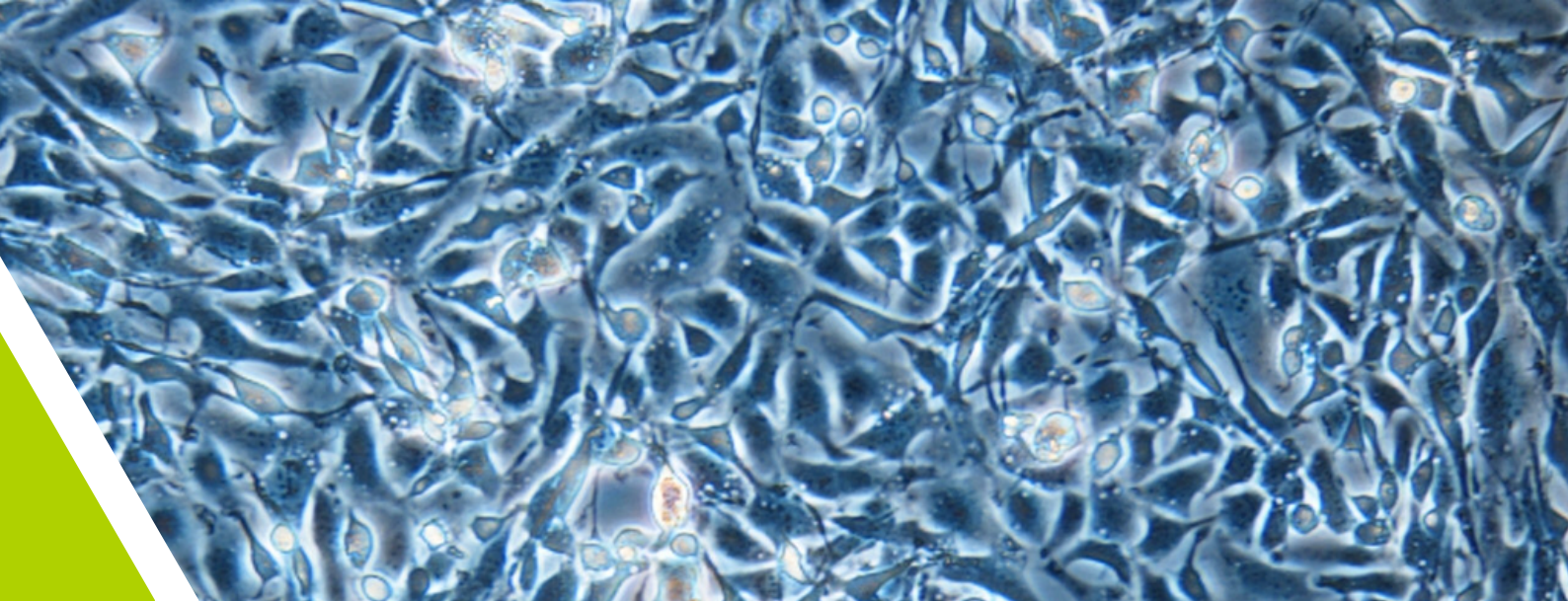




# Genetic Analysis in CHO Production Cell Lines

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

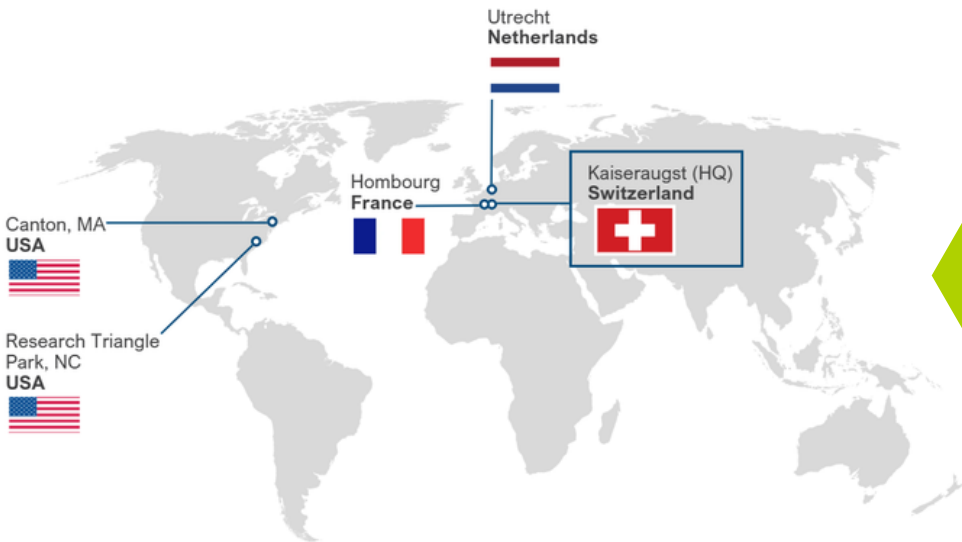


# How our experts help

| Service packages                                                                                                                               | Stage | Regulatory                                                                                                                                               | Proven use in FDA/EMA filings | Turnaround       |          |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|------------------|----------|
|                                                                                                                                                |       |                                                                                                                                                          |                               | Expedited        | Standard |
| <b>Genetic stability</b><br>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 |
| <b>Vector copy number determination by ddPCR</b><br>Performed with Target Locus Amplification (TLA) service or as a stand-alone QC.            | IND   | ICH guidelines Q5B                                                                                                                                       | ✓                             | Project-specific |          |
| <b>Clonality assurance</b><br>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?

- CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
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- 23K m<sup>2</sup> of lab capacity
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