KBI BIOPHARMA

Biologics manufacturing using high-density microbial fermentation

Microbial Services

Our unique expertise enables us to express a variety of molecule types. Using scalable, high-density microbial fermentation, our clients benefit from shorter development at each phase and subsequently lower cost.

Fully supported production

- Process and analytical development for FIH and clinical programs
- Late stage commercialization: process characterization, process validation
- Materials management, operations, engineering, quality control, QMS

Two cGMP manufacturing lines

- 2000L SS fermenter in large scale suite
- 300L single-use production fermenters

DEPTH ACROSS MOLECULE AND CLINICAL STAGE

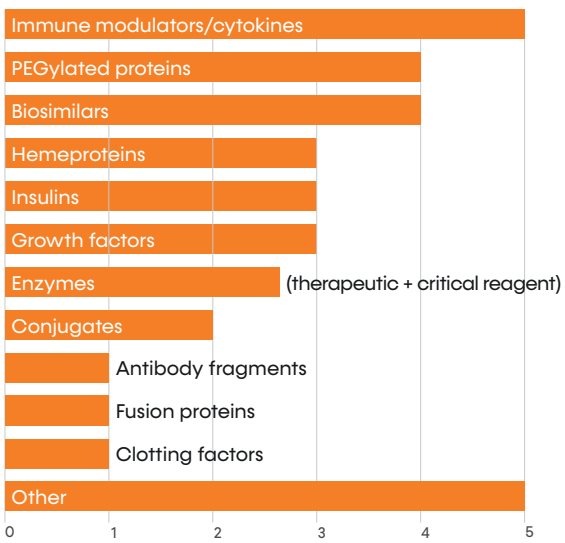
Development

- >50 recombinant clinical targets developed
- >10 transferred into cGMP
- >10 successful client quality audits

Late-stage

- >5 programs into process characterization
- 3 programs into Ph III and PPQ batches
- FDA PAI: 2016, 2018 (license approved)
- EMA/MHRA: 2017 (certificate received)

Programs by molecule



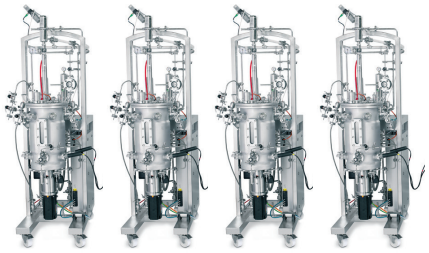
OPERATIONAL EXCELLENCE

- **Two existing commercial programs**
- **Full program development from CLD (Cell Line Development) to tox material generation**
- **70+ programs completed**
- **6-8 Annual INDs supported**
- **Clinical supply**
- **PC/ PPQ**
- **Licensed by FDA and PMDA for commercial production**
- **Multiple scales available**
  - 2000L stainless steel
  - 300L single-use technologies
- **Industry-leading large molecule particle characterization capabilities**
- **Capacity available**

PROCESS DEVELOPMENT & CHARACTERIZATION: SPEED WITH PROVEN SCALABILITY

250mL Scale

- Ambr 250®
- Screening
- Optimization
- DOE



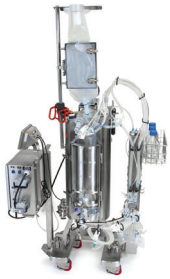
2000L SS cGMP (Custom)

1.5mL Scale

- BioLector® Pro
- 48 well screening
- Part of CLD

10L Scale

- Sartorius/Biolaffite
- Harvest development
- Scale-up confirmation



30L Scale – Single-Use

- Thermo Fisher SUF
- Harvest development
- Scale-up confirmation

300L GMP Scale – Single-Use (Thermo Fisher SUF)

PRODUCT LIFE-CYCLE MANAGEMENT

Capabilities to develop and manufacture clinical/commercial therapeutic protein products

- Proven record to "fast track" programs with successful direct lab-to-GMP delivery on tight timelines
- Experienced with regulatory inspections and filings, including on-site CMC regulatory group
- Highly-experienced team in late stage commercialization

PROCESS DEVELOPMENT

- Cell line
- Upstream
- Downstream
- Analytical
- Formulation

CLINICAL SUPPLY

- Technology transfer
- Proven scale up track record
- DS and DP release testing
- Stability program

PROCESS QUALIFICATION

- Process characterization
- Product/protein characterization
- PPQ and cleaning validation
- Facility specific microbial control strategy

COMMERCIAL SUPPLY

- Control strategy development
- Continued process verification
- Lean manufacturing systems
- Continuous improvement

Commercial process validation: A life-cycle approach to process understanding and control

Process Design

Product and process development and characterization

Build process knowledge and understand sources of variability through development, historical production, and characterization studies

Qualification of the Commercial Process

Demonstrate that the designed process and facility are capable of reproducible commercial manufacturing

Continued Process Verification

Demonstrate during commercial manufacturing that the process remains in a state of control, and identify opportunities for process improvements

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