



Selexis SURE^{technology} Platform[™]

The Biologics Engine for the 21st Century

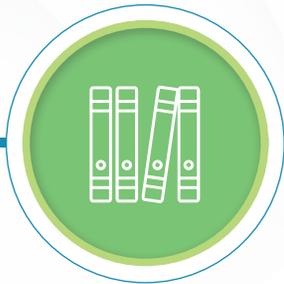
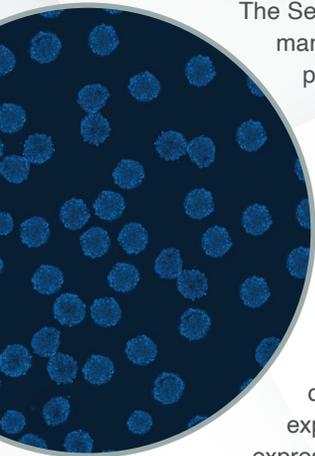
Selexis SURE CHO-M Cell Line[™] (CHO-K1)

The Selexis SURE CHO-M Cell Line is a proprietary high-performance mammalian cell line that is derived from CHO-K1 cells and used for the production of therapeutic recombinant proteins and monoclonal antibodies.

The growth and production properties of the Selexis SURE CHO-M Cell Line are well defined, and the feed strategy has been optimized, allowing for faster and more efficient scale-up to bioreactors.

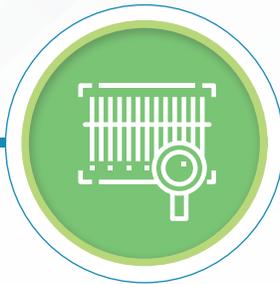
Therapeutics that have been generated using Selexis SURE CHO-M cells include more than 140 clinical trial, as well as 8 marketed products across a range of indications.

CHO cells have been used in the pharmaceutical industry for over 60 years. Nonetheless over 1/4 of the CHO gene repertoire is silenced due to mutations, leading to limitations in the range of proteins that can be expressed. Selexis has created tools that overcome these inherent CHO cell expression bottlenecks.



SURE CHO-M^{plus} Libraries[™]

SURE CHO-M^{plus} Libraries represent a powerful, sophisticated and holistic approach that significantly de-risks expression and production issues of difficult-to-express recombinant proteins in mammalian cells, thus helping reduce attrition rates in biologic drug discovery and development. Since, with certain proteins, optimal expression cannot be achieved by elevated transcription alone. This platform offers unparalleled solutions for generating manufacturing cell lines that are specifically tailored to the expression and secretory needs of most recombinant proteins.



SUREscan[®]

With Selexis' exclusive bioinformatics tools, Selexis now has the ability to quickly analyze the entire genome and transcriptome of any research cell bank (RCB). Unlike other methods, SUREscan identifies transgene integration sites in host genomic DNA, covering the entire genomic framework and eliminating any bias. SUREscan gives Selexis partners insights into integration sites and copy numbers, transgene integrity, clonal purity of the RCB, and manufacturing risks, such as adventitious agents and gene mutations.

At a Glance

High Yield

- 2–7 g/L for MAbs (fed batch culture in shake flask)
- >1.5 g/L for bispecifics (fed batch culture in shake flask)
- >10 g/L in bioreactor
- Increase in recombinant protein expression levels by up to 20 fold

Efficiency

Selexis partners use the same research cell bank (RCB) from discovery to scale-up and commercial manufacturing.

Speed

With the accelerated RCB program Selexis can move from transfection to the transfer of a high-expressing and stable production-ready research cell bank in 8 weeks, a process that often takes other companies 8–12 months.

Safety

Selexis is committed to safety and is working on producing a virus-free cell line, a top industry goal.

Stability

Selexis research cell banks RCBs have proven stability of more than 90 generations.



ADVANCED GENE TRANSFECTION TECHNOLOGY AND PROCEDURES

The SUREtechnology Platform incorporates a number of proprietary technologies that are unique to Selexis:



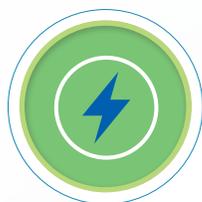
Selexis SGE® (Selexis Genetic Elements)

Selexis SGEs are unique epigenetic DNA-based elements that control the dynamic organization of chromatin in all mammalian cells and allow for higher and more stable expression of recombinant proteins.



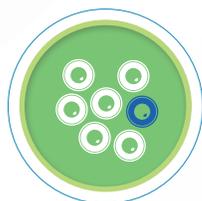
SUREtech Vectors™

Selexis SUREtech Vectors are proprietary vectors that are designed around Selexis Genetic Elements to ensure stable integration of a transgene into the host chromosome, ease of DNA cloning of the target gene into the vector backbone, and efficiency of transfection across a wide range of mammalian cell lines.



SUREfection Procedures™

The Selexis SUREfection Procedures have been optimized to ensure maximal transfection efficiency for both percentage of transfected cells (over 80%) and copy number per cell (typically 10 to 30 integrated gene copies per cell).



Lead Candidate Selection

Selexis can generate panels of up to 250 CHO-M cell pools, each expressing different protein variants. Typical expression levels in the supernatants for mAbs vary between 200–500 mg/L. Containing the recombinant proteins expressed with mammalian post-translational modifications, the supernatants can be readily assessed for activity. The pools expressing lead candidates may be banked (stored) and reused for further assays. The pools expressing the top candidates can be transferred to the Selexis SURE Cell Line Development Platform to generate high producing clonal cell lines (or RCBs) ready for cGMP manufacturing.

Productivity

Based on its capabilities and expertise, Selexis has been able to salvage assets that client companies could not express at commercially viable levels. Selexis has become the global leader in producing difficult-to-express proteins (e.g., Fc-fusions, bi-specific monoclonal antibodies, and novel scaffolds).

Clonality

Selexis is among the only companies in the world that can demonstrate clonality of mammalian cell lines using whole genome sequencing. This extensive mapping of Selexis RCBs supports high quality CMC submissions to regulatory agencies.

Adaptability/Transferability

Selexis is able to transfer RCBs, the feed strategy, and the scale-up process to any manufacturer or CMO, giving partners the choice. Technology transfer to the CMO takes less than one week.

Program Risk Reduction

Collectively, these advantages contribute to a significant decrease in development risks, regulatory challenges, and, ultimately, risks to the patient.

