Take control of glycosylation

Discover in vitro glycoengineering
We are CustomBiotech from Roche

In your operations, behind your decisions, powering your products

You are driving a paradigm shift. Scientific and technological advances emerging from creative companies across the globe are transforming the way we look at disease and breaking down boundaries for treatment. The untapped potential in these innovations is accompanied by many challenges. How do you secure a supply chain in a global landscape? How do you ensure compliance in a demanding regulatory environment? How do you remain competitive in a fast-paced market? Now more than ever, business success hinges on finding suppliers, collaborators, and other partners who understand your needs and allow you to focus on what matters.

What if all of those partners were one single ally – a market leader with decades of experience in biotechnology and *in vitro* diagnostics standing shoulder to shoulder with your team?

Welcome to Roche CustomBiotech.
Innovation
*Count on great ideas that work.* From research and development to manufacturing and logistics, our experts and facilities cover an unparalleled spectrum of skills and technologies to explore any idea.

Customization
*Invest time and resources into what you do best.* For everything else, rely on us. With customized development, manufacturing, labeling, packaging and filling of components, we streamline the path of your product to market.

Service
*Tackle problems with a smart ally.* From business and regulatory issues to production troubleshooting, we help safeguard your operations and market standing with fast answers to problems, anytime and anywhere.

Security
*Set your mind at ease.* Our global reach, stringent standards and state-of-the-art manufacturing mean a secured supply of products and services to drive your business forward, when and where needed.
**Take control of glycosylation**

*Discover in vitro glycoengineering*

**Optimized and faster**

Variation in glycosylation can impact the safety and efficacy profiles of a therapeutic protein. Therefore, continuous monitoring of glycosylation patterns is essential in biopharmaceutical development and manufacturing. With the right tools, glycosylation management can be uncoupled from the entangled processes of fermentation. Isolating glycosylation management from fermentation separates strategies to optimize glycosylation and yield, granting greater control over each. Instead, certain glycoforms can be enriched in downstream processing using discrete enzymatic reactions with clear kinetics and predictable outcomes. No more resources wasted on uncertain tweaking of the bioprocess, leading to faster development as well as improved control of the manufacturing process. Take control with *in vitro* glycoengineering.

**Gains from *in vitro* glycoengineering:**
- Time- and cost-saving generation of glycan variants to develop improved drugs
- Optimized glycosylation without compromising other CQAs or product yield
- Improved lot-to-lot consistency to reduce risk of product quality variation and resulting delays
- Generation of glycoprofiles which may not otherwise be generated
- Streamlined analytics in comparability studies

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**In vitro glycoengineering (IVGE) can improve control on quality of therapeutic proteins**

**Limited control on input variables**
- Substrates
- Various media components
- Cell growth & viability
- Metabolites
- Other ...

**Improved control on output quality**
- By modification of glycosylation pattern in downstream process

Improved glycopattern consistency
Enhanced engineering of glycan variants

Glycosylation has the potential to make or break the successful market entry of a drug. Unlike the limited manipulation during fermentation, in vitro glycoengineering enables the creation of high levels of galactosylation or sialylation to unambiguously select and implement the structure with the best therapeutic and pharmacokinetic profile. With in vitro glycoengineering, generating different glycan variants of a protein is selective, fast, and efficient since enzymatic treatments alter only targeted sugar residues, enabling creation of glycoprofiles which may not otherwise be synthesized. Results are no longer hindered by compromises inherent to glycan optimization using different expression systems, fermentation conditions, or media composition.

Controlled glycosylation from beginning to end

The quality of a therapeutic protein should emerge from profound knowledge of both bioprocess and product (Quality by Design, QbD). The reduced complexity of in vitro glycoengineering grants greater control over glycosylation at all project steps. The improved control simplifies technology transfers and lessens the risk of lot-to-lot variability and required corrective action. Thus, in vitro glycoengineering supports QbD by alleviating translation of protocols from early development to the same results at large manufacturing scales.

No compromises in critical quality attributes

Glycosylation is a Critical Quality Attribute (CQA) that often conflicts with other properties of biopharmaceuticals. Balancing these important production outcomes consumes time and resources. Optimizing expression systems and fermentation conditions during bioprocess development can drive CQAs out of specification range and force compromises or delay projects. Not if glycosylation is done directly. With a toolbox of enzymes and substrates, the glycan structure is systematically optimized after fermentation. The key advantage is controlled and direct manipulation of glycans, which saves time and effort commonly invested in difficult optimizations on the way to production scales.

α-2,3-Sialyltransferase is: For life science research only and not for use in diagnostic procedures.
α-2,6-Sialyltransferase, rec. EQ, β-1,4-Galactosyltransferase, rec. EQ, activated sugars, Alkaline Phosphatase, N-Glycosidase F and Neuraminidase are: For further processing only. Residual Protein α-2,6-Sialyltransferase Kit and Residual Protein β-1,4 Galactosyltransferase Kit are: For use in quality control/manufacturing process only.
This is the power of *in vitro* glycoengineering

**Profile and facts**

**Profile of the Roche glycoengineering toolbox**

Developed in partnership with Roche Pharma to meet quality and manufacturing requirements of the biopharmaceutical industry, the toolbox is a product of an ongoing, innovative program aimed at facilitating controlled manipulation of glycopatterns.

- Highly active enzymes to change glycosylation fast and efficiently
- Glycosyltransferases optimized for each drug development phase
- Milligram to kilogram scale and GMP quality upon request to integrate into manufacturing workflows

### Glycosyltransferases for research

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### Glycosyltransferases for drug development

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### Related products

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*No animal-derived materials were used in fermentation, purification, and final formulation.

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