

Biopharmaceutical Development Services

GPEX[®] Gene Product Expression Technology

A new standard in mammalian cell line engineering

Our GPEX[®] proprietary technology is used to construct stable, high-yielding mammalian cell lines with unmatched speed and efficiency.

The technology's signature advantages are:

Rapid development

From cDNA to milligram quantities of protein within two months; from cDNA to Master Cell Bank (MCB) candidate in five months

Higher yields

Higher expression per copy inserted compared to other technologies

Better flexibility

Cell lines for protein screening through commercial manufacturing

Unmatched versatility

No need for selectable markers; GPEX[®] technology facilitates additional transductions to increase copy number or to add other complementary genes

Increased stability

GPEX[®] keeps stability testing off the critical timeline path

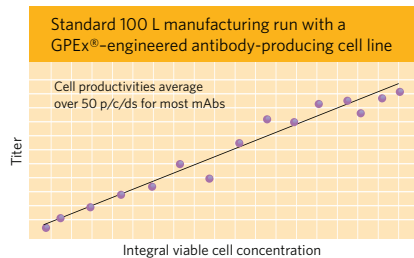
Whether you need to distinguish between multiple variants, increase yield or quickly construct an MCB, you can rely on GPEX[®] technology as an ideal solution for your mammalian cell line engineering challenges.

How it works

GPEX[®] technology uses a retrovector technology that ensures the stable transduction of targeted cells, approaching 100% efficiency. This level of efficiency eliminates the requirement for selectable markers—something conventional methods must use during selection and gene amplification.

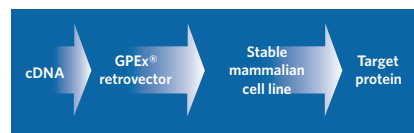
Using GPEX[®] technology, stably-transduced (selectable marker gene-free) cell lines are produced in less than five months. The technology can be applied to any mammalian cell line or used with in-house Master Cell Banked CHO parental cell line.

With favorable expression levels, expression stability and timelines to your product development cycle, GPEX[®]-based cell lines can be ready to support all of your future manufacturing needs.



Application feature: variant analysis

GPEX[®] technology is ideal for variant analysis. We can deliver milligram amounts of several protein variants from a cell pool quickly. A selected clone can then be used for a fast path to clinical manufacturing.



GPEX[®] technology generates stable cell lines from the outset.



A new standard in expression performance

The advantages of applying GPEX[®] technology to your product's development span from early feasibility studies, to clinical manufacturing, to commercial-scale production. We have produced over 100 recombinant proteins using GPEX[®] technology and prepared detailed project plans to help our clients meet their product development and business goals.

Reduced development time

- Stable pools of transduced cells producing target proteins are generated from the outset
- Milligrams of target protein can be produced within two months
- Clonal pools can be expanded to yield gram quantities for characterization and analysis
- Serum-free from the start means no time wasted for adaptation

Productivity from the start

- Selected clones have consistent productivity from 25 to over 50 picograms per cell, per day
- Process development with minimal inputs can consistently reach several gm/L in six months in batch-fed bioreactor systems

Increased safety

- Cell lines are developed in serum-free culture media
- No antibiotic selection requirement
- Testing and production regimen designed to meet regulatory requirements for the production of therapeutic proteins

Versatility

- Wide variety of mammalian cell types
- Single-gene or multigenic expression applications
- Demonstrated success with a wide variety of proteins

Multigenic applications

- Monoclonal antibody (mAb) heavy- and light-chain coexpression
- Receptors, coexpressed with a secreted surrogate
- Inactive proteins, coexpressed with associated processing enzymes
- Sequential transduction can be used to introduce required genes without antibiotic selection
- Expression can be enhanced by clonal selection or additional rounds of transduction without antibiotic selection

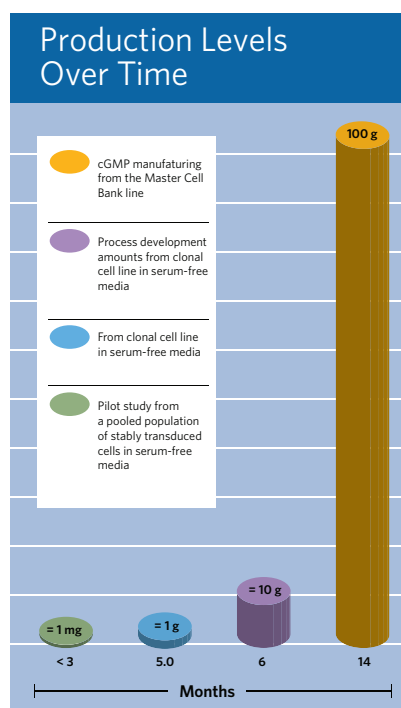
Accessing GPEX[®] technology from Catalent

Catalent will design a milestone-based development program to go from your cDNA to a stable MCB candidate. The program begins with a feasibility study and can lead to cell bank production, cell culture manufacturing and purification process development. Catalent can produce the protein in our cGMP compliant facility in Middleton, Wisconsin, or license the cell line for off-site manufacturing.

Catalent maintains a continuum of services for biopharmaceutical development, including biosafety testing, bioassay development, preformulation and formulation development, stability studies and fill-finish capabilities.

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Monoclonal Antibody (mAb) Production

GPEX[®] technology expresses all types of IgG mAb: full-length mAbs, Fab fragments, chimeric antibodies, antibody fusion proteins and single-chain antibodies.

Variable regions can be inserted into our retrovectors for cell line development and protein production. Catalent maintains backbone vectors containing the gamma constant region for human IgGs 1, 2, 3 and 4 and light-chain kappa and lambda constant regions as well as others. DNA sequences encoding IgG variable regions can be fused to any constant region in the GPEX[®] retrovector system. Using this system, we can produce virtually any desired IgG molecule.

For additional information about GPEX[®] technology, contact us today.

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