

GMP-Ready Mammalian Cell Line Development Platform

Fully Integrated Stable Pools to GMP Solution

For innovative new biologic therapeutics in the development pipeline to enter clinical phases, developers must successfully demonstrate the drug can be manufactured consistently while meeting appropriate quality standards. In the US, this comes in the form of an Investigational New Drug Application (IND) to the US Food and Drug Administration (FDA).

Drug developers are often under pressure from stakeholders and investors to rapidly reach IND application and demonstrate a return on investment. But on the pathway to IND, cell line development (CLD) is a common bottleneck, sometimes taking up to a year to produce a stable cell line.¹

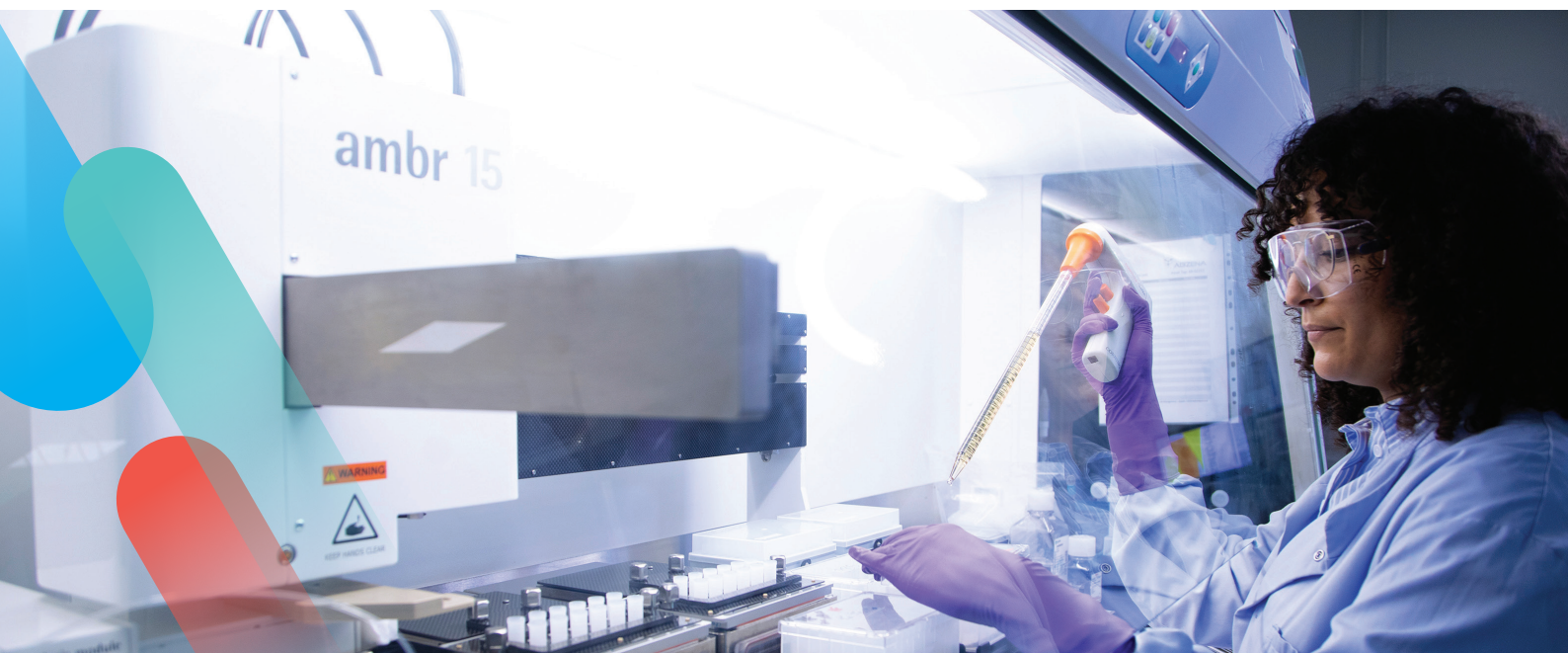
Abzena's AbZelectPRO™ platform offers a solution by streamlining CLD to achieve highly stable pools in 3 weeks and go from DNA to research cell bank (RCB) in just 10 weeks and GMP in 6 months, with up to 10g/L in high-performing titers. This streamlined platform de-risks processes by removing the gaps, dependencies & delays that slow your program from cell line to GMP.

Optimizing productivity and quality with AbZelectPRO™

Abzena's AbZelectPRO™ CLD platform has been developed with a focus on optimizing three key areas with improved efficiency in mind:

- **The vector** — Codon optimized transgenes using ProteoNic's 2G UNic® vector technology
 - Optimized dual promoters
 - Improved mRNA transport and translation
 - Higher rates of transcription
 - Epigenetic stabilization
 - Reduced gene silencing
 - Greater clonal stability & % of high producing clones
- **The host cell line** — CHO-K1, CHOSOURCE GS KO, or CHOSOURCE GS KO ADCC+ host cell lines:
 - Fast PDT and High VCDs
 - Optimized and grown in commercially available SF, CD media and feeds
 - PQA integrated into all stages, full traceability & compliant with ICH-Q5
- **The process** —Optimized Process:
 - From transfection to stable pool and clone generation to maximize efficiencies and reduce timelines
 - High-quality mAb titers up to 10 g/L, sustained over 60 generation
 - Engineered for scalability with robust bioreactor performance from the very start

These optimizations enable the rapid generation and selection of high-yielding stable CHO cell lines for therapeutic protein and recombinant vaccine production. As a result, highly productive clones can be generated quickly with consistent quality, helping to ease manufacturing efforts as the project scales.



The Abzena Advantage: One Partner. Less Time in Development. Less Risk

De-Risk Your Critical Path

- Analytical, formulation, & downstream PD run in parallel with CLD to reduce bottlenecks
- Stable, predictable material reduces late-stage reformulation & process failures
- One integrated partner removes handoff risk & keeps momentum

Faster to Drug Substance

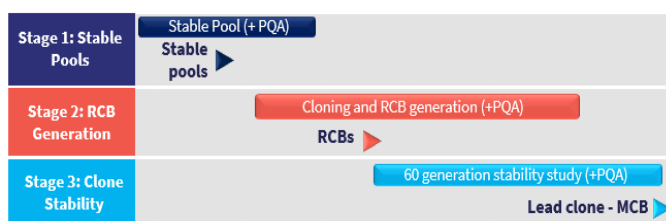
- Stable pool material enables downstream, analytical & formulation work to start immediately
- Fewer upstream PD cycles compress your timeline to IND-enabling studies
- Tox material provision decoupled from final cell line selection

Scale Confidently

- Consistent, high-titer material at 50L, 500L and 2,000L — no performance cliffs
- Minimal upstream process development (PD)
- High-quality stable pools & clones that perform the same at every scale

We help compress your development timeline and eliminate the white space so that you reach patients faster.

Speed & Quantity Without Compromising on Quality



The Stable Pool Advantage

Abzena addresses the challenges of CLD by optimizing stable pool generation early in just 3 weeks: tailoring vector design to each modality, testing multiple expression-ratio sets for complex formats, assessing growth, productivity, & product quality attributes, and selecting the best pool set before CLD progression into development. We offer a variety of options for generating material that are from mg to gram scale:

- Generate stable pools on multiple candidates for lead candidate selection
- Generate early material (10-20 g scale) from CHO stable pools in as little as 8 weeks from transfection
- Consistent product quality between pools & clonal cell lines

Streamlining IND application

Backed by the extensive experience of Abzena's experts in developing biologic therapeutics and delivering them successfully to clinical phases, the AbZelectPRO™ platforms simplify the IND application process.

The platforms have been built with ICH guidelines in mind at every step and are supported by Abzena's analytics platform, which has been carefully developed leveraging years of biologic production experience. Ensuring quality and compliance throughout the process, Abzena provides a comprehensive report that can be easily integrated into the IND filing. Stage-appropriate, fit-for-purpose assessments and technologies include biologics characterization, developability assessments, mass-spec capabilities, method development and formulation development.



Partnering with Abzena

As a contract development and manufacturing organization (CDMO) with over two decades of experience in CLD, Abzena has expertise in expressing biologics ranging from antibodies, antibody fragments, fusion proteins, and vaccines. Let us help you seamlessly bridge from CLD to GMP and reach patients faster.

To discover how Abzena's AbZelectPRO™ platform could streamline your program to IND, get in touch with us today at abzena.com or info@abzena.com.

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