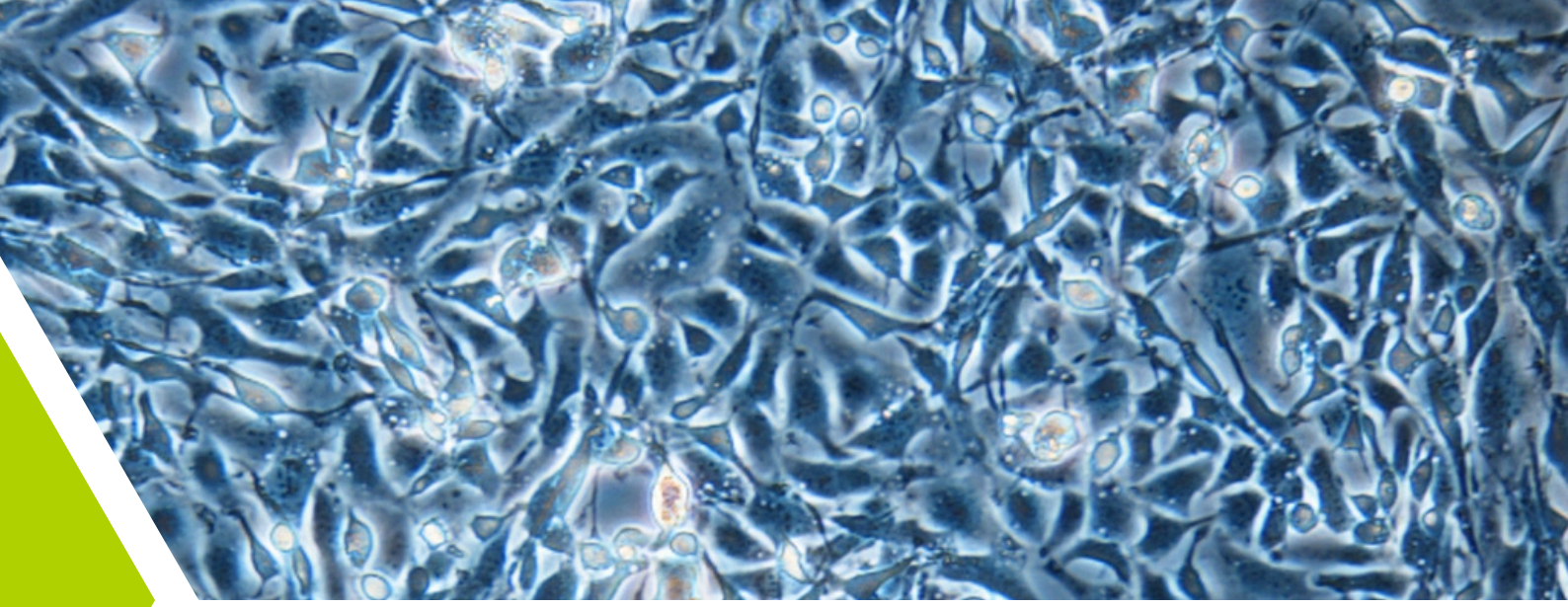

Genetic Analysis in CHO Production Cell Lines

Avoid jeopardizing drug development timelines & regulatory approval

A stable CHO cell line producing consistent and predictable expression of the therapeutic gene is essential from a regulatory and a drug viability position. Quality attributes such as vector copy number (VCN) and genomic coordinates of integration site(s) are critical in assessing the stability of the cell line in bioproduction. In addition, it is important to assess whether off-target modifications have been introduced.

Genetic QC is crucial in safeguarding timelines, regulatory approvals and commercial success in bioproduction:

- ✓ Identifies stable cell lines with desired VCN, minimizing reliance on protein production for clone selection
- ✓ Enables comparison between different CHO lines
- ✓ Provides clonality evidence for legacy cell lines
- ✓ Avoids production inconsistency and minimizes genetic instability trends via cell bank testing

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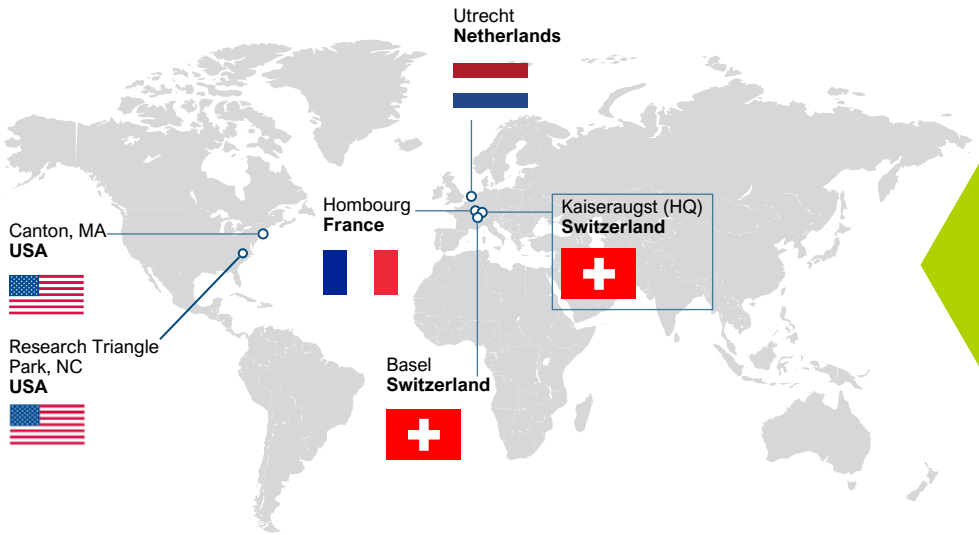
How our experts help

Service packages	Stage	Regulatory	Proven use in FDA/EMA fillings	Turnaround Expedited	Turnaround Standard
Genetic stability Identify and monitor genetic drift during biologics or viral vector production.	IND	Q5B & Q5D both refer to stability. The expression construct should remain intact & at the same copy number throughout production (i.e. from MCB to EOP).	✓	6 weeks	10 weeks
Vector copy number determination by ddPCR Performed with Target Locus Amplification (TLA) service or as a stand-alone QC.	IND	ICH guidelines Q5B	✓	Project-specific	
Clonality assurance A rapid and cost-effective approach to analytically assess the probability of monoclonal derivation of your MCB.	BLA	ICH guidelines Q5B & Q5D, CTD module 3.2.S.2.3	✓	6 weeks	8 weeks

Why partner with us?

- CDMO/CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 22.5K sqm of lab capacity
- 700+ customers worldwide
- 6 centers of excellence



Contact us to speak with an expert: info@solvias.com

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