

Process Development: One Size Does Not Fit All

SynCo Bio Partners believe that contract manufacturing should not be “one size fits all” and that the biopharmaceutical contract manufacturing industry needs to explore different collaborative business models in the development of production processes with prospective clients.

Most CMOs, including SynCo, offer complete, full process, and analytical method development from the upstream fermentation/cell culture stages to the final purification steps. For small virtual companies to larger organizations with limited available internal resources this can be a good option. However, for the client, loss of control over its development project can be a genuine concern.

There are a number of options for working with a CMO on a process development program including the following.

OUTSOURCE FULL PROCESS AND ANALYTICAL DEVELOPMENT

Outsourcing full process and analytical development to the CMO thereby empowers the CMO to deliver and simplifies reporting lines, which makes this type of project relatively easy to manage.



However, this can be an expensive option and the lack of control over the project and the process developed can be an issue. Solid relationships combined with excellent communication between the CMO and client should counter this.

OUTSOURCE PROCESS DEVELOPMENT ONLY

If outsourcing only process development to the CMO, a company develops analytical methods in-house (subsequently transferring to the CMO for qualification and batch release). This is a more complex project structure to manage, but because assays are developed in-house, the client retains a greater degree of control and internal staff remain engaged in the project.





A SynCo manufacturing operator adding cleaning solution to an ultra filtration system

DEVELOP THE FULL PRODUCTION PROCESS IN-HOUSE

A company can develop the full production process in-house, then contract a CMO to complete transfer and scale-up. This option does allow for full control and on the surface appears to be less expensive. However, process modifications would almost certainly be required to accommodate the chosen CMO. This transfer, process modification, and scale-up can be costly both financially and timewise compared to Option 1.

Alternatively, a company can develop the full production process in-house, but contract-in the CMO sooner to involve it on a consultancy basis in process development. This allows full control over the in-house, developed process but brings expertise in scale-up and process accommodation from the CMO to the project team earlier in development. This is likely to be the least expensive route, ensuring a streamlined technology transfer later to the CMO with minimal or no process modifications. However, few CMOs work according to this model, and good and open communication is essential to success.

SynCo Bio Partners, a Netherlands-based GMP CMO established in 2000, works with a broad client base on a range of biopharmaceutical development projects. These include the development of processes for the GMP manufacture of recombinant and wild type proteins, polysaccharides, and live-microbial-based products. SynCo has experience of all of the approaches outlined above and believes flexibility is paramount to client satisfaction. Whichever approach is taken, success is always dependent on establishing a strong and openly communicative partnership where both parties equally contribute to the successful delivery of the program. 🌐

Joanne McCudden, PhD, is director of marketing and sales at SynCo Bio Partners B.V., Paasheuvelweg 30, 1105 BJ Amsterdam, The Netherlands; 011-31-655-34-80-74; j.mccudden@syncobiopartners.com; www.syncobiopartners.com.

Trust us to make it right.

www.synco-biopartners.com

Support when you need it most.

Biotech and pharmaceutical companies around the world rely on SynCo to develop scalable production processes and manufacture their licensed biopharmaceuticals.

In the last year alone, we have developed manufacturing processes for numerous clients and produced a wide variety of different vaccines, live bacterial products and recombinant proteins in our state-of-the-art, GMP-licensed facilities.

These are now making a real difference to the lives of many people. With proven manufacturing expertise like this,

you can trust us to make it right.



SynCo
Bio Partners