



GPEX[®] TECHNOLOGY

Proven development of high-performance production cell lines

Get to clinic faster with proven GPEX[®] technology. GPEX[®] proprietary technology creates stable, high-yielding mammalian cell lines for even the most difficult to express proteins. The advantages of applying GPEX[®] technology to your product's development span from early feasibility studies, to clinical manufacturing, to commercial scale production.

Reliable

Productivity from the start Selected clones have productivity from 50 to over 100 picograms per cell, per day and final titers up to 7 gm/L in fed-batch bioreactor systems

Increased stability Demonstrated up to 100 generations. No need for selectable markers; GPEX[®] technology utilizes additional transductions to increase copy number or to add other complementary genes

Efficient

Rapid development From cDNA to 100s of milligrams of protein available from early cell pool; rapid production of Master Cell Bank (MCB) candidate including two rounds of cloning

Reduced development time Stable pools of transduced cells producing target proteins are generated from the outset and removes stability testing from the critical path

Proven

7 commercially marketed biosimilar mAbs use GPEX[®] Technology

460+ different antibodies / antibody fusions

50+ different recombinant proteins

30+ ongoing clinical trials

40+ current clients / with over 80 active projects

Flexible & Versatile

Proven success A wide variety of mammalian cell types and proteins for protein screening through commercial manufacturing, both in single and multigenic expression applications with in-house parent CHO cells available.



DEVELOPMENT



DELIVERY



SUPPLY

How It Works

The technology 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 and stable clonal cell lines are produced rapidly

SINGLE AND MULTIGENIC APPLICATIONS:

- Monoclonal antibody (mAb) heavy- and light-chain co-expression
- Receptors, co-expressed with a secreted surrogate
- Inactive proteins, co-expressed 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

GPEX[®] Technology at Work

	CLIENT A	CLIENT B
SITUATION	<ul style="list-style-type: none"> · Client required a human antibody expressing CHO cell line · In-house, the Client had difficulty achieving commercially viable expression levels using a hybridoma cell line expressing the antibody 	<ul style="list-style-type: none"> · Client required a recombinant mAb fusion protein expressing CHO cell line · In-house, the Client had difficulty achieving commercially viable expression levels for this difficult to produce protein
SOLUTION	<ul style="list-style-type: none"> · Client contracted with Catalent to use GPEX[®] technology to produce its mAb · A cell pool expressing antibody was produced within 12 weeks · A clonal cell line expressing >2.5g/l was produced in less than 5 months · Commercially viable titer enabled client to continue on path toward pivotal clinical trial 	<ul style="list-style-type: none"> · Client contracted with Catalent to use GPEX[®] technology to produce its mAb fusion · A cell pool expressing antibody was produced within 12 weeks · A clonal cell line expressing >3.5g/l was produced in less than 5 months · Client stayed on track towards its clinical trial scheduling

Advanced Technologies. Integrated Solutions.

Your Partner for Biologics Development & Supply As your strategic partner for biologic drug development success, Catalent Biologics creates smart, tailored solutions with our superior GPEX[®] cell line engineering, our SMARTag[®] ADC Technology Platform, clinical manufacturing, integrated analytical, fill-finish, and clinical supply services to help you get better products to clinic, faster. Our extensive expertise and commitment to quality allows us to help improve the total value of your biologic treatments.

more products.
better treatments.
reliably supplied.™

Discover more solutions at catalentbiologics.com

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