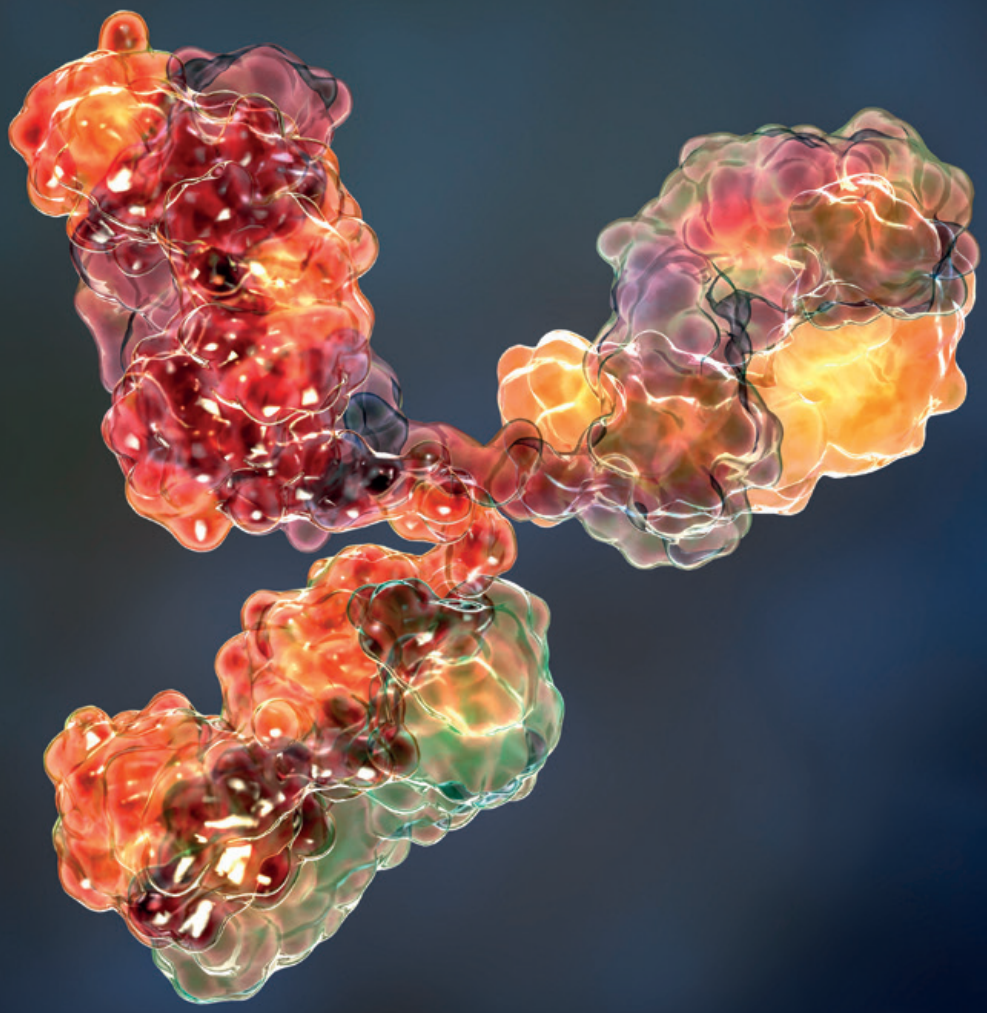
Enabling a healthier world

Lonza
Biologics

A Fully Integrated Toolbox for Therapeutic Protein Expression

The GS Xceed® Gene Expression System



As market demand continues to rise for more effective and potent therapeutics, drug developers are identifying novel disease targets and biological mechanisms for which medicines can be developed. As a consequence, biologic pipelines are evolving from standard antibody formats to new molecular formats. Now more than ever before, there is a real need for proven and scalable expression platforms that can keep pace with the requirements of these proteins.

With more than 35 years of experience in developing mammalian expression technologies that underpin our development and manufacturing services, we are ideally placed to supply you with a robust and versatile expression platform to optimize production of your biotherapeutic.

Key benefits

*Subject to the terms and conditions of the license agreement

The Next Level of Therapeutic Protein Expression...

Biologics hold vast therapeutic potential, but producing these proteins can be challenging

It is difficult to develop a clonal cell line that can express biologic products at consistently high yields with the desired quality and functionality. A suboptimal expression system can slow product development, result in significant delays and increased costs to the project. With this in mind, our extensive experience has enabled us to develop a robust, scalable and state-of-the-art expression system for the production of biologics: the GS Xceed® Gene Expression System.

How the GS Xceed® Gene Expression System can enhance gene expression

The GS Xceed® Gene Expression System is a comprehensive toolbox for development of biologics. It has been successfully used to develop not only monoclonal antibodies but also a wide variety of new molecular formats: from bispecifics and one-armed monoclonal antibodies to Fc-fusion proteins to enzymes, hormones and more. Fully integrated system components and versatile applications make GS Xceed® a system of choice whether at a large pharmaceutical company or a small biotech.

The Lonza GS Gene Expression System® has proven success, enabling expression of more than 70 commercial products, with hundreds more in the clinical pipeline.

Vectors

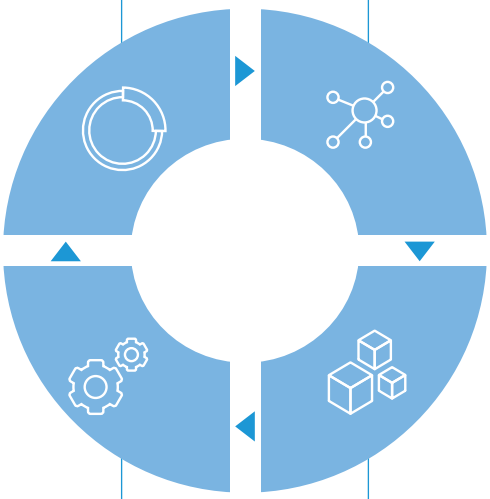
GSquad® vectors

GSquad® constant region vectors

GS® site-specific conjugation vectors

Host cells

GS Xceed® CHOK1SV GS-KO®



Know-how

GS® manual portal
- Vector construction
- Cell line development
- Platform processes

Expert technical and regulatory support

Technologies and Systems

GS piggyBac® transposon technology

GSv9® media and feed system

GS Discovery® transient expression system

...We'll Reach it Together

With its integrated toolbox, the GS Xceed® Gene Expression System optimizes production of biologics and is developed with manufacturability in mind, paving a streamlined path from gene to market.

Stable, scalable, productive cell lines

The CHOK1SV GS-KO® host cell line is an industry-known and well-established cell line with proven performance. The cell line is adapted to grow in suspension in a chemically-defined animal component-free (CDACF) environment. Derived from Lonza's CHOK1SV® cell line, the CHOK1SV GS-KO® results in high average product titers of between 2 and 8g/L, across a range of molecular formats, which can be further improved with process optimisation. Due to its limited use of growth-inhibiting methionine sulfoxamine (MSX) after transfection, the cell line has improved cell growth and accelerated doubling times.

Unique GS piggyBac® transposon technology

Lonza has exclusive human therapeutic rights for GS piggyBac®, a proven transposon-based technology that preferentially targets regions of the genome associated with stable, highly expressed genes. The GS piggyBac® technology improves gene expression efficiency and accommodates large DNA cargos of >200kb. GS piggyBac® generates cell lines that are able to produce high yields with reliability and consistency, which is ideal for new molecular formats that can be difficult to express. Furthermore, GS piggyBac® enables fast stable pool generation, delivering high quality and highly representative pool material to bridge new biologics from discovery into clinical development.

Versatile, efficient GSquad® vectors

New molecular formats such as such as bispecific antibodies and fusion proteins require the expression of multiple genes. Lonza's GSquad® vector system makes it simpler to create a GS piggyBac® expression vector that encodes for up to four product genes. With speed and reliability in mind, a rapid two-step vector construction process is effective for both simple proteins and proteins that are complex in design or difficult to express.

High titer transient expression with GS Discovery®

Lonza's new transient expression system, GS Discovery®, enables you to use the GS® system from early phase discovery through to commercial production. With simplicity, flexibility and yield in mind, we offer two transient expression processes to suit your project needs.

GS® system provides...	
Expertise and experience	The GS System® has a long, proven track record of product success and is familiar to regulators, minimizing diligence- and compliance-related costs and delays. Coupled with Lonza's expertise and ongoing support, the platform de-risks the partnering process to give confidence and peace of mind.
Full integration	The GS System® combines disparate elements of biologic production into one integrated platform, taking you from discovery to commercial with one toolbox.
Versatility, robustness, scalability, portability	The GS System® supports a diverse range of biologic drugs and molecules. Its versatility and portability suits applications and laboratory settings across the globe, accelerating development without compromising on performance.
Continual improvement	The GS System® draws from Lonza's exceptional expertise, ongoing innovation, and proprietary technologies to improve efficiency, reduce time to market, and give a competitive edge.

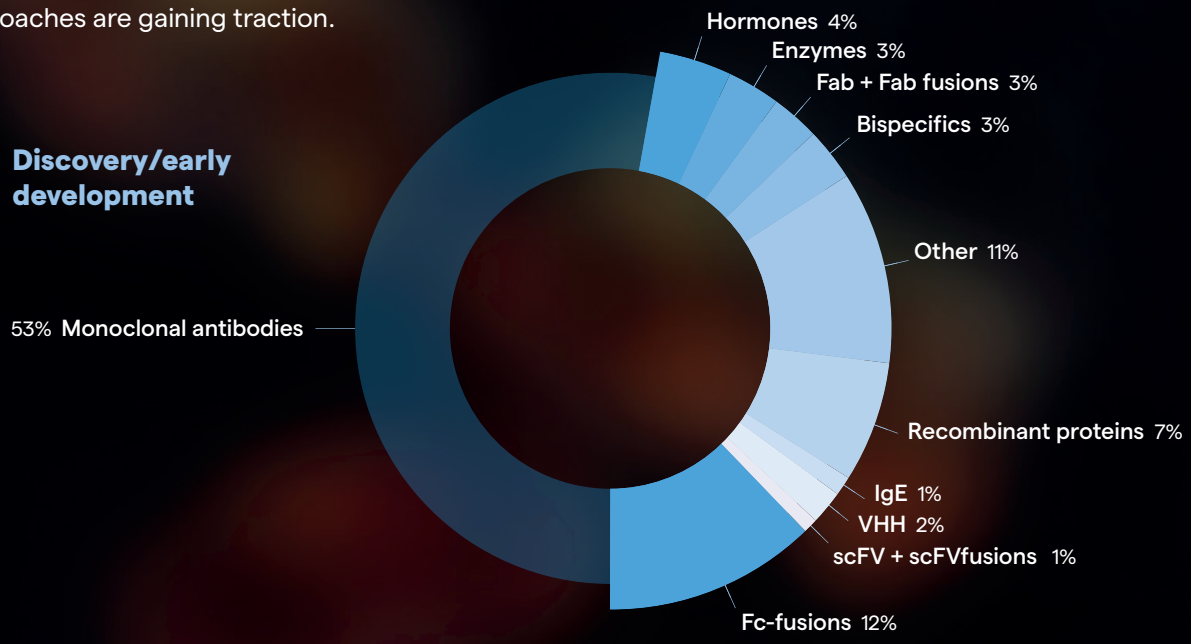
GS Xceed® Gene Expression System

A scalable, integrated, proven platform for developing biotherapeutics as quickly, reliably and smoothly as possible, supported by extensive system and industry know-how.

GS Xceed® is the ideal workhorse to produce proteins with ease and consistent yields. The reliable, fully integrated system uses robust processes and components that have a proven track record with regulators, while new tools are constantly added to support the needs of new molecular formats in pharmaceutical pipelines. The integrated GS® toolbox of cell lines, vectors, technologies, media systems and know-how enable optimal gene expression and cell line development, expediting potentially life-saving biologic therapeutics to the clinic, and to patients in need.

More Than Just IgG Antibodies

Proven track record with development pipeline and marketed products. Over 1300 products have been expressed, purified and analysed using Lonza platforms since 2012. mAbs still currently dominate, but new approaches but new approaches are gaining traction.



Complex Protein Expression with GS piggyBac®

Biologic pipelines are evolving from standard antibody formats to new molecular formats. GS piggyBac®, a unique and versatile cell line engineering technology, helps address the need for robust and scalable expression platforms that can keep pace with this shift towards more complex protein formats.

GS System®

1992:
Lonza GS System® launched

2003:
Launch of CHOK1SV® cell line

2006:
pConPlus vectors for mAbs introduced

2012:
GS Xceed® launched

2017:
GS Xceed® site-specific conjugation vectors launched

2018:
GS Xceed® Multigene vectors added to the GS® Toolbox

2022:
GSquad® vectors launched

piggyBac®

1983:
Barbara McClintock receives Nobel Prize for discovering transposition

1997:
First synthetic transposase and transposon system available

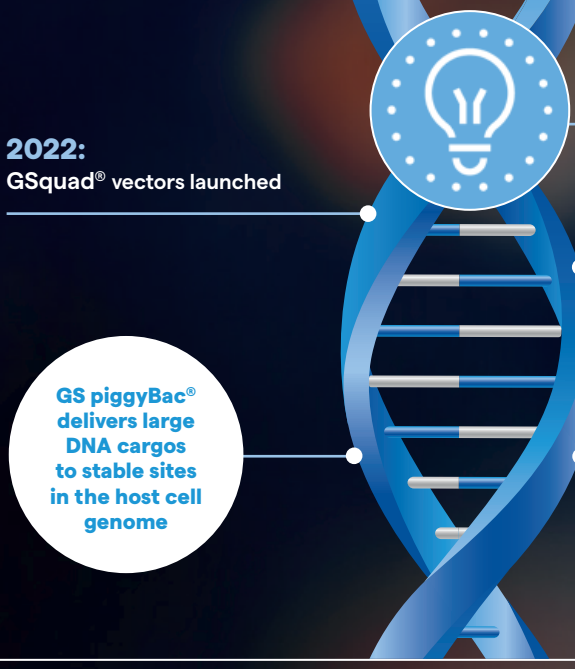
2006:
piggyBac®, shown to be highly flexible and active compared to other transposon based technologies in mammalian cells

2016–2018:
Several published studies highlight the benefits of CHO and piggyBac® technologies in supporting complex protein expression

2018:
Lonza acquires exclusive rights to piggyBac® for bioprocessing applications

2019:
GS piggyBac® launched

2023:
GS Discovery® transient expression system launched



GS piggyBac® delivers large DNA cargos to stable sites in the host cell genome

Combining the GS System® with piggyBac® results in increased yields for challenging proteins

Contact us

To access Lonza's next-generation expression technology, visit **www.lonza.com/biologics/expression-technologies/gs-expression-system** or contact us at **GSLonza@lonza.com**.

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