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The Transformation Taking Place in Life Sciences Facility Development

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Drug and medical technology breakthroughs, data management and integration opportunities, and a growing body of research are pushing the life sciences industry forward at an ever-faster pace. This rapid growth is impacting the facilities constructed by major pharmaceutical companies, drug discovery companies and contract manufacturers in different ways.

The $1.8 trillion life sciences market is growing at an accelerated rate, with pharmaceutical revenues alone on track to expand nearly 40 percent between 2019 and 2024. Medical device, biotechnology and contract research companies are on similar growth protectories.

Many factors are contributing to this growth, from improved access to medicines and an aging global population to higher rates of new drug approval. Small and emerging pharma companies are playing an outsized role in bringing new drugs to market, which is also helping to fuel growth in the outsourcing market. Amid this growth, traditional approaches are being disrupted and new opportunities created by the shift to personalized therapies and the more complicated process controls and logistics they require, along with large-scale digital transformation. Dubbed Pharma 4.0 by the International Society of Pharmaceutical Engineers, this digital transformation will allow life science companies to use data, connectivity, automation, artificial intelligence and analytics to transitions from reactive to more predictive business models.

These market conditions are influencing not only the business cases for the life science work being done but also the facilities built to house these activities. The futures of large multinational pharmaceutical companies, small drug discovery companies and contract manufacturers will all be impacted. As a result, the design and construction services they need are evolving as well. Let's take a closer look at each segment.

Big Pharma

Large, vertically integrated pharmaceutical companies participate in the entire drug pipeline, beginning with drug discovery and clinical trials, through scale up, manufacturing, licensing, distribution and marketing. In addition to traditional therapeutics, their products can now include genetic therapies and molecular organic compounds that regulate biological processes or alter targeted cells.

When a new molecule or cell line shows promise in Phase I and II trials, these companies are prepared to move quickly. They typically do so one of three ways. Those with strong

visibility into Phase I or II clinical results may choose to undertake a greenfield manufacturing project, scheduling completion to coincide with the drug's FDA approval. Others may review existing assets throughout the world that might be re-engineered to produce the new product. A third option is to engage a contract manufacturer for production.

Their ability to identify the most efficient path to full-scale production is aided by inhouse engineering and construction organizations with knowledge of available systems, platforms and manufacturing processes. Not only can they move quickly to scope new projects, but they can also stop them quickly should research findings change.

How Big Pharma Facility Needs Are Changing

When retaining outside design and construction firms, pharmaceutical companies have traditionally sought experienced teams that can turn on a dime to execute against strict production deadlines and goals. The ability to scale up quickly and perform effectively remain key.

But a growing number of large pharmaceutical companies are now also seeking additional help as they embrace Pharma 4.0 and the digital transformation of their operations.

The impact of Pharma 4.0 is far-reaching, touching everything from the qualification and operation of facilities to their design and construction. Interconnected frameworks of resources, information systems and processes will enable companies to anticipate and address potential challenges across the drug development life cycle. The great promise of Pharma 4.0 is improved product quality, process control, quality and supply chain management.

Pharma 4.0 goes hand in hand with the Industry 4.0 concepts currently revolutionizing the manufacturing sector. With Industry 4.0, facilities themselves are also getting smarter. Increased access to real-time data throughout all stages of an asset's lifecycle — from design through to construction and maintenance — can be leveraged to inform materials management, maintenance and other issues. Data from connected machines can also be analyzed to identify patterns and insights that enable life science companies to optimize building performance, save energy and lower production costs.

The intelligent buildings and systems will need to be designed for the more frequent changeovers and smaller batches that will be typical of new personalized therapies. The increased connectivity will also demand greater levels of cybersecurity protections as well.

Life science companies benefit from working with resources that can help guide them through the facility changes this transformation requires. While traditional life sciences architects, engineers and constructors will continue to play acritical role, the niche experience of professionals in cybersecurity, process controls and other Industry 4.0 segments can add significant value to the result.

Drug Discovery Companies

In addition to maintaining their own R&D staffs, major pharmaceutical companies often partner with companies that are dedicated to the discovery and design of new molecules, cell lines and drugs. For example, the partnership between Pfizer and BioNTech, a German immunotherapy company, resulted in the development of a COVID-19 vaccine in record time. In other cases, large pharmaceutical companies expand their portfolios by purchasing small drug discovery companies with products that show promise.

These drug discovery companies work on a very small scale on early-stage drug development. Big Pharma offers these smaller companies a direct path to commercialize their discoveries. Contract development and manufacturing organizations (CDMO) organizations can also support these smaller companies in the scale up and manufacturing of their new product.

Drug discovery companies operate under these arrangements because they allow them to focus on and invest in their science, rather than licensing, drug formulation, manufacturing and distribution — tasks only needed when a discovery proves viable.

How Drug Discovery Facility Needs Are Changing

The primary focus of drug discovery companies is science. When they need lab space for a new project, many are best-served by leasing facilities at universities or other places that cater to early-stage drug discovery. This approach enables them to remain agile. If their discovery efforts bear fruit, they can renew a lease. If they don't, they can move on.

When new labs and other facilities are needed, most seek developers or design/construction partners that understand their needs and can address them efficiently. Some are also interested in resources that can help them implement niche Pharma 4.0 solutions that speed the discovery process. For example, an increasing number are employing AI-driven software that can, among other things, help link genes to diseases and evaluate the possibility of repurposing known drugs to support and speed their efforts.

CMOs and CDMOs

In the same way that the pharmaceutical market relies on drug discovery companies for early drug development, it looks to other companies for later stages of drug development and, when successful, manufacturing. CDMOs provide these services.

They, along with contract manufacturing organizations (CMOs), compete for assignments — often against lower-cost international manufacturers. Some focus on specific technologies or dosage forms to gain a competitive edge. Others may market the efficiency of their operations or end-to-end nature of their services. But all must ultimately respond to a CRO or major pharmaceutical company's Request for Proposal, which means they must ultimately compete on price, quality and their ability to manufacture a product that will pass FDA scrutiny in the fastest manner possible.

How CMO and CDMO Facility Needs Are Changing

Neither CMOs nor CDMOs have the luxury of allowing their production assets to sit idle. Uptime is critical, which creates pressure to win and execute contract awards quickly so they can move to the next project.

A constant challenge is the ever-condensing timeframes between RFP release and manufacturing startup. Visibility to the project pipeline is low; CMOs and CDMOs often only have a limited window into new projects on the horizon. FDA licensing approval can take up to two years for new construction, further constraining schedules.

All these challenges and constraints point to the need for an engineer-procure-construct (EPC) project delivery method that mitigates their cost and schedule risk by enhancing teamwork and value, while reducing upfront time and investment in procurement.

With the EPC method, the owner selects its EPC contractor based predominantly on qualifications, experience and past performance. This shaves time from the procurement timeline, eliminating the need to manage multiple bidders, approaches and proposals. Together the owner and EPC contractor parse through the owner's goals and requirements, looking for opportunities to optimize design and construction, thereby reducing cost, risks and schedule. The result is a project scope, schedule, preliminary design and a Guaranteed Maximum Price (GMP) to complete detailed design and construction.

Summary

A transformation is taking place in life science facility design and construction. But the challenges facing major pharmaceutical companies are different from those of drug discovery companies and contract manufactures. By working with design and construction professionals who understand and appreciate those differences, owners can find an efficient and collaborative path to projects that reflect their vision, needs and budget.

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