certainty.

GeneSuites Offers cGMP Biomanufacturing solutions for:

Cell & Gene Therapy

Advanced Therapeutics

Biologics

Biopharmaceuticals

Chemical Manufacturing

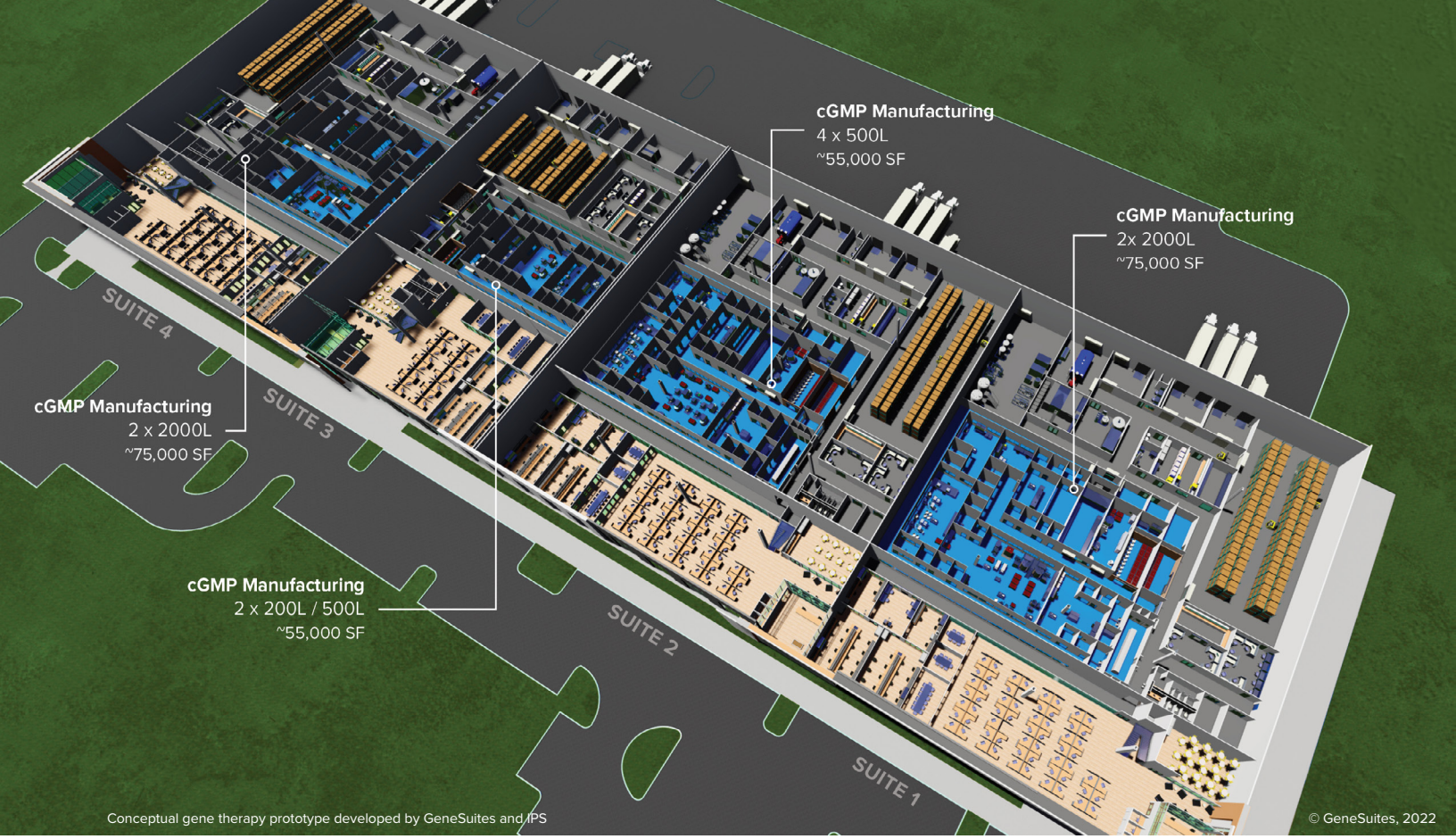
What we know – Two traditional biomanufacturing strategies for advanced therapy companies

Traditionally, biomanufacturing solutions involve two options: build in-house manufacturing ability / capacity **(Build)** or buy outsourced manufacturing services through a contract development and manufacturing organization **(Buy).**

The Build option offers flexibility and control over process and IP but is capital-intensive, time consuming and requires in-house expertise. Large pharmaceutical companies are best positioned to keep manufacturing in-house or opt for a hybrid of Buy and Build. The Build option is virtually unattainable for early to mid-stage companies because average build times may range between 18 to 30 months and typically cost more than $50 million in the first 3 years. Smaller companies with limited resources may consider outsourcing their manufacturing process but are subject to waitlists averaging 18 months, and that waitlist time is expected to increase.

In a survey conducted by BDO in October 2022, 46% of the 100 Life Science CFOs surveyed noted that their companies are looking towards outsourcing scientific and technical functions, including manufacturing as a way to preserve resources; however, a quarter of the respondents are finding constraints to identify qualified partners with the right technical skills.[1] Protecting the technology and IP contained within a company's highly optimized manufacturing environment only adds to the already complex biopharma pressures of balancing budgetary and manufacturing requirements while maintaining pace to market. For smaller companies with novel therapies, these risks pose challenges that can be detrimental.

> **"One of the biggest problems that GeneSuites is solving is providing cGMP manufacturing capacity at scale** for clinical or commercial products without the burden of a large capital investment or a time penalty associated with constructing and qualifying an in-house facility. Alternatively, outsourcing manufacturing leads companies to be at risk of joining a queue, affecting timing to secure manufacturing capacity, and losing process and IP control.
>
> Manufacturing know-how in advanced therapies is a competitive advantage. **We think it's beneficial to retain cGMP expertise in-house. "**
>
> **— Gary Schoenhouse, Chief Technical Advisor // GeneSuites**



Conceptual gene therapy prototype developed by GeneSuites and HPS

GeneSuites offers a novel third solution to optimize the best biomanufacturing advantages of both Build and Buy options with certainty and predictability.

Creative and inventive biomanufacturing solutions are necessary to meet the rapid growth trajectory of advanced therapeutics. Similar to a warm shell in a lab or office environment, GeneSuites' proprietary High-Performance Shell (HPS) is a purpose-built manufacturing shell designed in advance, with dedicated supporting infrastructure and procurement of long-lead time equipment that meet the needs of biopharma companies in terms of process, scale, amenities, warehousing and administrative space.

Read more about HPS on page 7.

> **GeneSuites facilities are designed for maximum flexibility and are able to support multiple CGT modalities including autologous, allogenic, gene modified cell therapies, and viral vector manufacturing.** Additionally, tenants have the option to occupy adjoining suites within the facility, allowing them the full segmentation of equipment and systems needed to manufacture their cell or gene therapy in one suite while concurrently producing its viral vector counterpart in the other.

For companies looking for a more plug-and-play approach,

GeneSuites can offer turnkey cGMP-capable facilities that require no upfront capital infusion other than fixed lease payments and the cost of specific processing equipment needed by the biopharmaceutical company.

This novel solution provides a financially sound option for companies and their investors and is the most predictable and cost-certain solution compared to in-house Build. Leasing a cGMP manufacturing shell can lower the barrier for entry into biomanufacturing for early-stage companies with limited budgeting flexibility by providing a predictable cost for budgeting needs and allowing companies to operate without impacting their liquidity and asset depreciation.

> **As with in-house manufacturing, partnering with GeneSuites allows companies to develop internal cGMP expertise and build robust manufacturing procedures and quality systems around processes, supply chain, materials and storage conditions.** Control over manufacturing processes and IP is ensured because companies install their own specialized equipment and manage their own facility and operations.

Company advancement and growth are also built into the GeneSuites solution. GeneSuites customers have the flexibility to optimize commercial manufacturing processes with confidence and simplify the transition to commercial production when the time is right by moving processes, equipment and documentation to a new location, whether through a GeneSuites manufacturing suite or an in-house manufacturing facility, via a hybrid solution. Leasing through GeneSuites offers companies the option to transition without the burden of the capital penalties that accompany facility ownership.

"GeneSuites customers can build their manufacturing team, SOPs, and all operational readiness documents because they're making product themselves at GeneSuites; they can even participate in the commissioning and qualification process if so desired. Once they're financially ready to transition to their next company milestone, they can pick up all the infrastructure that they've invested in and move it to their new facility.

Admittedly, because it's non-traditional, the third option takes a moment for an operating company's site selection team to understand this new model, **but it presents a huge advantage to early and mid-stage companies."**

— Tom Piombino, Managing Director - Americas // IPS

High-Performance Shell: cGMP Capacity at Scale

GeneSuites' High-Performance Shell (HPS) is a proprietary shell design that allows customers to benefit from significant landlord investments *already built into the building.*

	Typical Cold Shell	High-Performance Shell
MECHANICAL		
Chiller Plants	–	✓
Boiler Plants	–	✓
ELECTRICAL		
Backup Generators	–	✓
Switchgear	–	✓
ADDITIONAL INFRASTRUCTURE		
Mezzanine	–	✓
cGMP-Specific Components	–	✓

The result? GeneSuites customers save 9 to 15 months or more in their timeline with cost certainties for a building that has already secured and/or installed long-lead time equipment, cGMP-specific infrastructure, power, and other utilities. Because coordination between numerous vendors and contractors is handled by GeneSuites, customers reap the benefits of time saved while maximizing control over their space as if it were an in-house build — without the upfront capital required.

GeneSuites and leading cGMP industry experts have spent the last three years refining the design to achieve the ***"sweet spot"*** of maximizing a building's build-out without compromising customers' ability to customize their space. This think tank eventually formed the GeneSuites Technical Advisory Team to review technical aspects of development, facility, suites and equipment design, CGT technologies, production scales and cGMP requirements. Members of the GeneSuites Advisory Team include subject matter experts from IPS-Integrated Project Services, LLC, Germfree and CBRE, among others.

HPS is optimized for scalability, supporting multiple modalities from CGT, API/Biologics and monoclonal antibody.

The shell design can accommodate small scale manufacturing up to 2K liter single-use bioreactors.

“High-Performance Shell customers enjoy accelerated timelines and greater certainty on timing and cost. They no longer need to worry about material and supply chain delays that can bottleneck a project quickly.

The solution isn’t simply adding manufacturing capacity to the market.

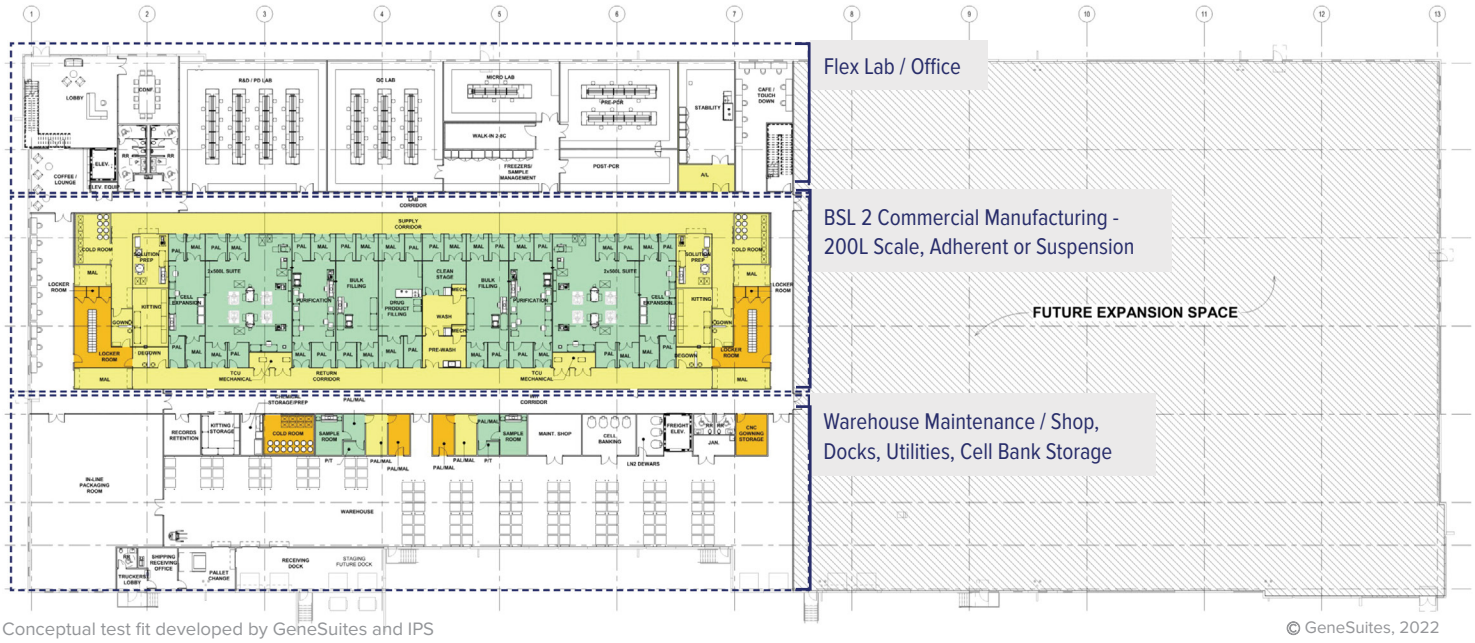
We’re championing our customers from the very beginning to remove variables that consistently cause uncertainty and friction in growth so that our customers can successfully meet the needs of both their customers and investors.”

— Gary Schoenhouse,
Chief Technical Advisor // GeneSuites

Catalyst BioCampus: Minimizing Risk through High-Performance Shell

GeneSuites’ flagship project, Catalyst BioCampus, is the first to offer HPS. Catalyst is a three-building cGMP biomanufacturing campus located in in the Town of Holly Springs in North Carolina’s Research Triangle region. The campus totals over 450,000 square feet, including over 300,000 square feet of cGMP space across two buildings and an additional 140,000 square feet of process development, lab and office space. Each cGMP building can be configured to accommodate one to four tenants up to 2k single-use bioreactors scale and associated downstream capabilities.

With the building shell complete, Catalyst has procured the switchgear, build-out of the mezzanine and other building infrastructure, and is the only development project in the region to have secured a power agreement for 6 MW to each building with the ability to secure more. As of the time of this whitepaper, Catalyst is under construction, ready for tenant improvements, and is on track to be operational by Q4 2023.



Conceptual test fit developed by GeneSuites and IPS

Next Steps

As the rapid development of CGT, advanced therapies and biologics continues, competition to be first to market will become more intense. The biomanufacturing capacity crunch is forcing these innovative companies to rethink how, or if, traditional manufacturing solutions fit their overall plan towards clinical and commercial production.

Biopharmaceutical companies are no longer limited to choose between sub-optimal traditional manufacturing solutions. GeneSuites has created a new third option for cGMP biomanufacturing in leasing a purpose-built cGMP-capable shell that saves companies time and resources as they work to move their therapies to commercialization. GeneSuites customers now have the option to maintain their competitive edge by minimizing upfront capital spend and still leveraging the advantages of in-house manufacturing while accelerating speed to market.

GeneSuites™
where cures thrive

GeneSuites is a cGMP-dedicated developer focused on developing, building and financing biomanufacturing cGMP-capable facilities for CGT and life science companies.

With the most advanced and cost-efficient cGMP multi-modal manufacturing solution, GeneSuites can help life science companies accelerate speed to market, minimize operating risk while maximizing process control, capital efficiencies and scalability. The GeneSuites team has a proven track record of developing, managing and negotiating multimillion square feet of life science and cGMP biomanufacturing space.

Learn more at: www.GeneSuites.com

Interested in learning how GeneSuites can help your company accelerate speed to market?

Set up a call with the GeneSuites Team:

GeneSuites.com/fiercepharma

Resources

1 BDO 2023 Life Sciences CFO Outlook Survey, February 2023