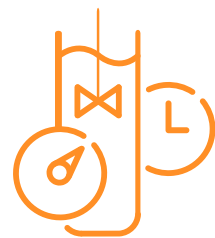




# Process Development

Focusing on optimization of your upstream and downstream processes



FyoniBio offers an extensive up- and downstream process development expertise shaped by multidisciplinary projects. We find 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. To achieve this, we offer a broad portfolio of analytical methods, acquired over years on miscellaneous proteins.

Over all stages of process development, we offer to include our analytical department for in depth quality determination of products and intermediates. Trust our experience in tech transfer to US and European GMP facilities to move your protein forward once the process is complete:

- Track record of successful process development for mAbs (including 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 – Bioprocess 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

## Upstream Process Development

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

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



## Downstream Process Development

During 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

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

As a result we achieve a robust and efficient process for the removal of host cell proteins (HCP), culture medium components, and host cell DNA as critical process related impurities. Special emphasis is given on the prevention of protein aggregation and fragmentation which might occur during production 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.

Of course, 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, 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 glad to support you throughout your projects**

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



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