



GlycoExpress® - Toolbox for high yield production of human glycooptimized biopharmaceuticals

GlycoExpress® (GEX®) has regulatory approval by **FDA, EMA** and **German regulatory authorities (PEI, BfArM)** for manufacturing of biopharmaceuticals. This screening and high yield production platform is based upon proprietary glycoengineered human cell lines for the development and production of biotherapeutics with a fully human and optimized glycosylation.

Expression of human protein-based biopharmaceuticals requires a biological system close to its human origin. Glycotope provides a well-established and characterized human expression technology platform for all proteins.

Modification and control of posttranslational modifications, especially glycosylation, is a key feature for the development of biotherapeutics due to its strong effects on key properties such as bioactivity, solubility, stability, serum half-life and immunogenicity.

Thus, modification and control of glycosylation are both important in developing such therapeutics.

Glycosylation is dependent on the host cell line. Biotherapeutic glycoproteins produced in hamster or mouse cell lines carry non-human and significantly different glycosylation, in some cases this leads to severe immunogenic reactions.

Human cells for human glycosylation

- Authentic human glycosylation for complex proteins
- No immunogenic non-human carbohydrate residues

Our broad toolbox of GEX® cell lines

Cell line	Glycooptimization abilities
1 mAb-Express®	used for products where high sialylation and core fucosylation is required
2 mAb-Express^{F-}	used for products where high sialylation and low core fucosylation is required
3 SialoMax®	used for products where high sialylation and high core fucosylation is required
4 SialoFlex®	allows gradual adjustment of the sialylation degree for screening of the optimal content of sialic acid on the product
5 FucoFlex®	allows gradual adjustment of the fucosylation degree for screening of the optimal content of fucose for the respective product

Further glycoengineered cell lines are continuously developed e.g.,

- A cell line for the production of glycoproteins with high amount of **mannose-6-phosphate** e.g., in the field of enzyme replacement therapy.
- SialoMax additionally glycoengineered to **eliminate** N-glycan linked **GalNAc** for products with further reduced serum clearance



Technology platform performance

Parameters	Areas of optimization
1 Sialylation	Bioactivity, bioavailability, immunogenicity
2 Fucosylation	Bioactivity, e.g. enhanced anti-tumor activity, ADCC
3 Galactosylation	Bioactivity, bioavailability
4 Bisecting GlcNAc/ Branching	Bioactivity, bioavailability, immunogenicity
5 Fully human glycosylation	Bioactivity, bioavailability, immunogenicity, adverse side effects

GEX® provides an established expression platform for different biopharmaceuticals:

- Antibodies of different isotypes (e.g., IgG, IgM, IgA)
- Defucosylated antibodies
- Bispecific antibodies / fragments (e.g., NK-cell/T-cell recruiters)
- Difficult-to-express and complex glycosylated proteins (e.g., rhSP-D and others)
- Blood factors (e.g., FVII)
- Protein hormones (e.g., FSH, HCG)
- Fusion proteins with extended serum half-life
- Enzymes (e.g., for enzyme replacement therapy)

Key features

- Human cell line with stable expression
- Platform manufacturing process with reliable outcome, stable product quality, esp. glycosylation and minimized batch-to batch variations
- High productivity for glycooptimized products (R&D):

Yields for different product classes

Product Class	Productivity*
IgG (high and low core-fucose)	15-30 g/L
IgA	10-15 g/L
IgM	~3 g/L
Factor VII	~2 g/L

*Yield per 30-40 day perfusion run per liter bioreactor volume

Preclinical manufacturing of protein biopharmaceuticals

We provide preclinical CMC services for your biopharmaceutical products

- Design and cloning of molecules e.g., antibody engineering or half-life prolongation
- Production clone and cell line development using the appropriate GEX® cell line
- Bioprocess development (USP)
- Protein purification and downstream processing (DSP)
- Bioactivity assays
- PTM analytics

We are open and ready to discuss your project and to help you find the suitable GEX® cell line for your demands.

For more information please contact us

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