

From frustration to innovation: a CDMO's mission to empower emerging biotechs

Capacity, capacity, capacity. This seems to be all the industry talks about. A global pandemic magnified the need for more biologics manufacturing capacity. Capacity, however, isn't the whole story

I was always able to find capacity. What I couldn't find was a contract development and manufacturing organisation (CDMO) that treated us as a partner and took our small programmes seriously. I know this from founding multiple biotech companies that worked with many CDMOs. Even when I did find capacity, it was never a satisfying experience. Personal attention, responsiveness, quality, flexibility and ease of communication should be table stakes in any biomanufacturing partnership. But my companies had small-volume programmes that were nothing more than an afterthought. Overall, we were spending massive amounts of money on manufacturing, but were not getting the attention we needed and deserved.

We could never compete with big pharma clients whose programmes had billings that were a hundred times more than our start-up. My innovator companies were handing our life's work over to manufacturing partners, only to realise that our small-volume or early stage programme wasn't a priority. It was an afterthought. Finding capacity solved one problem, but opened the door to a slew of new headaches.

These ongoing frustrations with our CDMO vendors continued, so I started a list of what I would want from a CDMO if I were to start one from scratch. I would want a CDMO that recognised me as an important client. I wanted a partner with full transparency and a flat structure. If issues arose, I wanted to be able to talk to the CEO without waiting weeks or going halfway around the world. I would want the highest quality standards to drive the organisation, from equipment to cleanrooms to SOPs to experienced personnel who would treat my product like their own.

This list became the foundation for Scorpius BioManufacturing, a boutique CDMO I founded to serve the specialised needs of clients with small-volume biologics production projects. Our mission was to build a CDMO that partners would want to keep coming back to. We seek to support and empower sponsors with our caring and open approach and build a true partnership in which we treat our partners' products as our own. We created capacity; but, more importantly, we addressed the need for a better model to help our partners advance their smaller biologic programmes to the clinic and beyond.

Global impact for a small-volume project

Fina Biosolutions (FinaBio), an early client of Scorpius, is exactly the kind of innovative company we envisioned partnering with when we founded the company. We have partnered with FinaBio to manufacture their *E. coli*-expressed CRM197, a genetically detoxified diphtheria toxin that's widely used in conjugate vaccines (marketed as EcoCRM). FinaBio's mission is to make vaccines more affordable and widely available, especially for the developing world. The company's founder, Dr Andrew Lees, needed help designing a manufacturing partnership that could support their unique "not-for-much-profit" business model and sought a CDMO partner with lean offerings and flexibility. Scorpius will provide FinaBio with recovery and downstream process optimisation, analytical method implementation and validation, scale-up and cGMP bulk drug substance manufacturing.

It's an honour to work with Dr Lees and FinaBio's team. EcoCRM and the FinaXpress platform have transformed an otherwise expensive component of vaccines to reduce the cost per vaccine dose by one third. This is the type of innovation that can change the world; yet, most CDMO business models are not designed to support this kind of small-volume project. This might "only" be a 100 L cGMP batch, but it has the potential to become a longstanding partnership that impacts millions of lives.

Build versus buy: what's the best way to launch a CDMO?

I founded Scorpius in November 2020. Starting a company during a global pandemic that was rife with supply chain chaos was not for the faint of heart. Looking back, it might have been easier to purchase an existing facility; but, there were two main reasons why we decided to build Scorpius from the ground up. It was important to us to start from scratch as we didn't want to inherit the inevitable problems and inefficiencies that would have come with purchasing a dated facility. We wanted to start with a clean slate. This allowed us to design a purpose-built plant for small-scale manufacturing. Building a new facility also meant we could fill it with new state-of-the-art cleanrooms and equipment.

We wanted to build a facility that would allow us to focus on clinical and small-scale commercial



programmes — the kind that I'd worked on throughout my career but were an afterthought or, sometimes, a nuisance, to large CDMOs. Our first campus in San Antonio (TX, US) is rightsized at 76,000 square feet and houses a process development lab, analytical lab, state-of-the-art mammalian and microbial manufacturing suites and a large warehousing space across three main buildings. All are specially designed to efficiently manufacture smaller scale biologics to meet our partners' specific needs.

Young company, experienced team

Once we decided to build the facility, our attention quickly turned to staffing. Every CDMO has a facility and equipment. It's the people at the CDMO that make the true impact on clients. Since 2020, we've added team members who truly understand the specific challenges faced by smaller companies. We sought out professionals from small biotechs, large pharma companies, top-tier academic research labs and other CDMOs. We set out to build a team from all sides of the industry who could relate to clients on a personal level, not just a scientific one.

Our VP of Manufacturing Operations said it best: "This is a once-in-a-career opportunity to build a premier biomanufacturing company from the ground up and to build it the right way." Several of our early team members have worked together before and recruited each other. Our VP

of Process Sciences worked with our Senior Director of MSAT more than 20 years ago. An advisory board member first worked with VP of Quality and Regulatory Affairs nearly a decade ago. This combination of "getting the band back together," plus drafting an all-star line-up, has made for a natural team chemistry.

A CDMO model supporting innovators

Scorpius will grow with our clients. Although San Antonio is our flagship facility, it won't be our last. Plans are under way to build a commercial-scale facility in Manhattan, Kansas. We're starting with a small footprint so we can best support small-volume programmes as they progress through the clinic. Our vision is to continue to support those programmes all the way through to commercialisation.

Scorpius wasn't founded solely to address capacity shortage. We built a new CDMO to address a different kind of shortage — a lack of respect for the unique manufacturing needs of early stage companies and small-scale programmes. There is more innovation than ever in this industry, but there are not enough true partnership models that allow this innovation to flourish. We're on our way to building the CDMO I wish I had the opportunity to work with as an early biotech founder: one focused on responsiveness and client respect.



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