



Why Fina Biosolutions Partnered With Scorpius BioManufacturing for cGMP Production of EcoCRM® (CRM197)

Fina Biosolutions (FinaBio) has a clear mission: **Make conjugate vaccines more affordable.** FinaBio is unique in that it is a privately held, self-funded biotechnology company. The company needed an equally unique CDMO partner for cGMP manufacturing of EcoCRM®, FinaBio's CRM197 (genetically detoxified diphtheria toxin) which is globally used as the carrier protein in conjugate vaccines.

After evaluating more than 10 CDMOs, FinaBio selected Scorpius BioManufacturing for recovery; downstream process optimization; analytical method implementation; and phase-appropriate validation, scale-up, and cGMP bulk drug substance manufacturing.

FinaBio and Scorpius are a natural fit because of each company's commitment to flexibility, a secure supply chain, and passion for advancing the work of small biotechs.

Flexibility Drives Affordability

The FinaBio team spent months evaluating CDMOs before choosing Scorpius as a long-term manufacturing partner. The search for a CDMO was especially challenging since they are a “not-for-much profit” company, a phrase coined by FinaBio's founder and CEO Dr. Andrew Lees.

“The biopharmaceutical industry is increasingly focused on COGS when it comes to cell and gene therapies, but there is still a lot of work that needs to be done to make well-established technologies more affordable,” Lees said. “Conjugated vaccines have been on the market for decades but are still not affordable for underdeveloped parts of the world. The availability and affordability of CRM197 is a step in the right direction to make advanced vaccine technology a global reality.”

To make the company's mission a reality, Lees did not want to seek dilutive funding for FinaBio. Any external investment was likely to drive up the cost of EcoCRM® in the long run, a non-starter for Lees. Fortunately, a

boutique CDMO like Scorpius can support FinaBio's business model by providing a truly customized, flexible partnership.

Scorpius didn't treat FinaBio as simply another RFP for a microbial manufacturing program. Lees had access to the entire Scorpius team during the evaluation process, all the way up to founder and CFO.

"We are a relationship company, not a transactional company," Lees said. The relationships built with the commercial, scientific, executive leadership, and program management team all factored into FinaBio's decision. Despite being a newly established CDMO, FinaBio was confident in the expertise and experience on the Scorpius team.

Security of Supply

When FinaBio decided to look for second manufacturer for EcoCRM® to ensure long-term supply security, Lees knew he wanted a U.S. CDMO. That decision was driven by the need for IP security, the highest quality standards, and ease of communication.

In search of a more cost-effective partner, FinaBio evaluated several overseas manufacturers. However, they found that those candidates would have increased the price of EcoCRM® with added shipping and cold-chain costs. Additionally, the added headaches of dealing with customs and time zone differences ultimately made an entirely U.S.-based CDMO preferable for FinaBio.

Among the US-based CDMOs that FinaBio evaluated, Scorpius stood out for its microbial manufacturing expertise.

EcoCRM® is produced in FinaBio's Fina Xpress™ platform, a highly efficient *E. coli* expression system. Having a separate building on Scorpius' campus entirely dedicated to microbial programs was another plus for FinaBio. Scorpius' dedicated team, equipment, resources, and cleanrooms for microbial manufacturing ensures EcoCRM® can be reliably produced for years to come. FinaBio wasn't looking for a CDMO to produce a single cGMP batch; they needed a long-term partner.

Small Biotech Making a Big Impact

FinaBio sought a long-term CDMO partner that would not push its program aside when a large, commercial client came knocking. With Scorpius, FinaBio felt confident their program would always have a seat at the table. Weekly calls with the program management team, high attention to detail, and timely responses to day-to-day communication reinforced FinaBio's belief that the partner-



ship is both a scientific and a cultural fit.

Scorpius recognizes that, while EcoCRM® might only need up to 200-L microbial fermentation capabilities for cGMP production, it will make a large global impact.

For example, FinaBio's conjugation chemistry licensed to the Serum Institute of India Pvt. Ltd. (SIPL) is used to link proteins in MenFive®, the first conjugate vaccine to protect against the five predominant causes of meningococcal meningitis in Africa. And Eco-

CRM® is already being used in several clinical programs for promising vaccine candidates.

Scorpius exclusively caters to small-volume programs at its facility in San Antonio, TX. Being a boutique CDMO means every client takes priority. "Scorpius decidedly made us feel like we were a prime customer," Lees said. "They made us feel like getting our project done was a high priority for them. So far, every bit of the way they have met that expectation." ■

ABOUT THE COMPANIES



Fina Biosolutions

Fina Biosolutions was founded in 2006 by Dr. Andrew Lees, the inventor on over 25 patents and with 75 peer-reviewed publications. The company serves as a strategic R&D partner and licenses its technology to companies globally. FinaBio is pleased to offer both research grade and cGMP EcoCRM®, economical CRM197 from *E. coli*, to the research and vaccine manufacturing community.



Scorpius BioManufacturing

Scorpius BioManufacturing is a boutique, US-based biologics CDMO with available capacity for mammalian, cell therapy, and microbial-based programs. Scorpius provides integrated bioanalytical, process development, and cGMP manufacturing services to efficiently scale up biotherapeutics to the clinic and beyond. Scorpius specializes in working with start-ups and emerging biotech companies, giving small-volume programs the attention and flexibility rarely found at large CDMOs.