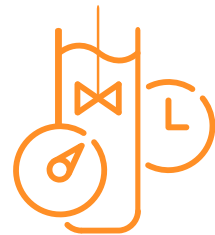




## Process Development

### Development or Optimization of Your Upstream & Downstream Processes



FyoniBio offers extensive up- and downstream process development expertise shaped by multidisciplinary projects. We select the most appropriate cell line for the expression of your recombinant protein, optimize productivity, and establish a high-yield purification process while constantly monitoring quality.

Analytical characterization can be integrated across all stages of process development for in-depth quality determination of products and intermediates. Building on our experience in technology transfer to US and European GMP facilities, we smoothly transfer your protein to the selected CMO upon completion of the process.

- Track record of successfully developed processes for mAbs (incl. defucosylated Abs, bispecifics, antibody fragments, fusion proteins), enzymes, hormones, blood factors, and other glyco-optimized or difficult-to-express proteins.
- High-yield expression combined with high reproducibility and scalability.

### Our Core Competencies

- USP and DSP development services ready for tech-transfer and scale-up to pilot and production level
- Bioprocess engineering and optimization of existing processes
- Considering purity demands in accordance with GMP/ICH guidelines and control strategy implementation
- Application of design of experiment (DoE), robustness tests
- Formulation development
- Stability studies under R&D
- Development of drug-specific analytical assays
- Protein modification

# Process Development Services

## Upstream Process Development

Upstream process development at FyoniBio offers biotechnological contract research and development based on mammalian cell culture systems such as GlycoExpress®, CHOnamite®, and CHOFlow®.

In addition to standard fed-batch and perfusion processes, we are experts in intensified fed-batch processes.



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

- Clone screening at 10-15 mL scale in batch, fed-batch or mock perfusion mode (Sartorius Ambr 15)
- Upstream process development and optimization from 12 mL to 5 L scale for batch, fed-batch, intensified fed-batch or perfusion operation
- Cell retention for up to 5 L working volume with ATF (Repligen) or Centritech (Carr) technology.



## Downstream Process Development

Downstream process development (DSP) must preserve the structural and functional parameters of the recombinant protein while removing all potential impurities.

Downstream process development for protein purification includes

- Chromatographic purification development (capturing, intermediate polish and polish steps)
- TFF/diafiltration development

As a result, robust and efficient processes for the removal of host cell proteins (HCP), culture medium components, and host cell DNA as critical process related impurities are developed. Moreover, particular focus is on removing potential protein aggregation and fragmentation that can occur during manufacturing and purification.

## Development of Analytical Methods

- HPLC (e.g., SEC, WCX, WAX, RP, HIC)
- ELISA, SDS-PAGE, Western Blot, IEF
- Protein-specific functional assays (activation, clotting, binding, affinity etc.)
- PTMs, N- and O-glycans etc.

Every assay is customized or can be newly developed from scratch.

## Formulation Development

During long-term storage of proteins, degradation or loss of functionality can occur. Most prominent problems are aggregation, fragmentation, deamidation and oxidation. FyoniBio uses accelerated stress studies for liquid or lyophilized storage buffers to optimize the stability of your protein. As additional tool, we use buffer screening by the means of changes in intrinsic or dye fluorescence.

## Protein Modification

Do you need modified proteins? We conjugate your molecule with toxins (ADC), streptavidin, biotin or label it fluorescently or customized. Or do you want to create your own affinity chromatography matrix? We couple your protein to NHS-activated resin or magnetic beads.

## The FyoniBio Team Is All Set to Bring Your CMC Project to the Next Level!

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



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