FyoniBio 15



Cell Line Development

Find the best host cell match for each individual biotherapeutic

Best possible bioactivity is not always achieved from one cell host as product quality attributes may differ widely from one biotherapeutic to another. Therefore, finding a suitable expression host is critical to support desired product characteristics. With FyoniBio's GlycoExpress® and CHOnamite® cell platforms the most suitable host cell line solution can be found.

GlycoExpress® (**GEX®**) is a screening and high yield production platform of proprietary glyco-optimized human cell lines for development and production of biotherapeutics with fully human authentic PTMs e.g., glycosylation. GEX® enables high quality expression of "difficult-to-express" glycoproteins.

CHOnamite® is an in-house developed CHO platform originating from CHO-K1 and CHO-DG44 cells. The technology enables high yield production of antibodies, complex mammalian proteins and can be used to find the right solution for biosimilar development. Find best matching quality attributes by double tracking in our multiple cell line platforms.



Characteristics and Selection Criteria

CHOnamite®

- "Dual cell line" platform originating from CHO-K1 and CHO-DG44 cell lines
- High-yield production in fed-batch processes
- Applications: standard mAbs, biosimilar development, complex mammalian proteins
- Direct integration of PTM/ glycan analytics into CLD procedure possible

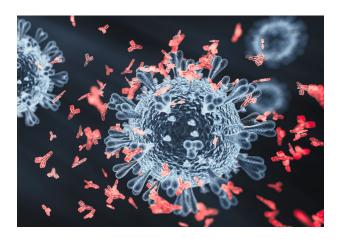


GlycoExpress®

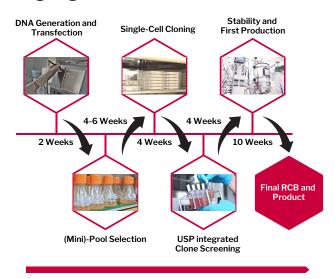
- · Genuine human glycosylation
- High productivity for glyco-optimized products
- Toolbox of glycoengineered cell lines: adjustment of sialylation, fucosylation, and mannose-6-phosphate
- Established expression platform for difficult-to express, complex glycoproteins, and defucosylated proteins

Cell Line Development

At FyoniBio state-of-the-art cell line development is carried out to find highly productive cell clones with excellent quality parameters. With a customized feasibility study you can compare your protein in both GEX® and CHOnamite® cell lines for a reasonable price. Flexible, royalty-free licensing models are provided.



Cell Line Development: Highlights and Timeline



Stability tested RCB obtained in 6-7 month

Fast Track Cell Line Development

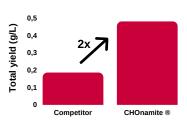
Acceleration of cell line development is the key for a costefficient development of a biopharmaceutical manufacturing process. At FyonBio we combine eager cell lines and **selected expression vectors** for clone development to find the best approach to your project. **Combining pool and minipool** selection procedures increases probability to find high producing clones even further.

Single cell cloning uses 3-4 highest producing (Mini)-pools bringing forth clones with varying traits. Multiple rounds of clone screening are performed starting with initial 96-well screening up to **USP integrated screening** in batch, fed-batch and perfusion mode using suitable down-scale models to directly find a process fitting monoclonal cell line.

Stability testing and the possibility for **early USP optimization** complete the cell line development procedure and enable a direct transfer to GMP manufacturer.

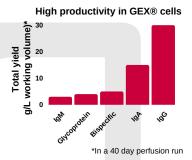
Reliably, High Producing, Glycooptimized and Stable Cell Lines

Competitor and CHOnamite ® titer of a complex mAb fusion protein



CHOnamite® cell lines in combination with fed-batch enable classically high yield productivities up to 3-6 g/I. A combination of clone screening with media testing results in selection of the best process conditions for high yield production.

Glyco-optimized GEX® cell lines are optimized for perfusion processes which are characterized by high reproducibility, scalability and product quality.



The FyoniBio team is glad to support you throughout your projects

FyoniBio offers high quality ISO-9001 compliant services. Fore more information please contact us.



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