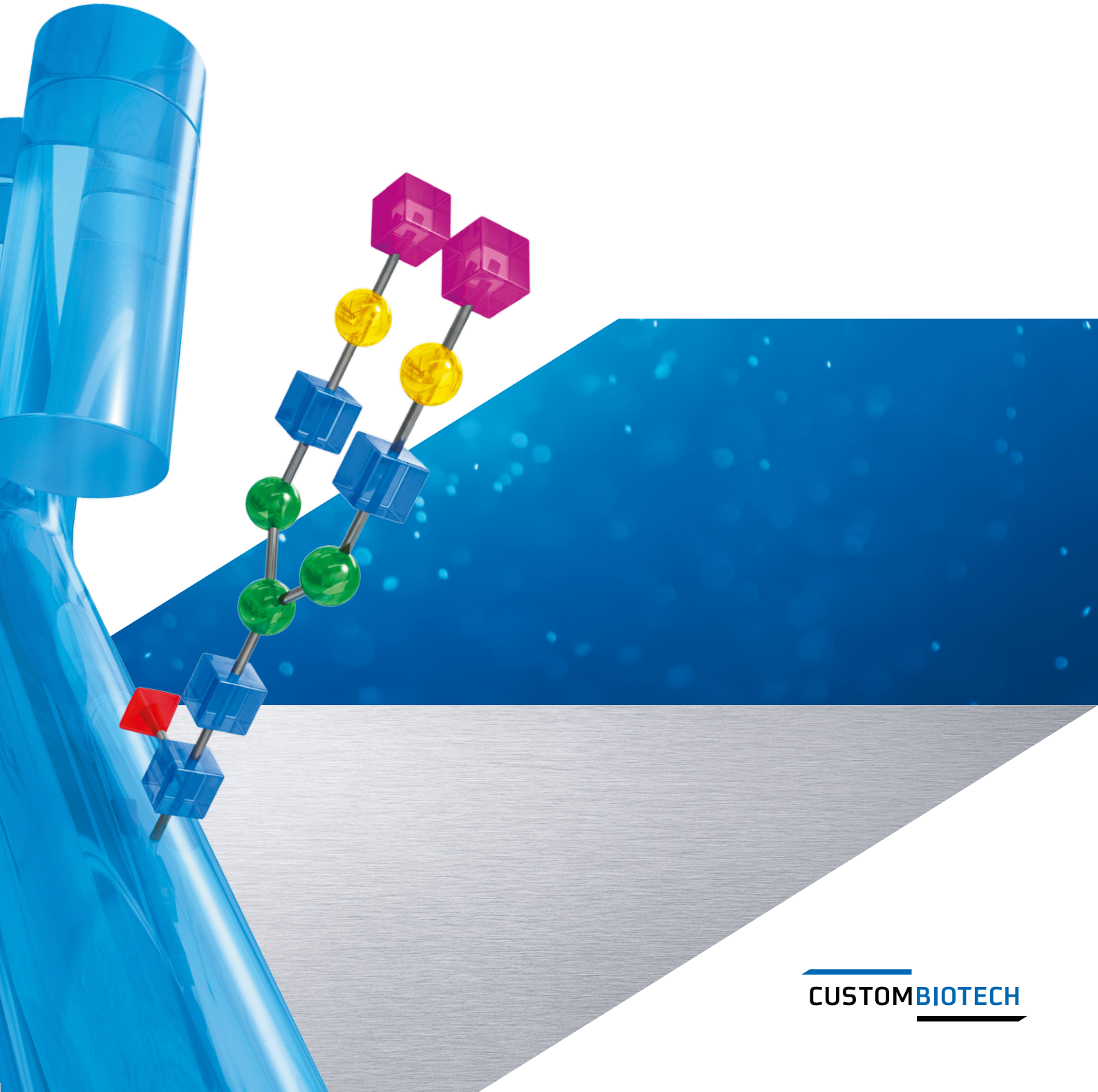
Roche

Control from beginning to end

The in vitro glycoengineering toolbox



CUSTOMBIOTECH

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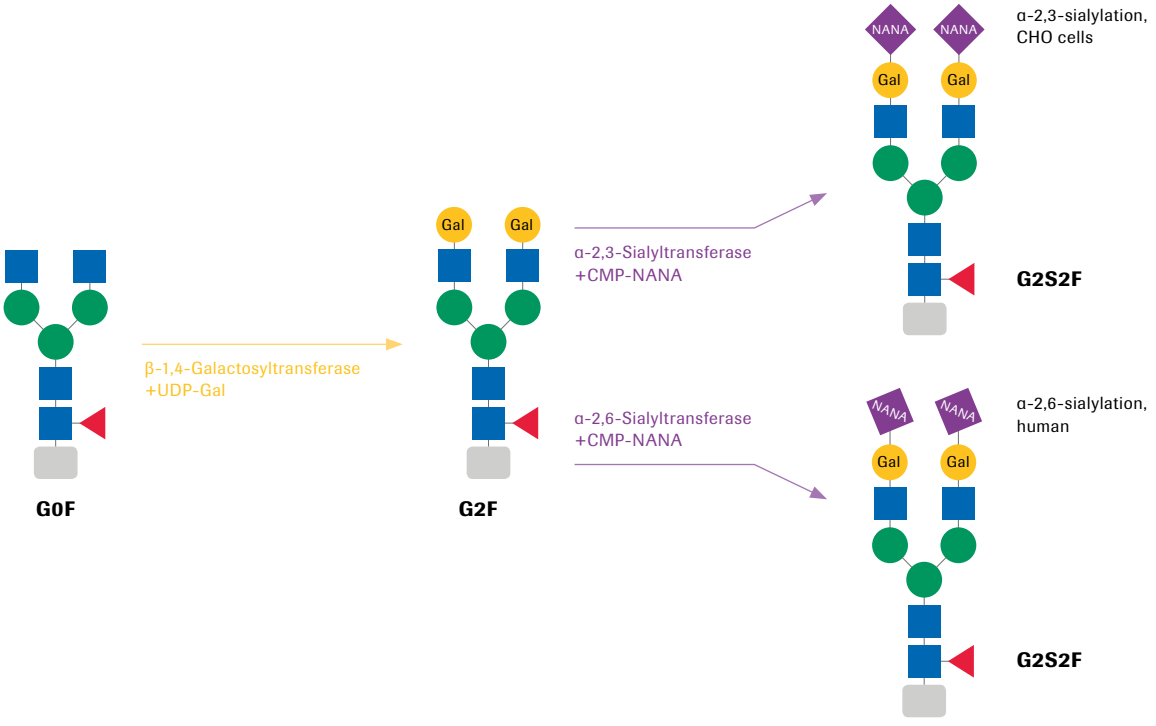
Optimized and faster

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

In vitro glycoengineering concept



The tools to steer glycosylation

The CustomBiotech *in vitro* glycoengineering toolbox is a portfolio of well-characterized enzymes and activated sugars designed for specific and efficient alteration of sugar moieties. Developed in partnership with Roche Pharma to meet quality and manufacturing requirements of the biopharmaceutical industry, the toolbox is product of an ongoing, innovative program aimed at facilitating controlled manipulation of glycopatterns. The glycosyltransferases in the portfolio have demonstrated high activity and are available in gram to kilogram amounts and good manufacturing practice (GMP) quality on request.

Glycosyltransferases optimized for each drug development phase

- Glycosyltransferases for research, available in small amounts (mg)
- Glycosyltransferases of enhanced quality (EQ) for drug development:
  - low levels of host cell impurities
  - available in gram scale
  - GMP quality on request

Glycosyltransferases for research	Catalog number	Pack size	Animal-free*
β-1,4-Galactosyltransferase, rec.	07 215 118 103	Custom fill	
α-2,3-Sialyltransferase, rec.	07 429 916 103	Custom fill	
α-2,6-Sialyltransferase, rec.	07 012 250 103	Custom fill	

Glycotransferases for drug development	Catalog number	Pack size	Animal-free*
α-2,6-Sialyltransferase, rec. EQ	08 098 174 103	0.2 g	
β-1,4-Galactosyltransferase, rec. EQ	08 098 182 103	0.2 g	

Activated sugars	Catalog number	Pack size	Animal-free*
UDP-Galactose animal-free	07 703 562 103	Custom fill	
CMP-N-Acetylneuraminic acid	05 974 003 103	Custom fill	
UDP-Glucose	10 154 938 103	Custom fill	
UDP-N-Acetylglucosamine	11 787 900 103	Custom fill	
UDP-N-Acetylgalactosamine	06 369 855 103	Custom fill	

Related products	Catalog number	Pack size	Animal-free*
Alkaline Phosphatase	03 137 031 103	Custom fill	
N-Glycosidase F	06 538 355 103	500U/vial	
Neuraminidase	10 269 620 103	Custom fill	
Residual α-2,6-Sialyltransferase Kit	08 011 478 001	96 tests	

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

α-2,6-Sialyltransferase, rec., α-2,3-Sialyltransferase, rec. and β-1,4-Galactosyltransferase, rec. are: For life science research only. 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 α-2,6-Sialyltransferase Kit is: For use in quality control/manufacturing process only.

Regulatory disclaimer

α-2,6-Sialyltransferase, rec., α-2,3-Sialyltransferase, rec. and β-1,4-Galactosyltransferase, rec. are: For life science research only. 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 α-2,6-Sialyltransferase Kit is: For use in quality control/manufacturing process only.

License limitations

The sale of the product does not exhaust or grant any rights in third party patents including patents of companies of the F. Hoffmann - La Roche AG group of companies, in particular, for the use of modified antibodies obtained by using the product.

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