How continuous biomanufacturing can transform biologics production

Just – Evotec Biologics explores how, through offering enhanced productivity, cost efficiency, agility and more, continuous manufacturing processes and facilities are improving global access to biologics

Biologics have emerged as life-changing therapies for a broad range of health conditions. However, despite their potential, global access to biologics remains limited, in part, due to high production costs.

One of the main reasons behind these high costs is the reliance on conventional fed-batch biomanufacturing processes. Production occurs in separate, sequential steps, requiring large facilities and significant labour inputs. This is highly inefficient, limiting scalability, creating difficulties in adapting to demand and introducing operational risks, all of which contribute to the high-cost structure of biologics. Continuous biomanufacturing offers an effective solution to overcome these challenges faced in biologics production. For the last decade, the CDMO Just – Evotec Biologics has been driving advancements in the continuous manufacturing approach. The company has built on world-class expertise and technologies to develop innovative cGMP facilities termed 'J.POD®'; which contain its continuous manufacturing platform.

In this article, we discuss how Just – Evotec Biologics' J.POD facilities, in combination with this platform, can elevate the cost-efficiency, productivity, scalability and agility of biomanufacturing.

Cutting the costs of biologics production by up to 75%

Continuous manufacturing drastically reduces the costs of biologics production. A key component of any biomanufacturing platform is the cell line. Cell lines optimised for fed-batch cultures can achieve maximum antibody titres of around 5g/L, whereas continuous perfusion cultures can achieve 4+g/L/day over 25 days.[1] This represents an order of magnitude increase in bioreactor productivity compared to fed-batch. The full potential of continuous biomanufacturing is beginning to be realised by combining Just – Evotec Biologics' innovative Continuous Manufacturing platform with its proprietary J.CHO™ High Expression System, a Chinese hamster ovary (CHO) cell line engineered for continuous perfusion culture. The J.CHO High Expression System can produce standard or complex antibody formats through advanced cell line development capabilities. Specialised cell lines producing afucosylated antibodies, cytotoxic products, or advanced glycan modifications can be developed on behalf of partners to meet their needs. Combining the high expression system, CM platform and J.POD manufacturing environment further optimises productivity and cost efficiency. Together, these factors increase production outputs while significantly reducing facility footprint.

Building scalable, agile processes

Scalability is another major benefit of a continuous manufacturing approach. Just – Evotec Biologics' perfusion culture platform is suitable for early-stage clinical production through to large-scale commercial supply. Output can be increased simply by running the same process for longer. This avoids lengthy and expensive technology transfers to new large-scale facilities, ensuring a rapid and low risk transition from clinic to market.

The modular design of J.POD facilities further improves scalability and provides unmatched agility and flexibility. New J.POD modules can be installed readily into existing facilities, allowing the facility to be adapted to meet varying production demands. Depending on the number of bioreactors in operation and the length of the production run, a single J.POD facility can produce up to 2,000kg of biologics per year.[2]

The flexible infrastructure of J.POD facilities ensures critical medicines, including treatments for global pandemic diseases, are developed and supplied in a timely manner without the delays that can be incurred by having to build and commission large-scale stainless steel facilities.

With the ever-increasing demand for biologics, such agile and flexible biomanufacturing has never been more important.

A lower-risk approach

Transitioning from fed-batch to continuous manufacturing systems can substantially reduce risk in biologics production. Increased automation and control along with advanced real-time process monitoring help prevent human errors and improves process consistency and reproducibility, lowering the risk of costly batch failures.

Continuous manufacturing helps to mitigate external risks, including those relating to the supply chain. With a global network of decentralised J.POD facilities, production can be seamlessly distributed between sites to reduce reliance on a single supply location or mitigate geopolitical risks.

Innovative, integrative biologics development and manufacturing

J.POD facilities support partners through each step of the development and manufacturing process. They cover from process development, through to early- and late-stage clinical supply, all the way up to large-scale commercial production, all under one roof.

From the start of the development journey, in silico molecule optimisation can be conducted using innovative artificial intelligence and machine learning tools, providing partners with the best possible molecule for their disease target. Integrated product and process development capabilities include the development and optimisation of cell lines, upstream and downstream processes, and product formulation, therefore optimising productivity and quality throughout the whole process.

Highly integrated development and manufacturing capabilities offered by Just – Evotec Biologics ensure a fast and smooth transition, reducing the costs and risks associated with biologics production. Innovative technology platforms are combined throughout the pipeline, utilising decades of combined expertise across a broad range of biologics, including monoclonal antibodies (mAbs), bi- and multi-specific antibodies, and biosimilars.

Expanding the global biomanufacturing network

The newly opened site J.POD Toulouse, France complements the well-established J.POD Redmond, Washington, facility and J.Plant in Seattle, both in the US. The new continuous biomanufacturing facility is already making waves in Europe and beyond, with the recent announcement of an expanded tech partnership for biosimilars with Sandoz. This marks a significant step towards transforming biosimilars development and manufacturing, securing patient access to vital medications.

Partnerships drive biopharma success

Innovation and collaboration are central to Just – Evotec Biologics' continuous manufacturing approach. In addition to offering traditional CDMO fee-for-service approaches, the company excels in strategic partnership development. Whether starting from early development stages, or transitioning existing biomanufacturing processes, flexible partnership models can be developed that are tailored to each molecule, with the opportunity to out-license proprietary biomanufacturing technologies.

Join Just – Evotec Biologics in shaping the future of biomanufacturing:

www.evotec.com/en/services/just-evotec-biologics

References:

1. *Visit: sciencepool.evotec.com/j-cho-high-expression-system-blog-article/*
2. *Garcia FA, et al (2023). 'Reducing biopharmaceutical manufacturing costs through continuous processing in a flexible J.POD® facility', Drug Discovery Today, 28(7), 103619*
3. *Visit: evotec.com/en/news/just-evotec-biologics-expands-tech-partnership-for-biosimilars-with-sandoz*

Just EVOTEC BIOLOGICS

Just – Evotec Biologics, wholly owned by Evotec SE, is a first-to-industry biologics platform company that leverages AI/ML technologies and world-leading molecular design, cell line development, process intensification and continuous manufacturing strategies to advance biotherapeutics from discovery through clinical stages to commercial launch. The Just – Evotec Biologics team combines deep industry experience in the fields of data, protein, process and manufacturing sciences including automation with highly integrated and flexible capabilities to break through the scientific and economic barriers associated with the development of protein therapeutics. Our focus is to accelerate and expand access to biotherapeutics through scientific and technological innovation for our proprietary projects and on behalf of our partners.