AbZelectPRO™: Enhanced Cell Line Development Platform

Rapidly progress your therapeutic protein and recombinant vaccine projects from DNA to RCB in 10 weeks, de-risking the IND journey

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Abstract

Our **fully integrated AbZelectPRO™ platform** enables the rapid delivery of stable, high-producing cell lines for complex biologics or bioconjugates. AbZelectPRO™ combines our CHO-K1 mammalian cell line with **ProteoNic's 2G UNic®** premium vector technology and a tailored optimised process to boost expression levels and generate **fast doubling, higher-producing, stable cell lines, expressing up to 10 g/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, bi-specifics, vaccines and other novel modalities. Backed by the **extensive experience** of Abzena's experts **in developing biologic therapeutics**, which are **supported by Abzena's comprehensive analytics portfolio**, the AbZelectPRO™ platform simplifies the IND application process and delivers client therapeutic proteins successfully to clinical phases. In addition, the platform enables activities such as downstream method development and formulation to be removed from the CLD critical path by using **Early Material Generation** from **Stable Pools**, which can also be run stand-alone as part of the Abzena offer.

Flexible Platform Options

ProteoNic Biosciences

AbZelectPRO™

Cell Line: CHO-K1
- GMO: None
- IND: 10+

Vector*: 2G UNic®
- Selection: Low MSX
- IND: 20+

*License fee at IND

ProteoNic Biosciences + revvity

AbZelectPRO™KO

Cell Line*: CHOSOURCE™
- GMO: GS -/- KO
- IND: 90+
- MA†: 4

Vector*: 2G UNic®
- Selection: No MSX
- IND: 20+

*License fees at IND † Market authorisation

Timeline for standard mAb

- DNA to Stable Pools: 3 wks (1-2*)
- DNA to RCB: 10 wks (1-4*)
- DNA to Lead Clone Selection: 26 wks (1-6*)

Figure 1. Multiple Platforms – One Seamless Experience. Abzena integrates leading partnered technologies such as 2G UNic® (ProteoNic) and CHOSOURCE™ GS KO cell line (Revvity) to streamline and accelerate CLD workflows. This unified approach enhances productivity, flexibility, and performance across platforms.

* Numbers as per AbZelectPRO™ CLD Process stages shown below.

Optimised CLD Process

1. Vector Construction

- **ProteoNic's 2G UNic® GS vector**:
  - Optimised dual promoters
  - Reduced gene silencing
  - Epigenetic stabilisation
  - Improved transcription and translation efficiency

2. Transfection

- **Optimised CHO-K1 Host Cell Lines:**
  - Fast PDT (18-20 hrs)
  - High VCDs (≤ 40 E+06 cells/mL)
  - Optimised to grow in bioreactors

  → **Stable Pools** (**3-5 g/L**) with small scale productivity and **PQA**
- Optional: **Early Material Generation**

3. Single Cell Cloning

- **Cyto-Mine®** Single Cell Cloning with HT FRET selection
- **Cell Metric®** imaging for clonality assurance

4. RCB Generation

- RCB generation on 24 lead Clones

  →**GMP-ready RCB**

5. ambr®15

- 24 lead Clones in **ambr®15 bioreactors** with **PQA** on top 12 expressing Clones
- **2 L STR** scalable characterisation of lead Clones for further manufacturing purposes
- Optional: **Early Optimisation** of lead Clones

  → **Top Clones: Up to 10 g/L**

6. Stability Study

- Top Clones progress to **60+ Generation** stability study (representative of a 2000 L bioreactor)
- Small-scale productivity and **PQA**

  →**Lead Clone selected for MCB generation**

- **Higher product** yield from Stable Pools and Clones
- **Greater percentage** of high producing Clones
- **Faster** doubling times
- **Improved** Clonal stability
- **Reproducible PQA** at all stages

The entire **CLD Process** has been **optimised** to improve efficiency, ensuring high productivity from Stable Pools and Clones while providing a **robust process from DNA to RCB and beyond**.

2. Early-Stage Stable Pool Material Generation (≥ 10 g)

→ Accelerate development using **Stable Pools** to generate **≥ 10 g** material for non-GMP studies:
- Formulation, Analytical and early DSP method development
- *In vivo* studies

Figure 2. Stable Pool Material Generation (≥ 10 g for standard mAbs). Purified using state-of-the-art ÄKTA™ systems yielding ≥ 95% purity and low endotoxin.

3. Single Cell Cloning: Population Enrichment and Clonality Assurance

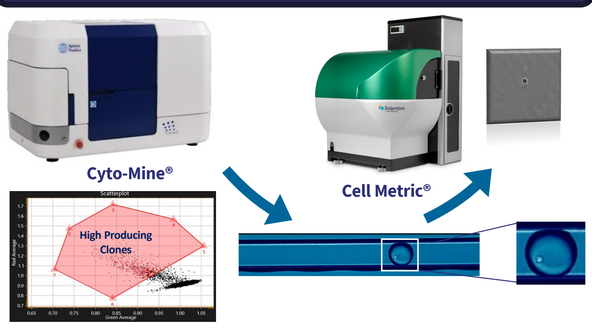


Figure 3. **Early population enrichment** using Cyto-Mine® microfluidics and Cyto-Cellect™ FRET probes **for multiple molecule types**, providing single cell encapsulation for initial evidence of monoclonality. Secondary evidence of monoclonality using Cell Metric® images throughout the single cell outgrowth time-course.

4-5. RCB Characterisation in ambr®15 and 2 L STR

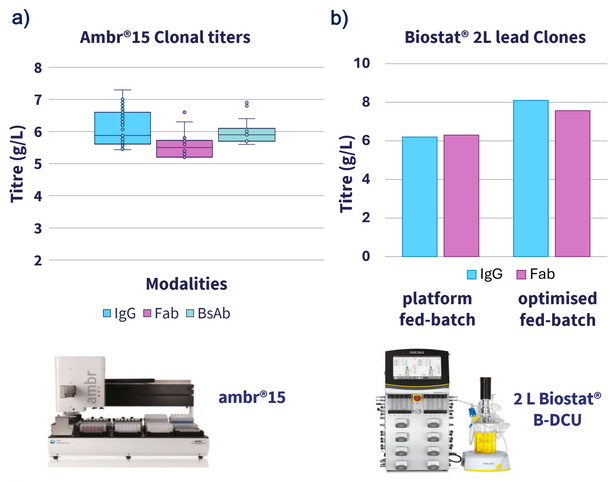


Figure 4.

a) AbZelectPRO™ RCB titres under platform fed-batch conditions in **ambr®15** for top-performing clones across **three molecule types: IgG, Fab, and Bi-specific.**

b) 2 L Biostat® B-DCU production runs using platform conditions for standard IgG and Fab molecules demonstrate robust scalability from ambr®15. **Early process optimisation** significantly **enhances titres**.

Titre quantitation was performed by Octet® BLI with quantitative HPLC final titre confirmation.

6. Clonal Stability Study (60 Generations)

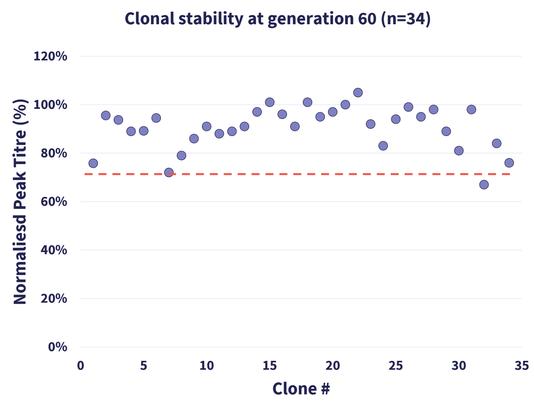


Figure 5. AbZelectPRO™ Clones exhibit **>97% stability** over a 60+ generation time-course, based on normalised titre relative to Generation 0. Data is representative of 34 clones of **different molecule types**.

Clone stability is further supported by consistent cell-specific productivity (Qp) and PQA (data not shown). Enhanced clonal stability is attributed to the 2G UNic® vector, which employs epigenetic mechanisms to reduce gene silencing.

AbZelectPRO™ - PQA and Analytical Capabilities Supporting Different Modalities

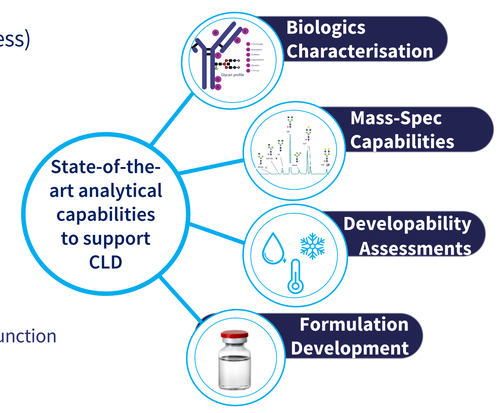
Platform PQA methods:
(used throughout the CLD Process)

→ SE-HPLC / CE-SDS
→ RPC-MS / cIEF

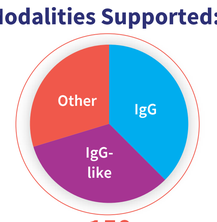
Extended PQA methods:

Structure:
→ N-Glycan
→ Sialic acid
→ Peptide mapping

Function:
→ Immunogenicity assays
→ Cell-based assays
→ Binding ELISA
→ Biacore™ SPR



Modalities Supported:



150+
Individual CLD programs with CHO-K1 cell line

IgG: IgG1, IgG2, IgG4, including variants thereof and other species

IgG-like: BsAb and Multi-specifics, Fabs, VHH, scFV, Fc-fusions

Other: Nanoparticles, Protein Fusions, Enzymes, IgA, IgE, Viral Sub-Units, Vaccines

Biosimilars represented in each group depending on modality

Overview

Trusted technology: AbZelectPRO™ is built on established CHO-K1 platform – well recognised in industry and by regulators. 2G UNic® technology used in 20+ IND filings and CHOSOURCE™ GS knockout cell line used in 90+ IND filings with 4 market authorisation.

Experienced team with proven track record: CLD team has delivered 150+ individual CLD programs with CHO-K1 cell line, including 10+ cell lines for clinical programs.

Compliance assured full traceability: Records of Host Cell Line, CLD processes and all contact materials. Established robust processes compliant with ICH-Q5 guidance.

Integrated platform with end-to-end support under one organisation across all stages of the drug development process.