SELEXIS®

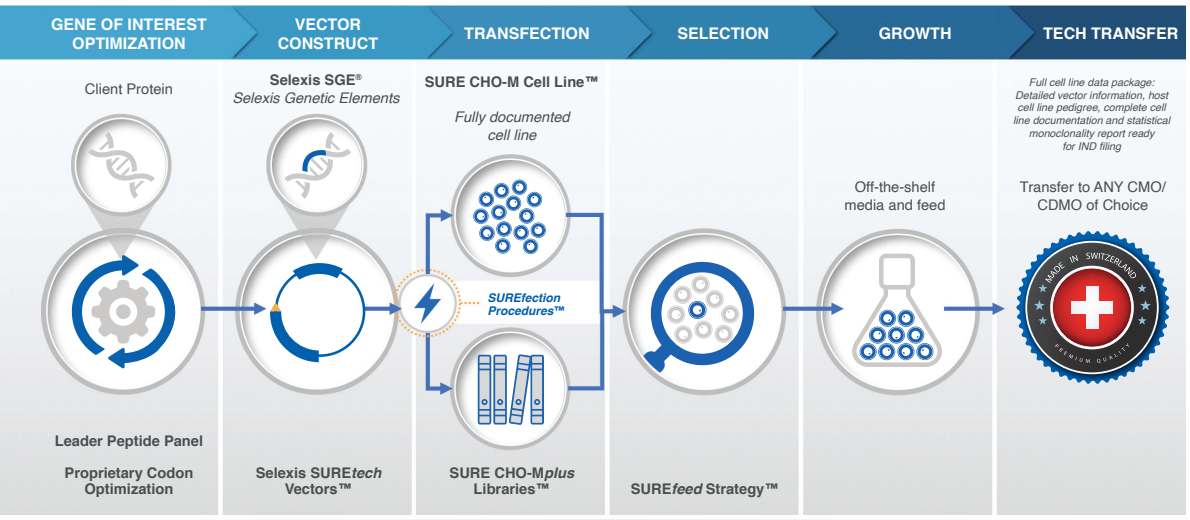
Driven by Excellence.
Guided by Science.

Research Cell Bank Development

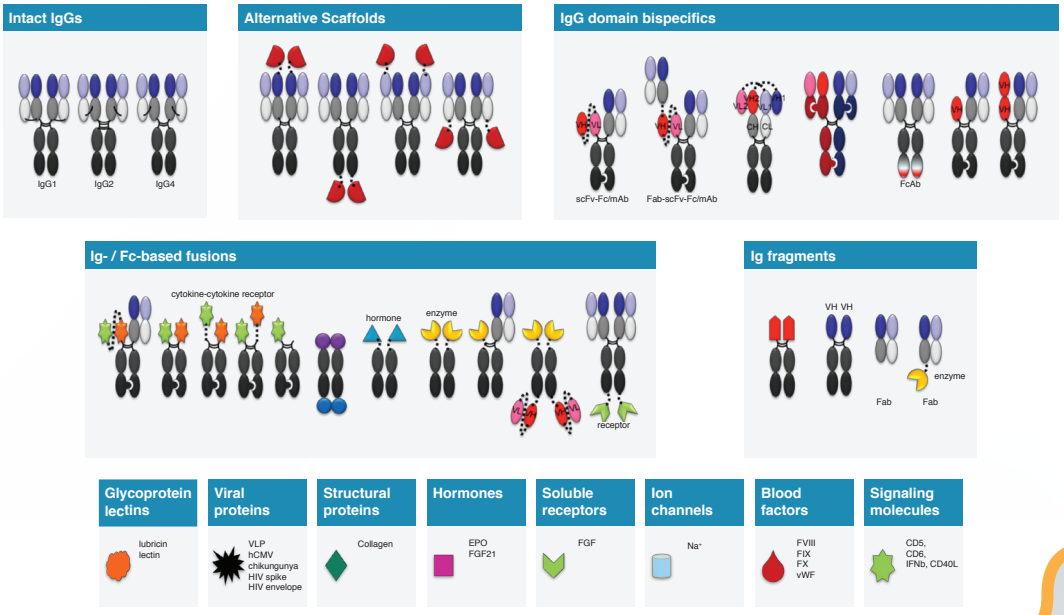
Selexis SURE Cell Line Development™

Introduction

For nearly 20 years, Selexis has helped its partners predictably, rapidly and cost-effectively generate life-saving biologic medicines and vaccines. Its SURE*technology* Platform™ is being used by global partners in 32 countries, resulting in more than 134 biologic drug products in clinical and commercial manufacturing. Selexis is able to generate stable and high-expressing (2–7 g/L for MAbs, >1.5g/L for bispecific antibodies, fed batch in shake flask, >10 g/L in bioreactor) research cell banks (RCBs) in as little as 8–14 weeks.



Novel Scaffolds Expressed with the SURE*technology* Platform™



SURE Cell Lines at a Glance

Speed

- 3 weeks for Selexis SURE*pools*™
- As little as 8-14 weeks for research cell banks with our accelerated RCB program

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

Stability

- Stable purity of bsAb (%heterodimer) over 60 generations
- Not associated with chromosomal rearrangements or breaks

Flexible

- Can adress a wide range of unnatural proteins (Fc fusions, bispecific mAbs, new scaffolds)
- Highly effective in a variety of cell lines
- 500 stable CHO cell pools in 5 weeks for screening campaigns

MADE IN SWITZERLAND
PREMIUM QUALITY

www.selexis.com

Research Cell Bank Development

Selexis SURE Cell Line Development™

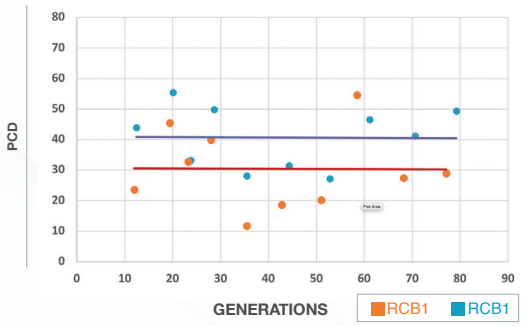
Cell Line Performance

The Selexis SURE CHO-M Cell Line™ (CHO-M) is a proprietary high-performance CHO-K1-derived cell line, whose genome and transcriptome have been extensively characterized. The growth and production properties of the CHO-M Cell Line are well-defined, allowing for faster and more efficient scale-up to bioreactors.

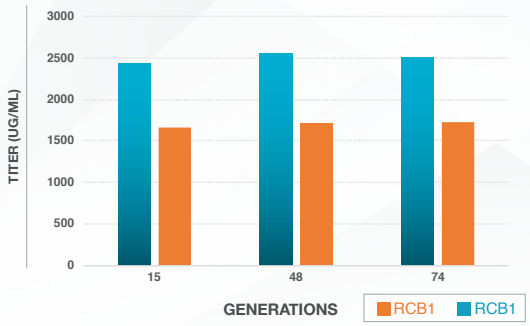
Selexis CHO-M Cell Line Stability

Stability of SURE CHO-M cells expressing IgG clones: **(A)** PCD fed-batch over generations, **(B)** titers over generations, and **(C)** FISH karyotyping over generations.

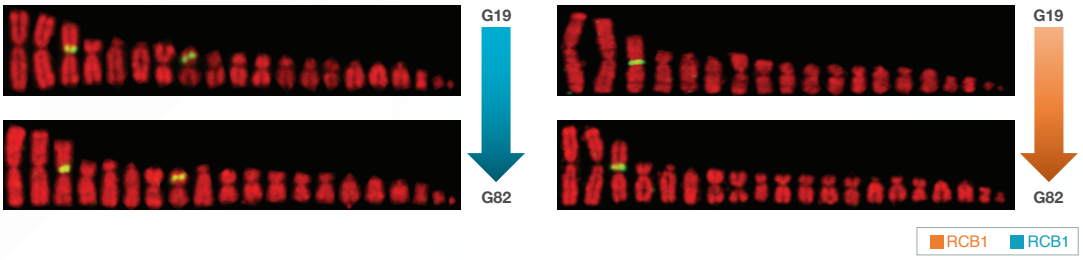
A



B



C



Direct Assessment of Clonality with Bioinformatics

Selexis SURE*scan*® combines next-generation sequencing technologies with Selexis' exclusive bioinformatics tools. Selexis can now quickly analyze the entire genome and transcriptome of any generated RCB. SURE*scan* gives Selexis' partners insights into integration sites and copy numbers, transgene integrity and can establish clonality of RCBs.

	NGS	PCR	FISH	Southern	TLA
Cell purity and identity	✔	✔	✔	✔	
Integration Site	✔				✔
Transgene integrity	✔			✔	✔
Cell line clonality	✔		✔	✔	
Gene copy Nb	✔	✔		✔	
Gene survey	✔		✔		
Adventitous agents	✔				
Full alterations (INDELs, SNPs)	✔				

Selexis SURE Cell Line Development

Proprietary technology platform and comprehensive services for fast and reliable cell line development:

- ✓ Highly adaptable non-viral vectors with no carrying-capacity limitation
- ✓ No gene amplification required
- ✓ Novel high-throughput approach to address product-specific expression bottlenecks
- ✓ Proven track record in the expression of MAbs, enzymes, Fc-Fusions, GPCRs, ion channels and more
- ✓ Precise mapping of the transgene integration site(s)
- ✓ World-class science, project management and highly efficient tech transfer to CMOs

High Performance, Stable Research Cell Banks

- ✓ No viruses
- ✓ Strong expression vectors
- ✓ High-performance host cell
- ✓ Chemically defined, serum-free medium
- ✓ Feed strategy

Proven

- ✓ 128 drug candidates from post-IND filing to 6 commercial products have been generated with the Selexis SURE*technology*™ Platform
- ✓ More than 100 partners worldwide have used/are using the technology