

Process Development

Process Development Services and Capabilities

ABL routinely conducts upstream and downstream development and optimization studies for our clients—an essential step towards efficient design of cGMP-compliant manufacturing processes. We draw on our manufacturing and quality expertise to design processes that optimize product yields and minimize regulatory risk.

ABL has successfully translated >100 processes from the laboratory bench to the GMP suite for potential vaccine and therapeutic candidates. Teams of highly skilled well trained scientists are embedded in every ABL manufacturing facility, each specializing in a critical area of bioprocessing:

- □ Upstream cell culture growth and production optimization
- □ Downstream purification and product recovery
- □ Final drug-substance formulation
- □ Analytical development, qualification & validation to measure product yield and activity

Optimizing and scaling biological processes seldom follow a linear path. ABL scientists leverage the knowledge achieved over collective decades of experience to create efficient process development programs designed to maximize a successful transition to GMP compliance.

Upstream

Services

- □ Thawing and expanding cells for production scale
- □ Host cell line screening and selection
- • Transfection or infection optimization
- □ Media screening, feed strategy
- □ Cell growth dynamics
- □ Adaptation to animal derived product-free, suspension-based or adherent processes
- □ Bioreactor optimization and scale-up
- □ End of Production (EOP) cell evaluation

Downstream

Services

- □ Purification and recovery of recombinant proteins and viruses
- □ In-house column packing and qualification
- □ Resin screening and selection
- □ Column cycling and aging studies
- □ Reduction of process residuals

- □ Scale down modeling for viral clearance

Upstream

Capabilities

- □ Sartorius Glass bioreactor 2 L, 10 L
- □ STR tank, single-use Sartorius bioreactors 50 L, 200 L
- □ iCELLis Nano
- □ HYPERStacks, Hyperflasks
- □ Cell Factories
- □ Roller Bottles
- □ Shake flasks
- □ Microcarriers
- □ Multiple DOE studies in flasks & bench-top bioreactors

Downstream

Capabilities

- □ AKTA pilot, chromatography
- □ AKTA Pure, chromatography
- □ Q Sonica
- □ KrosFlo KMPI TFF systems
- □ KrosFlo KR2I TFF systems
- □ Centrifugation and Ultracentrifugation

Integrating expertise in translational science together with operational excellence to solve challenging PD problems

- □ Designing processes that optimize product yields and minimize regulatory risk
- □ Holding the same platforms in PD are in GMP suites
- □ Translated more than 100 product processes from bench to GMP suites
- □ Helping companies define and optimize their processes to produce material that will enable them to proceed to early phase trials
- □ Providing expertise in process optimization; > 80% of our biomanufacturing clients rely us for this
- □ Working as an extension of your team, guiding you through scale-up processes to achieve GMP compliance
- □ Customized, comprehensive product development plan—outlining each step and highlighting risk

Contact us today to see how our process development can advance your product to clinic!

contact us today

