ABZENA

Improving Cell Line Development Efficiency with AbZelectPRO™

Rapid & High-Yielding Cell Line Development

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]

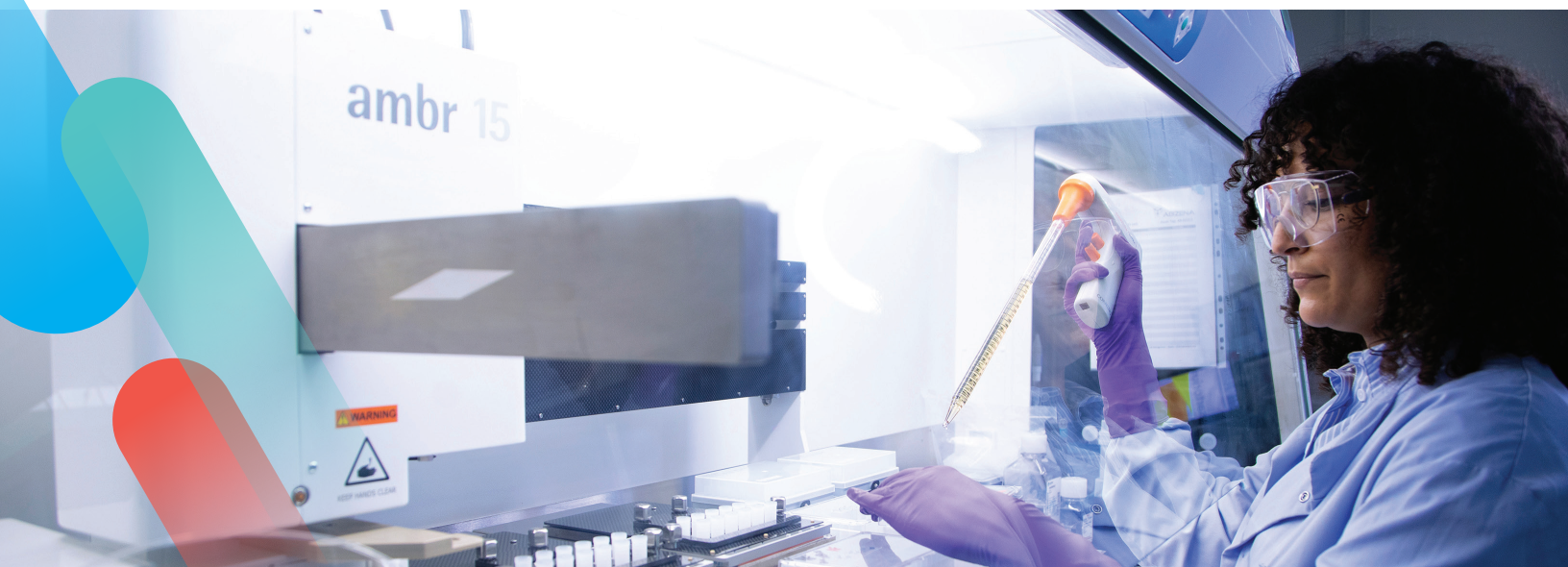
Abzena's AbZelectPRO™ platform offers a solution by streamlining CLD to achieve lead candidate sequence to research cell bank generation timelines of 10 weeks and de-risking future processes for improved efficiency.

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 —** AbZelectPRO™ combines Abzena's CHO cell line with ProteoNic's premium expression vector technology 2G UNic. The 2G Unic vector is compatible with our glutamine synthetase (GS) selection system to efficiently isolate highly productive stable cells. Through optimized expression cassettes, the vector enhances productivity in stable pools and clones.
- **The host cell line —** Through directed evolution in bioreactors, Abzena have isolated an enhanced host CHO cell clone, based on CHO-K1. The AbZelectPRO™ CHO host has improved growth, with shorter doubling times and higher viable cell densities in bioreactors, providing a strong starting point for the generation of robust production cell lines.
- **The process —** From host and vector development to transfection, fast stable pool formation and cloning, the entire CLD process has been optimized to improve efficiency, ensuring high productivity from stable pools and clones.

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.

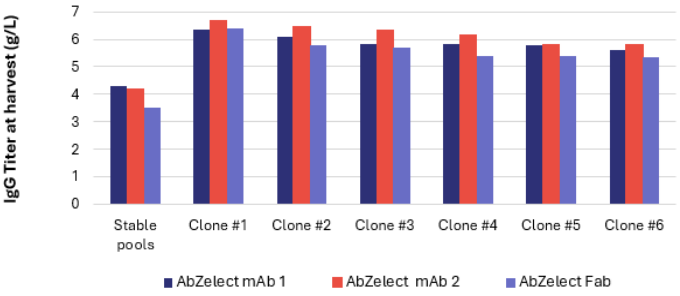


Supporting next-generation therapies with AbZelectPRO™

To achieve the highest production levels, AbZelectPRO™ combines our CHO-K1 mammalian cell line with ProteoNic's 2G UNic® premium vector technology to boost expression levels and generate higher-producing, stable cell lines up to 8g/L of product. As a result, the AbZelectPRO™ platform supports the efficient and stable production of antibodies and more difficult-to-express proteins such as fusion proteins, bispecifics and other novel modalities.

The 2G UNic™ technology offers a unique double promoter, which drives higher levels of transcription and is optimized to enhance the stability of the messenger RNA transcribed resulting in more protein per gene copy. This allows the AbZelectPRO™ platform to achieve a higher cellular productivity (qP) and further increase productivity by 50–200% in comparison with competitor's cell lines.

Top 6 clones using AbzelectPRO™



References: 1 – Vuksanaj K. Mapping the Future of Cell Culture and Cell Line Development. GEN - Genetic Engineering and Biotechnology News. Published August 2, 2021.

De-risking future processes

The AbZelectPRO™ platform has been designed for the efficient generation of multiple fast stable pools, allowing the in-depth characterization of multiple candidates. Collecting this data at early stages enables developability and manufacturability risks to be mitigated as early in the process as possible. This information aids the selection of the best lead candidate and allows developers and manufacturers to proactively identify solutions to potential risks and avoid delays.

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™ platform simplifies the IND application process.

The platform has 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.

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Partnering with Abzena

As a life science 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.

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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