Life Sciences greenfield builds

Capgemini

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The pharmaceutical manufacturing industry is in the midst of a transformation. As new therapies, precision medicines, and biologics continue to expand, manufacturers are increasingly focused on building advanced greenfield facilities to scale up production capacity, meet evolving regulatory requirements, and integrate pharma 4.0 initiatives. Greenfield builds—projects where facilities are constructed wholly or mostly from scratch—are becoming essential for companies that need to scale up manufacturing capabilities quickly to meet growing market demands. These facilities represent a forward-looking investment in quality, resilience, and innovation, setting new benchmarks in operational excellence.

Why greenfield manufacturing took a backseat: Historical barriers to new facility development

In the previous decade, greenfield manufacturing projects were often sidelined in favor of brownfield expansions due to practical, financial, and strategic considerations. Manufacturers typically relied on upgrading existing facilities, allowing them to bypass the high upfront costs and complexities involved in building new sites.

Regulatory constraints also played a role. The life sciences industry operates under stringent safety and quality standards, and constructing new facilities often entails lengthy approval processes that, as a result, did not have favorable payback. Additionally, without the high demand for specialized, advanced therapies and the explosive growth of new biologic therapies seen today, there was less urgency to build customized facilities for cutting-edge treatments.

In past decades, tax incentives and favorable tax rates specifically designed to encourage greenfield projects were less common, which made retrofitting existing sites a more financially viable choice. Differences in tax rates across regions did not present the same incentives for relocating or expanding operations, leading companies to consolidate activities at existing sites where they could benefit from known tax structures and avoid the added costs associated with new builds. Additionally, in an era with minimal geopolitical pressures, there was little need for manufacturers to diversify their locations to ensure supply chain resilience. Consequently, expanding established facilities was often viewed as the most efficient, cost-effective, and low-risk strategy for meeting production demands.

Renewed focus on greenfield manufacturing: Expanding life sciences capacity for the future

Over the past few years, the life sciences industry has witnessed a significant rise in greenfield investments, with levels more than doubling that of the previous decade. This has been driven by the expansion of advanced therapies, biologics, and precision medicine, as well as shifts in tax incentives and increased geopolitical pressures, which are driving the need to diversify supply chains.

Investment data from recent years highlights the potential growth trajectory for greenfield builds in life sciences. From 2021 to 2024, capital investment grew by more than 25% annually, with leading companies like Novo Nordisk, Eli Lilly, and AstraZeneca and others making substantial investments in new facilities. According to this same publicly available data, biopharma companies are expected to invest more than $50 billion between 2024 and 2026, creating a new generation of manufacturing facilities equipped with cutting-edge technologies.

Year	Estimated investment (USD billion)	Theme
2021	$7B	Pandemic-driven investments
2022	$7B	Gene therapy & biologics expansion
2023	$11B	Sustainability and capacity
2024	$14B	End-to-end manufacturing
2025	$18B	Advanced therapies & digitalization
2026	$23B	Sustainability & precision medicine

* The data for this analysis was compiled from various publicly available articles on greenfield builds in the pharmaceutical industry. A full list of specific sources is included at the end of this article.

In 2021 and 2022, investments were driven by pandemic-related demands and the expansion of gene therapies and biologics. Covid-19 vaccine production spurred rapid facility growth, while gene therapy and mRNA projects focused on addressing supply chain and regulatory challenges. By 2023, sustainability and production capacity became major priorities, with investments in Active Pharmaceutical Ingredient (API) manufacturing and sustainable construction practices to support oncology, diabetes, and respiratory therapies.

From 2024 onward, there is a shift towards end-to-end manufacturing, advanced therapies, and digitalization, as well as a continued emphasis on sustainability and precision medicine. Facilities designed for streamlined integration from drug discovery to clinical production emerge in 2024, with modular and digital configurations enhancing operational efficiency. Investments in 2025 are expected to focus on automation and AI to optimize production, especially for new biologics and GLP-1 agonists, while 2026 projects are likely to center on environmentally sustainable, flexible manufacturing, supporting the increasing demand for personalized treatments.

This trajectory highlights the evolving priorities of the life sciences industry, from immediate pandemic response to long-term, sustainable production for advanced therapies. The 60+ individual, publicly announced projects making up the investments noted above are more than just expansions. They are catalysts for innovation, pushing the boundaries of what's possible in biopharmaceutical manufacturing. By investing in state-of-the-art greenfield sites, manufacturers are positioning themselves to lead in a competitive, highly regulated market while also driving job creation and contributing to economic development in the regions where these plants are located.

Key challenges and strategic considerations

While building new facilities offers significant growth potential, these projects come with complexities. Unlike brownfield projects, which involve upgrading existing infrastructure, greenfield builds require life sciences manufacturers to manage both the physical and digital aspects of facility construction from clean sheet, often in unfamiliar geographies. This calls for careful planning, robust project management, and an agile approach to technology integration. Additionally, to achieve return on investment from digital advances, greenfield builds require a seamless interplay of strategic planning, physical infrastructure, and digital systems integration. Major challenges include:

- Capacity analysis and business case development:

Every greenfield project begins with a robust capacity analysis to determine production needs, technical requirements, and future scalability. Building a solid business case that considers financial projections, ROI, and risks is essential for justifying the significant capital expenditure required.

- Site selection:

Location is key to a facility's long-term viability. Factors such as proximity to suppliers, regulatory environment, labor markets, logistics, and tax incentives are critical considerations. The complexity of regulatory compliance adds another layer of decision-making.

- Physical and digital integration:

Effective greenfield facilities require an integrated approach to physical and digital infrastructure. The physical build involves the construction of the facility, installation of equipment, and ensuring compliance with Current Good Manufacturing Practice (cGMP) and other regulatory standards. Concurrently, digital aspects—like Manufacturing Execution Systems (MESs), process automation, and cybersecurity—must be carefully aligned with physical components to optimize plant operations.

- Commissioning, qualification, and validation (CQV) compliance:

Ensuring that the plant meets regulatory standards and is operationally ready is a crucial phase. As regulatory scrutiny grows, companies need to implement stringent qualification and validation processes to achieve with cGMP compliance.

- IT/OT system integration:

Manufacturing today requires high levels of automation and data integrity. Advanced technologies, such as digital twins and AI-driven analytics, play a pivotal role in achieving real-time monitoring and optimizing plant operations. Integrating these technologies with operational technology (OT) systems is essential for maximizing productivity and operational flexibility.

The path forward: Optimizing greenfield builds for the future

For Life Sciences manufacturers looking to leverage greenfield builds, success hinges on adopting a holistic, integrated approach that balances strategic, physical, and digital elements including the following:

- Strategic investment in capacity and business models:

Companies should evaluate demand forecasting, technology requirements, and scalability at the outset. This helps ensure that new facilities can adapt to changing market needs and support the company's long-term business goals.

- Collaboration and strategic partnerships:

Greenfield builds often involve collaboration with multiple stakeholders, including engineering, procurement, and construction (EPC) firms, IT/OT integrators, and local government entities. Working with specialized partners enables companies to navigate complexities more efficiently, from regulatory compliance to digital system integration.

- Harnessing physical and digital synergies:

A successful greenfield facility is one where physical infrastructure, and digital systems are seamlessly integrated. With the right digital technologies—such as MES, process control, and automation—companies can achieve the real-time data visibility and agility needed to respond to dynamic production demands. Digital twins, for instance, can provide predictive insights, helping companies reduce downtime and enhance efficiency.

- Optimizing flow and building a foundation for continuous manufacturing:

Greenfield facilities present a unique opportunity to embed lean manufacturing concepts from the outset, creating a foundation that supports fully digital, highly efficient plants. By optimizing overall process flow and reducing bottlenecks, companies can achieve smoother production and greater operational efficiency. Designed with lean principles and continuous manufacturing capabilities, these facilities enable increased productivity, reduced waste, and a streamlined approach to meeting dynamic market demands. Moreover, they allow for an evolution toward truly continuous flow, where processes are seamlessly integrated and production can occur without interruption, further enhancing responsiveness and agility in the manufacturing environment.

- CQV and regulatory compliance:

Ensuring that a new facility complies with all regulatory standards is paramount in the life sciences sector. Companies must establish stringent commissioning, qualification, and validation processes to ensure that the facility is fully operational and compliant with GMP standards before production begins.

- Prioritizing sustainability and future-ready technology:

As sustainability becomes a critical business imperative, greenfield builds offer an opportunity to design eco-friendly and energy-efficient facilities from the ground up. However, integrating sustainable practices often requires additional upfront investment that may not yield immediate financial payback. It is essential to allocate budget within capital expenditures to support these initiatives, as they provide long-term competitive advantages, including reduced operating costs, enhanced corporate reputation, and alignment with evolving regulatory expectations.

- Addressing talent and staffing for the future:

Greenfield projects present an opportunity to build a workforce skilled in advanced manufacturing, digital systems, and automation. Companies must not only plan for recruiting, training, and retaining new talent with these specialized skills but also leverage the depth of experience within their existing workforce. By making current employees partners in future ways of working and providing them with training and incentives, companies can ensure a smoother transition and foster a culture of innovation and adaptability, ultimately supporting the facility's long-term goals in a rapidly evolving industry.

How next-generation greenfield pharma plants stand apart from their predecessors

Today's new greenfield pharma plants face unique challenges compared to those built in the past. To build future-ready biopharma greenfield plants, it's essential to consider technological advancements, global supply chain issues, operational efficiencies, and sustainability targets. Next generation builds prioritize the following elements in their design, setting them apart from past greenfield plants:

- Focus on pharma 4.0:

Modern greenfield plants must integrate digital solutions from the outset. This includes data analytics, industrial cybersecurity, and digital twins to optimize yield, quality, safety, and overall operational efficiency.

- Sustainability and energy efficiency:

Incorporating green building materials, sustainable construction practices, and sustainable raw material procurement for day-to-day operation is crucial. Achieving LEED certification is a must for new plants. Additionally, optimizing energy consumption and planning for renewable energy are critical elements of new-age greenfield plants.

- Flexible manufacturing:

New plants should be modular and flexible to meet market demands. Single-use technologies, which enable faster setup and reduced cleaning requirements, are key for multiproduct facilities. These plants should also be adaptable to new product types, such as cell and gene therapies and personalized medicines, which often require small batch sizes.

- End-to-end supply chain integration and automation:

Today's greenfield plants should seamlessly integrate with various supply chain elements, including suppliers, vendors, logistics partners, distributors, and Contract Development and Manufacturing Organizations (CDMOs). This integration helps monitor and track raw materials, finished goods, and services in real-time, ensuring compliance with regulatory requirements. Robotics and automated guided vehicles (AGVs) will play a pivotal role in material handling, including tasks such as material transport, inventory management, and packaging.

In summary, next-generation greenfield biopharma plants are significantly different from their predecessors. They are designed to minimize environmental impact and leave our planet in a better condition for future generations. Additionally, digital technologies will become a key element alongside core process technologies in greenfield builds, elevating digital solution providers to the same level of importance as core technology providers.

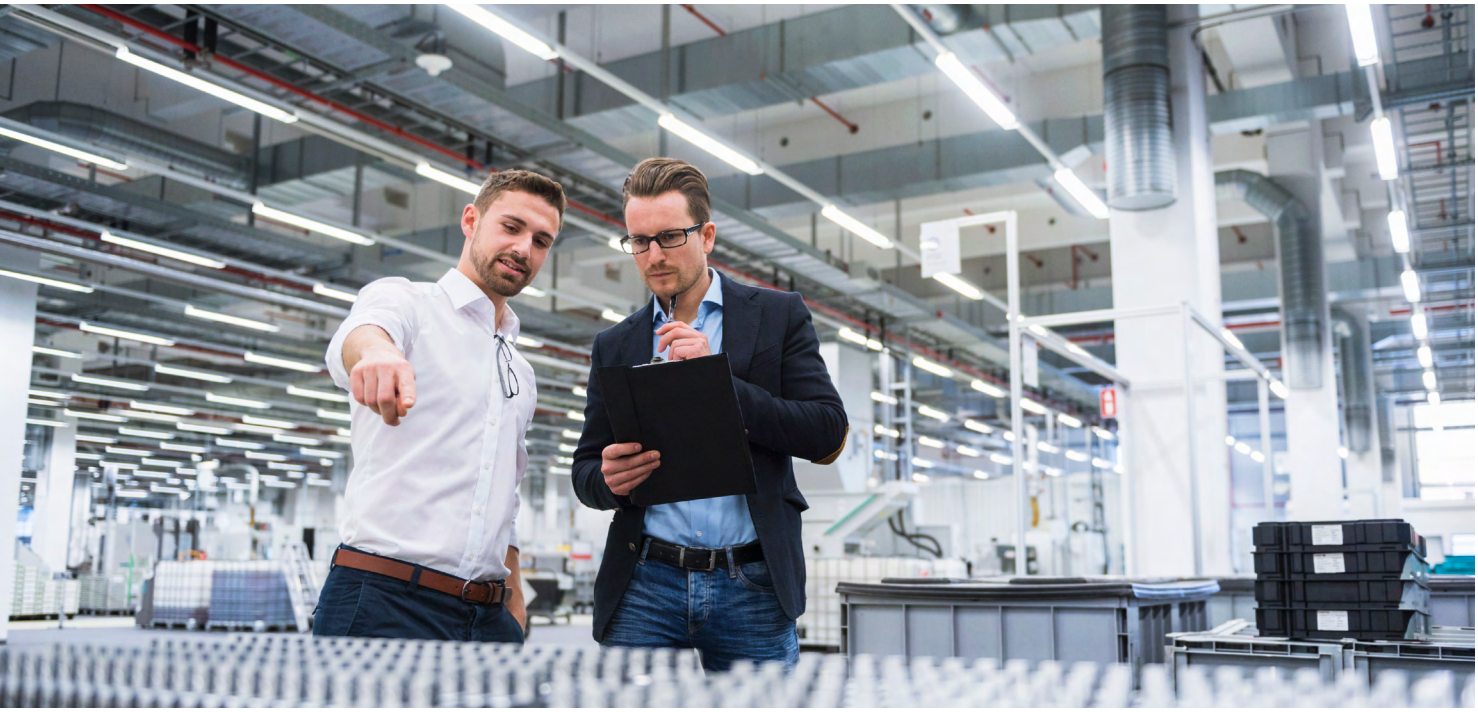
The role of third-party partners in greenfield manufacturing projects

In life sciences greenfield projects, third-party consulting and engineering firms play an essential role across strategic, physical, and digital domains. At the outset, strategic partners assist with capacity analysis, site selection, and business case development, guiding manufacturers to optimize locations and align projects with long-term goals. These firms also provide regulatory and market insights to support effective decision-making for project scope and scale.

During construction, engineering and construction management firms oversee physical elements such as facility design, infrastructure, and equipment installation to ensure compliance with industry standards. CQV providers then verify that facilities meet all regulatory and operational benchmarks, ensuring readiness for production. Meanwhile, digital system integrators embed IT/OT systems, automation, and data integrity solutions, enabling real-time monitoring and efficient workflows.

Other strategy, digital, and technology providers focus on digital integration, operations consulting, and cybersecurity, offering expertise in MES, IT/OT alignment, and automation. Drawing on robust pharmaceutical manufacturing experience, these providers advise on supply chain network optimization and technical transfer, helping manufacturers build scalable networks and ensure seamless production handoffs. Additionally, their cybersecurity services support secure operations and compliance, safeguarding digital assets within the connected environment of pharma 4.0.

This constellation of third-party partners collaborates with manufacturers at each stage of a greenfield project to ensure success. Strategic consultants help set the foundation, guiding capacity planning and site selection, while engineering and construction firms manage the physical build and regulatory compliance. Digital integrators focus on implementing IT/OT systems and automation, creating a connected and responsive manufacturing environment. Meanwhile, experts in CQV and cybersecurity support operational readiness, ensuring that both physical and digital infrastructures meet regulatory and security standards. Working in concert, these specialized partners enable manufacturers to navigate the complexities of greenfield builds efficiently, aligning each component for optimal performance and scalability.



Conclusion: Building the future of life sciences manufacturing

The rise of greenfield manufacturing in the life sciences sector marks a pivotal moment in the industry's evolution, driven by the urgent need for advanced production capacity, regulatory compliance, and rapid innovation in therapies. By investing in new facilities from the ground up, manufacturers are not only addressing immediate market demands but are also laying the groundwork for a future that emphasizes resilience, sustainability, and cutting-edge technology. These greenfield projects go beyond mere expansions; they represent a transformative shift toward operational excellence and adaptability in a highly competitive and regulated environment.

As manufacturers embark on this ambitious journey, a holistic and integrated approach is crucial. From strategic planning and capacity analysis to the seamless integration of physical and digital systems, each element of a greenfield build must be carefully orchestrated. Collaborative partnerships with state and local governments, consulting services firms, equipment and technology vendors, staffing firms and other specialized third-party providers further enhance the potential for success, allowing companies to tap into expertise across engineering, regulatory compliance, digital integration, and cybersecurity. With this collective effort, life sciences manufacturers can transform greenfield facilities into catalysts for innovation, positioning themselves as leaders in delivering high-quality, life-saving therapies to patients around the world.

In embracing the opportunities and addressing the challenges of greenfield builds, the life sciences industry is poised to enter a new era of manufacturing—one defined by sustainable practices, continuous production capabilities, and a workforce prepared for the demands of pharma 4.0. These facilities will not only meet today's production needs but will also be adaptable to future advancements, embodying the agility and foresight required to remain at the forefront of global healthcare innovation.

Continue the Conversation on Greenfield Builds

We invite you to start the conversation with us today. At Capgemini, we offer our expertise in greenfield manufacturing projects, supported by research and insights from the Capgemini Research Institute (CRI). Our team is here to help you navigate the complexities of building state-of-the-art facilities from the ground up. With our understanding of regulatory requirements, advanced digital integration, and sustainable practices, we are ready to partner with you to help transform your vision into reality. Contact us today to learn more about how we can support your greenfield initiatives and drive innovation in life sciences manufacturing. We would love to hear from you.

For more insights, explore our related research from the Capgemini Research Institute:

- https://www.capgemini.com/insights/research-library/advancing-net-zero-for-life-sciences-operations/
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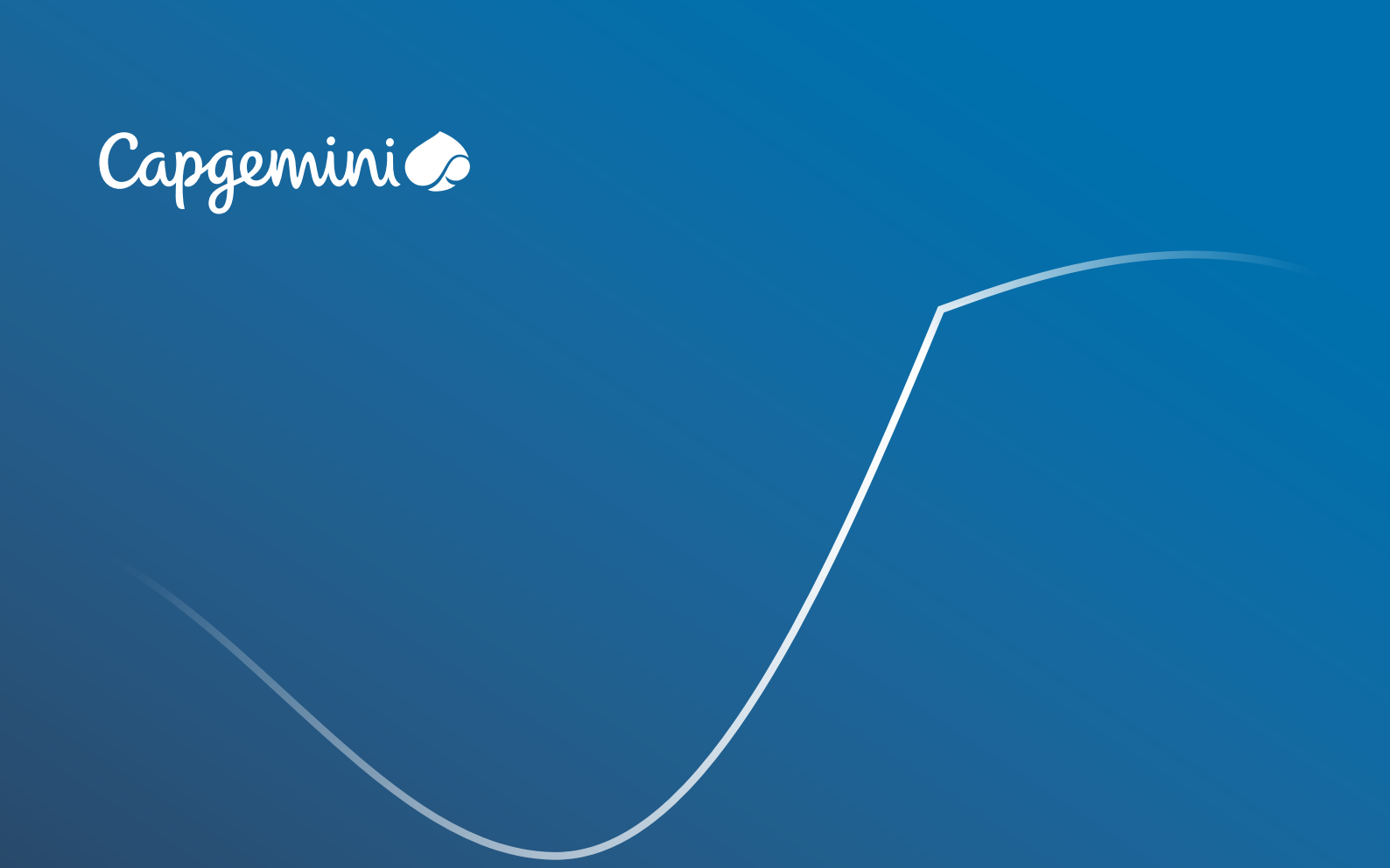

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Capgemini is a global business and technology transformation partner, helping organizations to accelerate their dual transition to a digital and sustainable world, while creating tangible impact for enterprises and society. It is a responsible and diverse group of 340,000 team members in more than 50 countries. With its strong over 55-year heritage, Capgemini is trusted by its clients to unlock the value of technology to address the entire breadth of their business needs. It delivers end-to-end services and solutions leveraging strengths from strategy and design to engineering, all fueled by its market leading capabilities in AI, cloud and data, combined with its deep industry expertise and partner ecosystem. The Group reported 2023 global revenues of €22.5 billion.

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