

## Cell Culture, IND Submissions, & Commercial Launches

**Industry Leading**  
scientific methodologies in high throughput  
process development

**40<sup>+</sup>**  
annual programs ranging from FIH process  
development to late-stage process development,  
characterization & validation

**15<sup>+</sup>**  
IND submissions supported annually

### Cell Culture Process Analytical Development

Cell culture process development activities at KBI 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.

The KBI team has worked with protein production processes at all scales from laboratory, pilot and clinical scales to commercial scales up to 2000L. We have characterized mixing conditions in bioreactors from ambr15 to 2000L scale. In depth understanding of the impact of agitation, aeration, and working volume at each scale has allowed us to tech transfer in wide variety of processes very successfully.

[Presentation | Scalability of a Single-use Bioreactor Platform for Biopharmaceutical Manufacturing](#)

[Presentation | Scale-up & Tech Transfer from Non-Disposable to Fully Disposable Systems](#)

KBI has been a pioneer in integrating new and cutting edge technologies into our process development platform. For example, use of high throughput miniaturized bioreactors and associated analytics for process optimization and characterization, ATF based high cell density processes, and targeted optimization of product quality attributes are services offered at KBI.

[White Paper | Integrated utilization of high-throughput bioreactors & high-throughput analytics for rapid & robust cell culture process development](#)

[Presentation | Debottlenecking Manufacturing Capacity: Initiating cell culture manufacturing campaigns using seed train cryopreserved in a disposable bag](#)

[Presentation | Optimization of Glycosylation & Charge Distribution Through Culture Parameters & Supplements](#)

The KBI CCPD team has experience with over 15 different mammalian cell line vendors. The nuances about the different cell line platforms allows us to develop high productivity, robust, and scalable processes within an expedited timeline. In addition to standard mAbs, KBI has extensive experience in developing Fc-fusion proteins, bi-specific antibodies, growth factors, enzymes, vaccine glycoproteins, PEGylated proteins, and other glycoproteins.

[Publication | Up to Speed: European Biopharmaceutical Review, July 2016](#)

Our unwavering customer focus and situational flexibility combined with a solid scientific base enable us to be the ideal partner for our clients.



Ambr 250®

## KBI's Cell Culture Process Development Capabilities

### Expedited Platform Process Development

- Robust, reproducible, and scalable processes using cell lines from more than fifteen cell line platforms from across the globe as well as with KBI's internal cell lines
- In-depth knowledge about vendor cell line platforms and ability to deliver the best possible output from a cell line
- Platform cell culture processes for our internal cell line systems
- Ability to rapidly deliver IND enabling Toxicology material
- Learn more: [Case Study | Improving Titer](#)

### Seamless Scale-up in Single-use Bioreactors

- Data from over 30 molecules from bench scale to 200-2000L
- Extensive mixing characterization studies at all scales
- Scale up of high cell density culture using ATF
- Accelerated development using in-house scalability data across cell line and process type
- Learn more: [Case Study | High Cell Density Process](#)

### Process Characterization & Scale-down Validation Studies

- Ability to provide extensive reactor characterization studies across all scales starting from ambr250 to the 2000L disposable bioreactor
- Qualification of scale down models for wide range of bioreactor systems

### High Throughput Cell Culture Process Development

- Miniaturized bioreactors through the ambr platform (ambr15 and ambr250)
- High throughput chromatographic screening capabilities (TECAN FREEDOM EVO)
- Complementary analytics (Octet QK384, Caliper LabChip GXII, and Cedex BioHT)
- Cost reduction of material and resources through the use of these technologies in [process characterization](#) studies
- Learn more: [Case Study | High Throughput Process Development Using Microbioreactors](#)

### Biosimilars Process Development

- Successful delivery of a large number of [biosimilar programs](#)
- Well versed in using multiple lots of innovator product to set ranges to drive clone selection and process optimization
- Strength in [analytical](#) and [biophysical characterization](#) capabilities
- Proven record of best in class process development
- Control of product quality through use of process parameters and supplements
- Learn More: [Case Study | Toolbox for Product Quality Optimization](#)

### Commercial Cell Culture Process Development

- Advanced process control tools and strategies
- Application of QbD principles to late stage development
- Use of PAT for improved process control

## 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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I'm primarily interested in:

This helps us connect you to the right person, as fast as possible. If "Other" selected, please give additional information.

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