

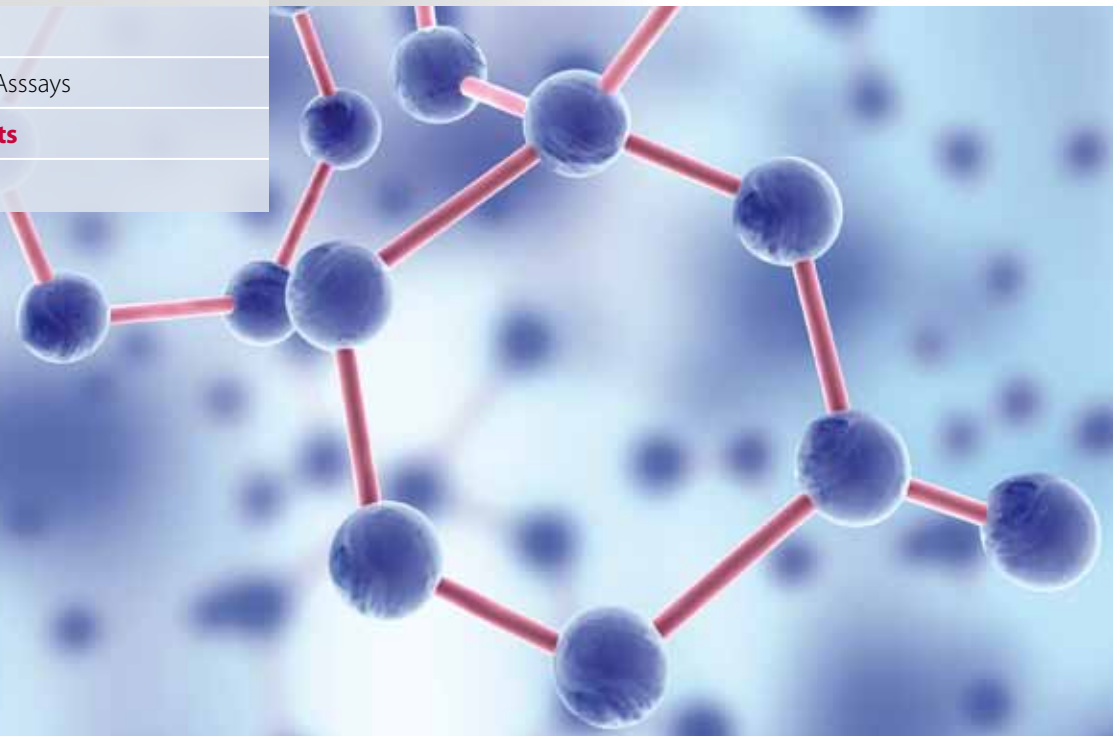
Analytical Services

Protein Analytics

Bioactivity and Cellular Assays

Host Cell Contaminants

Immunomonitoring



Host Cell Contaminants

Very strict quality and product-safety regulations are entailed on products isolated from biological sources. These products are potentially contaminated by nucleic acids or proteins derived from the host cell system or other components used during cultivation and purification.

Host Cell DNA Assay

Since most of biological pharmaceuticals are delivered directly into the blood stream of patients, there is a considerable risk due to oncogenic or other pathogenic effects of nucleic acid, especially the more stable DNA. Therefore, quantification of residual host cell or process related DNA in purified product is a pre-requisite for product release of biopharmaceuticals. Using the Threshold Total DNA Assay™ (Molecular Devices) it is possible to perform the quantitation of residual DNA with high precision and sensitivity (up to 4 pg/ml).

Host Cell Protein Assay

Recombinant biopharmaceuticals can be contaminated by residual host cell proteins (HCP). These proteins are produced by the host cell during cell culturing or fermentation and can cause an immune response in patients at levels as low as 10 to 100 parts per million (ppm). Glycotope Biotechnology offers generic enzyme immunoassays for the detection of host cell proteins from the following production cell lines: Chinese

Hamster Ovary (CHO), hybridoma cell line SP2/0, insect cell line SF9, yeast *Pichia pastoris* and *E. coli* bacteria. We also offer the development of a process specific HCP assay using the Threshold Immunoligand Assay (Molecular Devices). The sensitivity of this technology is usually below 10 ppm.

Our Core Competencies

- Development of sensitive and robust host cell contaminant assays
- Development of process and product specific pretreatments
- Validation according to regulatory guidelines (ICH Q 2 (R1))
- GMP-compliant product release testing
- Short turn-over time
- Client dedicated service

For more information please contact us

Phone: + 49 6221 9105-0

E-mail: mob@glycotope-bt.com

Glycotope Biotechnology GmbH | Czernyring 22

D-69115 Heidelberg | Germany | www.glycotope-bt.com