MAY 2025
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Bioproduction Capacity

Extending the Biopharmaceutical Industry's Global Reach

by James Choi; Josh Abbott, Shreeyashi Ojha, and Dan Stanton, with Brian Gazaille; and Katarina Stenklo with Helen Huls and Steven Keizer

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Planning for commercial biologic manufacturing is challenging, not least because it entails significant time, investment, and economic risk. As global demand for biologics climbs, drug companies will need to be resourceful to ensure that they can manufacture their products. Herein, *BioProcess Insider* reports on trends in capacity availability, with a particular focus on growth in Asian markets, while other eBook contributors explore strategies for mitigating capacity-related risks.

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The Art of Biomanufacturing

Ensuring Capacity While Managing Risk

James Choi

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Planning for commercial biopharmaceutical manufacturing is challenging. New facilities take years to build, production requires specialized equipment and expertise, and demand for biological products can fluctuate rapidly due to market changes, clinical-trial results, and more. Therefore, the significant financial investment that is required to increase production capacity carries some degree of risk. With many patients relying on such life-improving — and sometimes life-saving — products, the stakes are extremely high. Herein, I discuss effective strategies for mitigating production-capacity risk, and I summarize important factors to consider, especially when the path ahead involves selecting the right contract development and manufacturing organization (CDMO).

Meeting the Demands of a Growing Industry

The biopharmaceutical industry is expected to continue growing rapidly, with Fortune Market Insights projecting that biomanufacturing will be worth US$40 billion by 2033 (**1**). Several factors are driving that increase in the value of biopharmaceutical endeavors. In 2020, the World Health Organization (WHO) reported that people aged 65 and older outnumbered those younger than five years old, indicating an aging global population with increasing healthcare needs (**2**). In addition, demand for traditional biologics, such as monoclonal antibodies (mAbs), has remained stable despite the introduction of new modalities to the market. That trend can be attributed in part to diverse applications of antibody technologies, as can be observed with antibody–drug conjugates (ADCs).

The fields in which biologics are becoming viable options continue to grow as well. Oncology, immunology, and neurology departments now use biopharmaceutical products to address a breadth of diseases (**3, 4**). Moreover, many biologics are receiving label expansions, further driving demand for that class of medicines. For example, since the approval of checkpoint inhibitors for cancer treatment in 2014, the US Food and Drug Administration (FDA) has approved antibody-based products for more than 40 different indications.

To meet growing demand, the biopharmaceutical industry must ensure adequate availability of manufacturing capacity. That means not only increasing the size and number of available facilities, but also improving their efficiency. At the moment, global biopharmaceutical demand is estimated to be around 80%

of total production capacity, ostensibly indicating room to accommodate sudden increases.

However, that statistic does not capture the whole picture. Different biological modalities have different manufacturing requirements. Therefore, high-level capacity projections are likely to overlook production gaps within certain modalities or technologies. Such estimates also fail to account for the logistical reality that excess manufacturing capacity in one location may not be a practical option for production demands in another.

With exciting growth predicted for the industry, manufacturing capacity will need to expand continually throughout the coming years to prevent supply disruptions of crucial therapies. As companies begin to augment their manufacturing capacities, they must decide between building their own plants, outsourcing manufacturing to a CDMO, or exploring a combination of the two approaches. Capacity expansion is a significant investment of both time and money; therefore, companies should consider the best way to reduce risk while maximizing return on investment (RoI).

The Challenges of Building In-House Capacity

In-house manufacturing can be appealing to companies seeking to maintain control over key processes or to maximize perceived cost savings. However, several challenges to in-house production need to be considered alongside the approach's potential benefits.

Building new manufacturing plants for a given product is an investment that easily can exceed hundreds of millions US dollars. Capital will be tied up in construction, testing, and staff training for years before drug production can begin, exposing companies to significant risk in a market that shifts constantly. If new competition emerges or demand for a product decreases unexpectedly, a developer will be left struggling to repurpose a facility that no longer matches its needs. All too often, that capacity sits idle.

The technical nature of biologics production also can limit a company's ability to pivot. Plants producing biologics usually are designed to make a specific type of product or family of related molecules. If demand for one product class falls below projected numbers, finding a suitable alternative to manufacture within the constraints of a facility's specifications can be difficult. And risks for inaccurate projections and competing products increase when timelines are prolonged. Many biopharmaceutical companies will find that CDMOs have the necessary expertise and well-established practices to help them build production capacity much faster than they could internally.

CDMOs increasingly are considered to be valuable contributors in the biopharmaceutical ecosystem because they offer ways to share the risks of investing in manufacturing capacity. Top CDMOs can adapt to changing production demands, and they are better equipped than developers are to ensure that manufacturing capacity is available when and where it is needed. Although

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Contract development and manufacturing organizations increasingly are considered to be valuable contributors in the biopharmaceutical ecosystem because they offer ways to **SHARE THE RISKS** of investing in manufacturing capacity.

outsourcing dynamics benefit all parties involved, CDMO partnerships still involve a significant investment, so it is critical for companies to choose the right partner.

Finding the Right CDMO

Just as patients should expect reliable, high-quality medicines, biopharmaceutical companies should expect reliable CDMO partners. A developer should examine a candidate CDMO's track record to ensure that it delivers quality products consistently and efficiently. Some important indicators include high batch-success rates, a solid track record of regulatory approvals, and excellent technology-transfer protocols. Developers also should vet CDMOs to confirm that they will provide on-time capacity expansions when demand for a product increases.

Adjusting to new market conditions requires both flexibility and agility from a CDMO partner. CDMO facilities should be comprehensive and designed for effective manufacture of different molecules, including new and emerging modalities, such as ADCs. Broad experience in biologics is not enough when cytotoxic payloads and linker technology are involved, and entirely new supply chains need to be established. A CMDO partner also must be able to offer speed in facility construction and validation, vendor management, and technology transfers so that products can be made commercially available as soon as possible. Often, such speed comes down to empowering dedicated employees.

Biopharmaceutical companies naturally will want to work with the best in the field, and it is important to evaluate whether potential CDMO partners are recruiting skilled employees to their manufacturing science and technology (MSAT) teams. But even more important than individual hires is a CDMO's culture. Quality should be more than just a goal; it should be a mindset. True operational excellence comes when a company promotes quality throughout its entire operation. If a manufacturer prioritizes quality in all aspects of its business, from customer service to product management, then a prospective customer can be confident that final products and services will meet a high standard.

It is important also to assess a CDMO partner for financial and corporate stability. Drug development and manufacturing collaborations represent long-term partnerships. A CDMO should be prepared to invest in new technologies, facilities, and expertise as both companies grow. Finding a CDMO that meets all of the above criteria will be beneficial to a drug developer and, ultimately, to patients receiving treatment.

The Right Time Is Now

Reserving capacity for biomanufacturing can be a complicated endeavor for biopharmaceutical companies. Making accurate predictions that will stand the test of time can be difficult when dealing with a dynamic landscape. Building up in-house capacity

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True operational excellence comes when a company promotes **QUALITY** throughout its **ENTIRE** operation.

often can be cost-prohibitive and present undesirable risk. But with an experienced CDMO, such problems can be alleviated. An advanced, reliable, and adaptable partner can provide the stable platform that a customer needs to make innovative medicines happen. Regardless of where a client is in a given product life cycle, the doors to a trusted CDMO partnership will be open.

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Emerging Capacity in Asia

Opportunities Blossom for Establishing Global Bioproduction Capabilities

Josh Abbott, Shreeyashi Ojha, and Dan Stanton, with Brian Gazaille

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Drug developers and biomanufacturers increasingly are turning to Asia to cultivate global production capacity. In some cases, companies based in Asia intend to fill growing demand for novel therapeutics in their respective countries or regions. In other cases, organizations from the United States, Europe, and elsewhere seek to leverage operational benefits from multinational footprints. No matter the reason, seeds sown over the past few years now are budding as biocapacity comes online.

Growth in the Asian biomanufacturing space is neither new nor unexpected. The BioPlan Associates *Top 1000 Biofacility Index and Biomanufacturers Database* indicates that production capacity has been growing significantly in China and India for over a decade — and certainly began well before the COVID-19 pandemic, which confounded global supply chains and compelled companies to investigate regional capacity strategies (**1–3**). According to Smita Khanna (biopharmaceutical industry and healthcare market researcher/analyst, as well as director of technical research at BioPlan Associates), several factors have contributed to growth in those countries, including expansion of capabilities from those focused on generic small-molecule drugs to address needs for producing complex medicines, such as biosimilars and vaccines (**1**). Low prices, changing government policies, incentives for domestic manufacturing, and growing service capabilities have helped, too.

Current geopolitical circumstances could provide additional impetus to establish operations in Asia. Uncertainty continues to destabilize global markets as the United States federal government wavers about imposing "reciprocal tariffs" on imports (**4**). Although pharmaceuticals were not among the initial list of affected products, a separate tariff policy remains in the works. In many cases, tariff threats have incentivized companies to establish US footprints or reallocate resources to current US assets (**4**). However, the vacillations of the American government also could incentivize biomanufacturers to set up shop elsewhere — e.g., in India and other regions with growing infrastructure and markets.

Politics aside, news continues to pour in regarding Asia as an attractive option for establishing or supplementing production capabilities. In just the first quarter of 2025, *BioProcess Insider* has reported on multiple capacity developments in Asia, particularly in Japan and India. Below are salient reports, lightly edited, that

highlight biopharmaceutical-industry activity in and by those countries, as well as development prospects in the Middle East.

Setting Up Shop in Japan

Big in Japan — AGC To Install 5000-L Single-Use Bioreactors: Contract development and manufacturing organization (CDMO) AGC Biologics is adding two 5000-L single-use bioreactors (SUBs) at its plant in Yokohama, Japan. The US-based company broke ground on a four-story, 20,000-m^2 facility in January 2024 (**5**). Representing an investment of ¥50 billion (US$325 million), the plant will deal in mammalian-cell–expressed protein biologics, cell therapies, and messenger RNA (mRNA). It is expected to create 400 jobs locally.

Initially, the facility was expected to include multiple 2000-L and 4000-L SUBs. However, in a press release issued in April 2025, the CDMO confirmed that it also will install two 5000-L DynaDrive SUB systems from Thermo Fisher Scientific (**6**). The facility is slated to be operational by 2026, with good manufacturing practice (GMP) operations set to begin in 2027.

"The Yokohama site is designed to utilize SUBs to offer large-scale GMP manufacturing," said Christoph Winterhalter, chief business officer of AGC Biologics (**6**). "This location offers the capabilities to meet the commercial needs of customers in Japan and Asia, as well as global customers seeking capacity using the latest technology."

Thermo Fisher Scientific launched 3000-L and 5000-L HyPerforma DynaDrive SUB systems in 2021. According to the company, DynaDrive technology can decrease production costs by up to 25% through reductions in equipment, materials, consumables, and labor. In 2023, Aslan Pharmaceuticals partnered with Thermo Fisher to use such a system to produce its atopic eczema candidate, eblasakimab (**7**).

Daniella Cramp, president of Thermo Fisher's bioproduction business, said that the 5000-L format "is scalable, is flexible, and provides superior process intensification capabilities. AGC Biologics' site in Yokohama will be a premiere site in Japan for large-scale single-use technology thanks to our collaboration."

AGC already operates a facility in Chiba, Japan, about 70 km northeast of Yokohama. That site offers services for both mammalian-cell expression and microbial fermentation.

Kyowa Kirin Bolsters Biomanufacturing Footprint with $118 Million Plant: Japan-based Kyowa Kirin has opened a drug-substance facility at its manufacturing site in Takasaki, Japan, about 100 km northwest of Tokyo. Representing an investment of ¥16.8 billion ($118 million), the 510,000-ft^2 facility will use Kyowa's antibody technology and protein-engineering capabilities to manufacture drug substances. The GMP-compliant plant will leverage single-use technology to reduce risks of cross-contamination across products.

The site houses a training facility for biopharmaceutical manufacturing and quality control (QC), with an aim to provide

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*Find the original article, written by **Shreeyashi Ojha**, at https://www.bioprocessintl.com/facilities-capacity/big-in-japan-agc-installing-5-000-l-single-use-bioreactors.*

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*Find the original article, written by **Shreeyashi Ojha**, at https://www.bioprocessintl.com/facilities-capacity/kyowa-kirin-bolsters-biomanufacturing-footprint-with-118m-japan-plant.*

programs that combine practical and classroom-based learning. The building has additional space for future expansions to introduce continuous production, automation, and digitization.

"I am extremely pleased that the construction is now completed in the Takasaki plant," said Toshiyuki Kurata, chief supply-chain officer (CSCO) of Kyowa Kirin (**8**). Soon to join that facility is another under construction in Sanford, NC (**9**). Announced in March 2024, the 171,700-ft^2 Sanford facility will house two bioreactors (capacity not disclosed) to advance investigational drug production across multiple therapeutic areas, including hematology, oncology, ophthalmology, dermatology, and autoimmune diseases. "By establishing a global manufacturing structure," Kurata explained, "we aim to further accelerate drug development by manufacturing in-house drug substances, from early- to late-stage development and the initial stages of market launch."

In July 2024, Kyowa Kirin joined the Pharmaceutical Supply Chain Initiative (PSCI) to develop and maintain a robust supply chain until 2030 (**10**). PSCI is a nonprofit organization established in the United States in 2013 (**11**). To date, it has more than 80 member organizations.

India's Continuing Growth into a Strategic Biomanufacturing Hub

Shilpa Leveraging Mammalian and 200-kL Microbial Capacity To Enter CDMO Space: Based in Karnataka, India, Shilpa Medicare made the rounds on the global conference circuit in March 2025, telling delegates at both the Drug, Chemical & Associated Technologies Association (DCAT) and BIO-Europe Spring events about the company's jump into the CDMO space (**12**). Specifically, Shilpa unveiled a "hybrid CDMO" service forged by bringing together its microbial and mammalian biologics capabilities.

Despite the busy public-relations push, *BioProcess Insider* caught up by email with Shilpa chief executive officer (CEO) Sridevi Khambhampaty, who wrote that her company seeks to capitalize on resurging biotechnology funding and the growing trend for supply-chain diversification: "Biotech funding is making a comeback, and many companies are looking for reliable partners who can scale with them from early stage development to commercialization." She added, "India is increasingly seen as a strategic hub for high-quality, cost-effective biologics manufacturing," feeding current demand for diverse supply chains (**13**).

Shilpa's move into the CDMO space might be recent, but it quietly has been building up its manufacturing capabilities for nearly a decade. "We started our biologics journey in 2016, when we acquired Navya Biologicals Private Limited, a startup that had a few biologics assets in early development," Khambhampaty explained. "As we started building our manufacturing capability, we recognized the need for large-volume microbial production for

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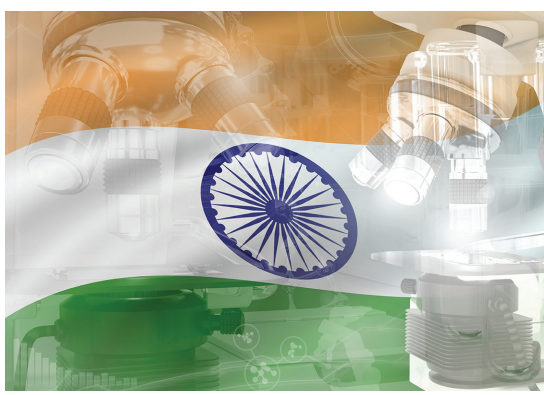
*Find the original article, written by **Dan Stanton**, at https://www.bioprocessintl.com/facilities-capacity/shilpa-leveraging-mammalian-and-200kl-microbial-capacity-to-enter-cdmo-space.*



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one of the assets: recombinant human serum albumin, a much-needed product frequently in shortage in many countries globally."

The company also set up capacity for mammalian-cell–culture products after the COVID-19 pandemic, having recognized the need for vaccine and biologics drug-substance manufacturing and fill–finish, Khambhampaty continued. "As we started building our internal product portfolio and servicing CDMO customers, we have formally recognized the need to structure ourselves and share our working model as a hybrid CDMO."

For biologics, Shilpa operates a dedicated facility covering drug-substance production, drug-product manufacturing, and final-product packaging. Along with 8000 L of single-use mammalian-culture capacity, which the company plans to increase to 16,000 L, Shilpa has established a facility with 200,000 L of microbial-fermentation capacity. The plant is expected to be operational later in 2025. Once it is open, Shilpa will offer the largest volume of microbial capabilities for therapeutic production in India — and one of the largest volumes among CDMOs globally.

That capacity can serve small-protein, enzyme, and peptide projects. "We are seeing increasing interest in these areas," Khambhampaty said. "Insulins and GLP-1s [glucagon-like peptide 1 agonists] are required in large volumes, and we have several requests for our microbial capacity for those products." According to Khambhampaty, the fermentation capacity is easily exchangeable between GLP-1s and other small biologics.

Shilpa has engaged several customers that are working toward investigational new drug (IND) filings. "We are able to cater to their requirements well. We do not foresee a challenge with our capacity for the next three years to serve our CDMO customers."

Enzene's India Site Secures GMP, Eyes US Growth: CDMO Enzene has received European Medicines Agency (EMA) certification for GMP at two of its facilities in Pune, India. Spanning 135,000 ft^2, those facilities offer both microbial and mammalian culture capabilities. With six production suites supporting fed-batch and continuous processes (20–2000 L), the company can produce up to 30 kg of monoclonal antibody (mAb) per month. Meanwhile, Enzene's drug-product facility provides automated vial, syringe, and cartridge filling. The facilities hold EU-GMP certification for both drug-substance manufacturing and fill–finish operations.

"With our Pune facility now certified by the EMA, Enzene is well positioned to accelerate its global growth trajectory," a spokesperson for the company told *BioProcess Insider*. "This certification opens new pathways for supplying biologics to regulated markets across Europe and beyond." The spokesperson added, "In India, our long-term plan is to continue strengthening our capabilities across discovery, development, and manufacturing, with a particular focus on scaling our fully connected continuous manufacturing (FCCM) technology."

The EnzeneX 2.0 platform with FCCM technology is designed to reduce production costs by 50%, the Enzene representative said.

*Find the original article, written by **Shreeyashi Ojha**, at https://www.bioprocessintl.com/facilities-capacity/enzene-s-india-site-secures-gmp-eyes-us-growth.*

Initially scaled at 200–500 L, the platform's capacity has expanded to 1000 L, and the company expects in 2025 to produce up to 40 kg of mAb/1000-L batch at a cost of US$40/g. According to the company, the EnzeneX 2.0 platform integrates advanced automation and machine learning/artificial intelligence (ML/AI) to enhance process efficiency, maintain product quality, and reduce waste. "Its predictive analytics optimize yield, minimize batch failures, and improve biologics production, including for complex proteins."

FCCM technology soon will be available at the company's New Jersey site. A subsidiary of Alkem Laboratories, Enzene took its first steps outside India in June 2023, opening a biopharmaceutical manufacturing plant on the Princeton West Innovation Campus in Hopewell, NJ (**14**). In January 2024, it leased a 54,000-ft^2 space, also in New Jersey, for multiple lines of its EnzeneX platform (**15**).

"In the US, we already have two operational production lines at our site in Hopewell, and the facility has space for four more. Our goal over the next two years is to have all six lines fully operational," the spokesperson said. "Given the global shortage in drug-product supply, and especially with GLP-1 drugs creating significant demand, we are also considering adding fill–finish capabilities at the site. We may explore further expansion too, potentially on the US west coast or in Europe."

Bharat Biotech Opens $75 Million CGT Facility in India: Bharat Biotech International has opened a 50,000-ft^2 cell and gene therapy (CGT) facility in Genome Valley, Hyderabad, India. Representing an investment of $75 million, the facility will focus on advanced viral-vector manufacturing, including high-titer production of adenoassociated virus (AAV), lentivirus (LV), and adenovirus (Ad), all of which represent essential components for CGTs.

Bharat Biotech anticipates launching its first therapy for critical conditions, including hematological malignancies and inherited blood disorders, by 2028. "CGTs represent some of the most intricate, scientifically advanced treatments available today, involving sophisticated processes that require expertise in precise genetic manipulation and specialized manufacturing capabilities," said Krishna Ella (executive chairman of Bharat Biotech) (**16**).

Talking about the impetus behind the expansion, Ella said that Bharat Biotech aims to produce human-grade vectors for clinical trials and thereby position India at the forefront of the global fight against rare and complex diseases. "Bharat aims to democratize gene therapies. Our established expertise in producing viral vectors is essential for CGT applications," with such delivery systems representing "crucial material for [treating] cancer and genetic disorders." She also highlighted the company's robust clinical development abilities for QC release.

Bharat Biotech's chief development officer (CDO), Raches Ella, added, "The facility has the capacity to manufacture multiple platform products for various disease indications. It will support a wide array of advanced therapies, including CD19 CAR-T [chimeric antigen receptor–T] cell therapy for blood cancers and gene therapy."

*Find the original article, written by **Shreeyashi Ojha**, at https://www.bioprocessintl.com/facilities-capacity/bharat-biotech-opens-75m-cgt-facility-in-india.*

In a press release, Bharat Biotech reported partnering with Pune-based Mylab Discovery Solutions to develop CAR-T cell therapies using AI. According to Krishanu Saha (professor of biomedical engineering at the University of Wisconsin), whose laboratory is involved in the collaboration, "Innovations in biomanufacturing for potentially curative CGTs originate worldwide. It's thrilling to witness the expertise and commitment to developing and scaling novel ideas in India, particularly at Bharat Biotech."

India in the CGT Space: Compared with its global counterparts, India remains in the early stages of CGT development. However, in 2021, the country's Department of Biotechnology (DBT) successfully administered its first CAR-T cell therapy to patients with acute lymphocytic leukemia at Tata Hospital Mumbai's Advanced Centre for Treatment, Research and Education in Cancer (ACTREC) (**17**). As India embarked on its journey to provide affordable medicines, that trial marked the country's first successful CAR-T treatments.

That achievement was followed in October 2023 by the Central Drugs Standard Control Organisation (CDSCO) granting marketing authorization to ImmunoACT for NexCAR19 (actalycabtagene autoleucel), a humanized CD19-targeted CAR-T therapy (**18**). The NexCAR19 product treats patients with relapsed or refractory B-cell lymphomas and leukemia. CDSCO approval was based on a multicenter phase 1–2 clinical trial involving 60 patients, results from which demonstrated an overall response rate of about 70% and a favorable safety profile.

In January 2025, Bengaluru-based startup Immuneel Therapeutics received CDSCO approval for its Qartemi (varnimcabtagene autoleucel), a personalized CAR-T therapy targeting advanced or relapsed B-cell non-Hodgkin lymphoma (B-NHL) (**19**). The approval followed the IMAGINE trial, which reported an 83.3% overall response rate.

Emerging Capabilities Among Persian Gulf States

Burjeel and Caring Cross Team Up To Optimize CAR-T Production in the United Arab Emirates (UAE): As high list prices for advanced therapies raise eyebrows, drug makers in the Middle East are partnering to drive down costs and improve patient access. In April 2025, Burjeel Holdings announced an agreement with US nonprofit Caring Cross to manufacture low-cost CAR-T therapies in the UAE.

Burjeel seeks to establish a GMP facility in Abu Dhabi, according to Ajlan Al Zaki, director of the Burjeel Hematology Oncology and Cellular Therapy Center. Al Zaki told *BioProcess Insider* that the "facility will be capable of processing up to 200 samples simultaneously, enabling the local delivery of cellular products."

Boro Dropulić, CEO of Caring Cross, added that the UAE is making a number of strategic investments to position itself as a regional leader in advanced biomanufacturing. His words echo those of Andrew Harmon, who spoke about the Middle East's

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*Find the original article, written by **Josh Abbott**, at https://www.bioprocessintl.com/deal-making/burjeel-and-caring-cross-team-to-optimize-car-t-production-in-uae.*

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biomanufacturing ambitions at the March 2025 BioProcess International West Conference in San Diego, CA (**21**). During a panel discussion, Harmon discussed how manufacturing hubs have changed in the wake of the COVID-19 pandemic, then shared that countries in the Middle East are poised to thrive.

Dropulić added that the UAE is working to create a favorable regulatory environment while investing in skilled workforce development. "The country is demonstrating a strong commitment to health equity by exploring decentralized, point-of-care manufacturing solutions that can deliver lifesaving therapies, such as CAR-T, at a sustainable cost and with localized control," he said. "These steps align closely with the UAE's long-term vision for healthcare innovation and regional resilience in medicine manufacturing."

He credits decentralized, point-of-care manufacturing as one of several factors that could reduce production costs for CAR-T therapies. "By enabling hospitals and regional centers to manufacture therapies onsite or near patients, we avoid many of the logistical and commercial markup costs associated with centralized models."

The Burjeel–Caring Cross partnership aims to combine manufacturing capability with successful technology transfers and knowledge sharing among local collaborators. "As a nonprofit," Dropulić said, "we reinvest resources into innovations that prioritize patient access and cost reduction, rather than focusing upon shareholder value."

Creating the Patient Experience: "Patients will undergo a rigorous screening process to ensure that they meet the eligibility criteria," Al Zaki told us. After a thorough orientation that outlines the entire treatment process, patients will have the opportunity to provide informed consent. "Each patient will be assigned a dedicated patient navigator to guide them throughout the journey." He added, "We will also collaborate with patient advocacy groups who will share their own experiences with CAR-T therapy and help address any additional questions that patients may have."

As manufacturing nears completion, patients will undergo lymphodepleting chemotherapy to prepare for CAR-T administration. After about seven days of in-patient observation for toxicity events, treated patients will be discharged and monitored in an out-patient setting twice a week for up to 30 days.

Global Collaboration: The partners hope that their work helps to pioneer improved CAR-T manufacturing methods that can be emulated globally thanks to collaborations with organizations in the United States, Europe, and Brazil.

Dropulić said that Caring Cross and Burjeel Holdings are working with hospitals, academic institutions, and national health ministries to bring manufacturing capacity closer to patients. He emphasized the importance of infrastructural investment, collaborative technology transfer, and policy alignment when working with regulators. "Caring Cross is committed to working

with governments and healthcare institutions around the world to make this vision a reality."

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Step Up to GMP Manufacturing or Outsource to a CDMO

Considerations and Tips

Katarina Stenklo with Helen Huls and Steven Keizer

Whether you are developing a new monoclonal antibody (mAb), cell therapy, gene therapy, or other large-molecule biologic, the decision to perform good manufacturing practice (GMP) manufacturing in house or to work with a contract development and manufacturing organization (CDMO) represents a pivotal crossroads in your product's journey to market (**1–3**). Below, we discuss key considerations to help you determine which strategy better suits your process, product, and team.

Getting GMP Ready for In-House Manufacturing

In-house manufacturing offers the appeal of having complete control over your product. Such an approach can provide long-term cost benefits. But are you and your team ready to take on the demands of GMP compliance? Here, we map out some general considerations and tips for succeeding in GMP manufacturing.

Learn the ABCs of GMP: *Good manufacturing practice* refers to specific manufacturing procedures required by countries and international organizations. The Food and Drug Administration (FDA) oversees GMP certification for drug development in the United States by enforcing current GMP (CGMP) guidelines (**4**). They provide a regulatory framework for making biological products of sufficiently high quality through proper design, control, and monitoring of processes and facilities. A manufacturing transition mandates compliance with GMP standards to ensure that treatments are safe and meet quality specifications.

"Compliance with governmental regulations is not something you choose to do," explains independent consultant Helen Huls. "It is something you must do if you plan to produce cellular therapies or other biologics approved for human use. Although [rigorous], the process is not difficult. If a laboratory has even an inkling that manufacturing may occur, they should start to plan and organize their body of work in a compliant manner." Huls adds that it is never too early to start establishing GMP compliance: "Regulatory approval is needed before a product can be infused into a patient. All relevant requirements must be met, and a safe-to-proceed letter received from the appropriate government authority."

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Chronicle automation software provides a unified digital platform to monitor cell-therapy manufacturing, operations, and supply-chain logistics.

Although GMP guidelines seem complex to understand and execute, they represent the minimal requirements for compliance. Regulations are purposefully flexible to offer manufacturers latitude on how best to implement necessary controls and continually improve upon them.

"The framework is not specific to any one type of biologic or cellular therapy; it is a way of doing manufacturing," says Steven Keizer, director of quality and GMP program manager at the Centre for Commercialization of Regenerative Medicine (CCRM) in Toronto, ON. "Processes need to be under control and perform as expected." To that end, Keizer observes, "You need to say what you want to do before you do it, do exactly what you said you were going to do, be able to prove it, and also be able to improve on the system. Manufacturing under GMP should be very boring and repetitive. When it is exciting, it typically means that something is wrong."

Build a Team That Understands GMP: A new production line typically will require significant investment into infrastructure, capacity, and resources. Compliance with GMP requirements needs to be a primary focus early on and throughout process development and manufacturing. All employees must understand the importance of GMP regulations and commit to upholding them consistently.

When building a production line from laboratory-based processes, keep in mind that staff who are primarily familiar with research might not know the specifics of regulations for late-stage drug production. Hiring manufacturing, quality assurance (QA), and quality control (QC) teams that are experienced with GMP principles can help your organization to ensure appropriate incorporation of regulations across the board. If limited budget or timing does not allow for building proficient internal groups, then consultants can help you to navigate complex compliance requirements.

Focus on Quality from the Start: Your team must build quality into facility design and manufacturing at every step to prevent problems and delays. Huls suggests incorporating a strong quality management system (QMS) that captures written procedures to manage manufacturing oversight. Appropriate reviews and approval processes should be in place, and your group should review and understand the testing criteria for meaningful measures of sterility, identity, purity, and potency. Quality systems are expensive and require time and resources, but they are invaluable in mitigating and addressing problems.

"The amount of documentation can be intimidating initially," says Huls. "A well-structured data and implementation plan will help to move the process forward smoothly. Expect new items to emerge that will need resolution."

A QMS comprises the documents, systems, and facilities involved in a product's manufacture. Documentation must be in place to back up label claims, and GMP-compliant procedures must be followed the same way every time. A QMS and its associated

"Manufacturing under GMP should be very boring and repetitive. When it is **EXCITING,** it typically means that something is **WRONG**."

—S. Keizer

software serve as an umbrella that covers quality, manufacturing, and marketing personnel to ensure that all are performing to established standards.

The field of biotherapeutic production is still developing the ins and outs of manufacturing, so a QMS needs the ability to evolve. Additionally, the amount of product needed for phase 1–2 clinical trials is low, limiting learning in early stages of development. A complex manufacturing process might be difficult to reproduce at scale, so a program should emphasize the importance of continual optimization to guide system direction.

Keizer uses the European Commission GMP guideline for advanced-therapy medicinal products (ATMPs) to develop the CCRM's framework (**5**). That regulation is entirely risk based and demonstrates broad understanding of regulatory changes that are needed to ensure that cellular therapies can get off the ground.

Huls shares the following related example for US work: "The FDA requires assurances about access to GMP-grade raw materials and reagents. With the appropriate validation procedures and prior discussions with the FDA, instances may be approved where 'for research use only' (RUO) products can be used if GMP-grade is not available. The decision is data driven; the FDA has the final say."

"If you want people to walk a certain path, you have to provide ways for them to stay on that path," Keizer adds. "To change behavior is challenging, and GMP includes a lot of behavior management. You have to choose between new procedures, new training, or new engineered solutions. Then you must monitor to ensure the change has the desired effect." At the same time, changes must be manageable: "You do not want your system to be cumbersome so people just push paper around all day, and you want the system to be highly visible so you or an outsider immediately know when something is out of control." Achieving the right balance "is an art and a science."

Other hurdles come from onsite audits, a standard business practice required by relevant health authorities. "You prepare all the time for the inspections. To make a facility auditable, the system must be transparent to easily reveal the level of compliance," Keizer explains. "Expect some human and minor documentation issues. But if an audit uncovers an issue with data integrity, that is a signal that the implemented system is not strong enough to handle the manufacturing processes. Data must be readable, easily retrievable, and permanent. Automated testing and manufacturing systems controls have to be properly in place to assure data integrity."

Automate and Close Biotherapy Manufacturing: In transitioning from lab-bench processes to manufacturing, underestimating scalability is common. Research scientists might be unfamiliar with manufacturing equipment. Or they might not have considered the logistics of preserving biologic integrity over time, transporting drug products safely, controlling documentation, and maintaining chain of custody. Those are critical factors in demonstrating product control.

"Expect some human and minor documentation issues. But if an audit uncovers an issue with **DATA INTEGRITY,** that is a signal that the implemented system is not strong enough to handle the manufacturing processes."

—S. Keizer

"Autologous cell therapy is a tough product," Huls says. "Consider the variability of the starting material of each patient; one size does not fit all. You have to prove that operating procedures for manufacturing processes are reproducible [and] that you are able to detect and investigate product quality and deviations." Companies also need to maintain reliable testing laboratories.

Regulatory agencies will want to see functionally closed manufacturing processes to minimize contamination during biotherapeutic production. Automation also eliminates variability from manual processes (**6**). Automated instruments promote process and product standardization because they are programmed to operate consistently. With added digital capabilities, you can monitor, measure, track, and promptly address deviations to maintain product quality. The opening photo to this article provides an example of a comprehensive cell-therapy automation platform (**7**).

Huls adds, "Scientists are invariably problem solvers." In manual processes, they often will fix problems without documenting their actions properly. "That is great for R&D," Huls says, "but for manufacturing, you need continual improvement. An automated system provides the data traceability to let you perform true root-cause analysis."

"Scientists are invariably problem solvers. . . . That is great for R&D, but for manufacturing you need **CONTINUAL IMPROVEMENT.** An automated system provides the data traceability to let you perform true root-cause analysis."

—H. Huls

Outsourcing with a CDMO

Rigorous regulations are in place for biotherapeutic production to ensure that only safe and effective treatments are tested in clinical trials. Achieving compliance can require more expertise and resources than you have available, making outsourcing an appealing option for quickly generating critical data or materials relevant to your next milestone. Here, we outline some of the many key factors to consider and obstacles to overcome when choosing to work with a CDMO (**8**).

Consider a CDMO if You Find the Right Fit: Finding a services provider that has both expertise and open capacity to develop and manufacture your product might be more challenging than you think. Capacity is increasing continuously to meet demand, but CDMO wait times can be 12–24 months (**9, 10**). That length of time might be prohibitive to bringing therapies to patients in need and could require creative workarounds to keep your process moving forward. You could find yourself paying large sums to secure capacity slots, far in advance of when you will require support and with the added pressure and risk that you might not be ready once the CDMO's services become available.

If you can wait for capacity to become available or if your strategy is based on unpredictable demand, leveraging CDMO support can lessen risks associated with building infrastructure. Working with a CDMO also can tighten cash flow internally before having a commitment that a drug product will meet approval in the market space. However, when speed to clinical trials is most important, recent advancements in modular facility designs can halve time to market (**11**).

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Lay a Strong Project Foundation: From the initiation of a partnership, your organization and a CDMO must work together to define project goals, clearly outline how the CDMO can help to execute your business strategy, and specify how information will be transferred between teams (**12**). Establishing a documented project plan and standard operating procedures encourages effective collaboration, sets individual roles and responsibilities, and facilitates an efficient handover process.

For milestones and deliverables, your organization and the CDMO should set and agree upon timelines so that you can track a project's pace and ensure its consistency with expectations. Change orders and contingencies are typical. Be prepared to revise and replan because the biology of a process can influence its pace of development. Create trust and drive teamwork by being adaptable and willing to negotiate during development.

Collaborate for Success: A drug developer and CDMO must operate as one team. Effective communication eliminates delays and misunderstandings that can create frustration and errors (**13**). When vetting CDMOs for your project, inquire about communication structures. CDMOs that do not outline plans for effective communication can compromise the strength and cohesiveness of your partnership.

Mutual respect comes from working side by side to understand how a CDMO's services are supplementing — rather than replacing — the expertise within your organization. You and your CDMO will work together to foster process improvement and facilitate knowledge transfer. Build training into your plans so that it occurs throughout your project and so that less time will be spent on training toward the end of the program. Such transparency gives you the ability to work autonomously when you return to your facility.

Reaping the benefits of an experienced CDMO that values transparency and open lines of communication can provide a path to market for high-risk, difficult-to-manufacture biotherapeutics. Such organizations offer expertise in developing safe and compliant production processes that can provide security and longevity to achieve commercial success.

Outline How To Protect Your Intellectual Property (IP): Working with a CDMO means sharing valuable knowledge and data about your product and process. Ownership of biotherapeutic IP almost always resides with a program sponsor, but you should establish upfront whether your partnership will involve co-ownership or exclusive ownership of the techniques, process, and platform technologies involved.

You might want some information blinded in a black-box approach to protect your product's critical quality attributes (CQAs). In such a scenario, a CDMO receives samples from its customer to test and has an open relationship about the CQAs without knowing what they are. Some cell-therapy CDMOs will not want to work that way because doing so complicates process development. Such

CDMOs might also be seeking long-term relationships in which they ultimately manufacture your commercial product. If you want to take a black-box approach, a CDMO's lack of internal capability or unwillingness to execute could indicate a poor fit for your project.

Choosing Your Drug's Best Path Forward

The promise of recent scientific discoveries and medical breakthroughs will reach a dead-end without compliant, efficient manufacturing processes. Taking time to critically evaluate the best arena for developing and executing your production plan is a pivotal part of the biotherapeutic approval process. Whether in house or with a CDMO, find the development strategy that fits your business and facilitates your product's journey to the clinic. The patients waiting there will thank you.

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