FyoniBio

Service Branch of Glycotope

Process development USP & DSP
Development of analytical methods
Formulation development

Working with us you can expect extensive process development expertise shaped by multidisciplinary projects encompassing immunology, cell biology, molecular biology and protein chemistry. We offer a broad portfolio of analytical methods, acquired over years on miscellaneous proteins.

Upstream Process Development

Upstream process development at Glycotope offers biotechnological contract research and development based on mammalian cell culture systems (GlycoExpress®, CHO-K1, CHO-DG44 and others).

Besides classical fed-batch and perfusion process development we offer as well the development of intensified fed-batch processes.

We are equipped with state-of-the-art bioreactor technologies from 5 ml to 10 L reactor volume:

- Clone screening at 10-15mL scale in batch, fed-batch or perfusion mode (Sartorius Ambr 15)
- Upstream process development and optimization at 12mL-10 L scale for batch, fed-batch, intensified fed-batch or perfusion (Xcell™ ATF or Centritech®) operation

Special emphasis is given to a include our analytical department for in depth quality determination during process development.

- Track record of successful process development for mAbs (including defucosylatad Abs), bispecifics / antibody fragments / fusion proteins, enzymes / hormones, blood factors and other glycooptimized or difficult-to-express proteins
- High yield expression combined with high reproducibility and scalability

Downstream Process development

In the development of downstream processes (DSP) the structural and functional parameters of the recombinant protein must be retained while simultaneously all potential impurities are removed.

We perform method development for protein purification processes including

- Filtration (cell separation and TFF/diafiltration development)
- Chromatographic purification development (capturing, intermediate polish and polish steps) in order to achieve a robust and efficient process for the removal of host cell proteins (HCP), culture medium components, endotoxins and host cell DNA as critical process related impurities

Special emphasis is given on protein aggregation and fragmentation which might occur during production and purification.

Development of analytical methods

To control the USP and DSP processes all analytical methods is available incl.

- HPLC (e.g. SEC, WCX, WAX)
- ELISA, SDS-PAGE, Western Blot
- Protein-specific assays (activation, clotting, binding etc.)
- Affinity determination using DRX2 (Dynamic Biosensors)

Formulation development

Denaturation of proteins during long-term storage must be avoided. Most prominent problems are aggregation, fragmentation, deamidation and oxidation. FyoniBio uses accelerated stress studies for the liquid or lyophilized storage buffer to optimize the stability of your protein.

Our core Process Development competencies

- Processes were successfully transferred to US and European GMP facilities.
- USP and DSP – Process development ready for tech-transfer and scale-up to pilot and production level
- Optimization of existing processes
- DoE, robustness tests
- Formulation development
- Stability studies under R&D
- Considering purity demands in accordance with GMP guidelines and control strategy implementation

FyoniBio offers high quality ISO-9001 compliant services. For more information please contact us.

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