# Biopharmaceutical process development services

Process, Analytical & Formulation Development



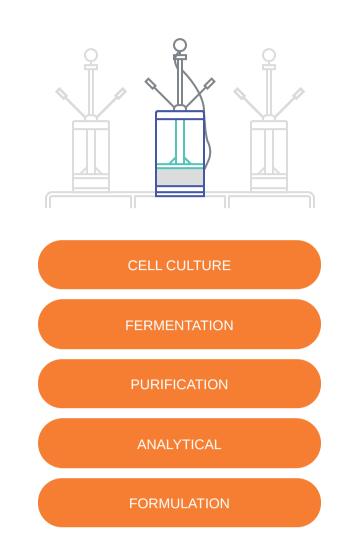












### Process, Analytical & Formulation **Development Capabilities**

The clinical and commercial success of biotherapeutics hinges on the development of robust, reproducible and scalable processes. KBI's extensive process development and analytical development capabilities help our partners generate active product at an attractive cost while enabling rapid, reliable transfer to cGMP manufacturing.

#### Biopharmaceutical process development and manufacturing

KBI process development activities cover the full development cycle, from supporting early-stage discovery efforts through small-scale protein production to fully-integrated, comprehensive process development programs leading to cGMP manufacturing to process characterization and scale-down validation studies. We take pride in our deep knowledge and experience in the science and practice of biopharmaceutical drug development. Our abiding customer focus and situational flexibility combined with a solid scientific base enable us to be the ideal partner for our clients' biopharmaceutical process development needs.

#### Our biopharma process development services include:

- Cell Culture
- Fermentation
- Purification
- Analytical
- Formulation

KBI has extensive experience with both microbial (E.coli, yeast) and mammalian cell culture derived proteins. The KBI team has worked with protein production processes at all scales from laboratory, pilot and clinical scales to commercial scales up to 20,000L. We have conducted cutting-edge research into several technologies that are fundamental to process development and are adept at solving challenging issues on very short timelines.

KBI has well-developed platform processes for monoclonal antibodies and Fc fusion proteins and has helped several clients create their own platforms for **novel therapeutic moieties**.

Our high throughput tools for process and analytical development include miniaturized bioreactors through the Ambr® platform combined with high throughput chromatographic screening capabilities and a complementary set of analytical tools to enable rapid progress in process development. Through our experience, we can readily develop optimal experimental strategies that can lead to the rapid development of robust, reliable and scalable processes.

KBI's full range of biopharma process development capabilities provide the tools to address client needs, whether they be in producing small quantities of proteins for research or in developing robust and scalable processes that can provide a solid competitive advantage.

#### Biopharmaceutical Process Development Case Studies: Learn More

**Publications & Presentations** Presentation | High Throughput Bioreactor Mimetic in Early & Late Stage Process Development

**Learn More** 

**Publications & Presentations** Publication | Viral clearance for biopharmaceutical downstream

**Learn More** 

## Contact Us

Are you looking to accelerate your program or just want to learn more about our services?

Connect with our team and we will get back to you quickly.

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