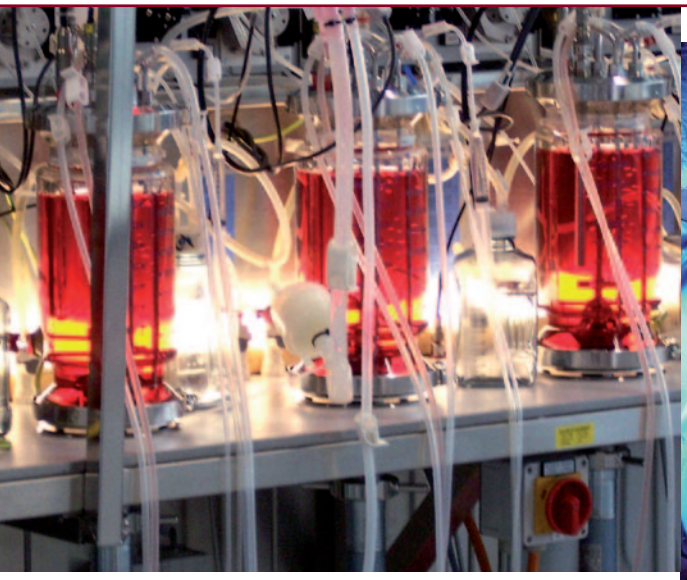
Value through Innovation

BI-HEX® -
Your high expression system

Boehringer Ingelheim



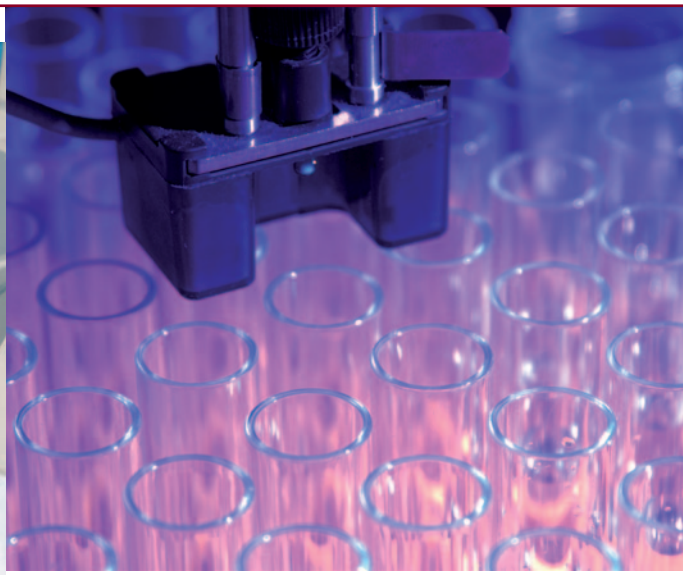
The BI HEX® Platform Technology

Boehringer Ingelheim's proprietary high expression system (BI HEX®) enables fast-track development of high-quality, high-titer processes for producing biopharmaceuticals from CHO cells. The BI HEX® platform meets both, demands for time-to-clinic as well as later large scale manufacturing. The platform addresses all important features including process performance, product quality, safety and comparability.

Cutting Edge Technologies in one Platform

- Ideal genetic elements and vectors settings for stable high-expression
- Suspension adapted CHO host cell portfolio with outstanding performance in chemically defined media
- High throughput screening platforms in Upstream and Downstream Development
- Chemically defined platform media and well-characterized down-scale models
- Improved feeding strategies based on state-of-the-art process monitoring
- Excellent scalability and comparability between stainless steel and disposable stirred tank bioreactors
- A perfect fit for your 2nd generation process

Summary BI HEX®	
BI-HEX® Host Cell Portfolio	• Suspension adapted CHO-DG44 host cells with different glyco-properties • Secretion-optimized conCERT cells • Serum-free throughout development
Expression System	• Proprietary genetic elements • DHFR-/neomycin-based selection system
Medium and Process	• Proprietary chemically-defined media • DoE, -omics approaches
Time to Tox Material	13 months from DNA receipt
Time to Clinical Material	18 months from DNA receipt
Productivity	Up to 100 pg per cell and day
Titer (depending on product properties)	• Up to 6 g/L in 11-day fed batch process • Up to 8 g/L in 19-day fed batch process



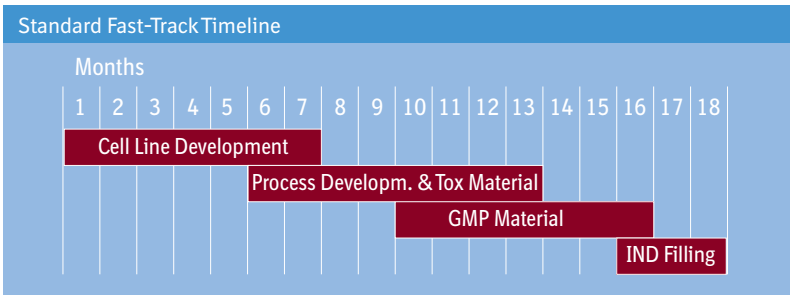
Productivity

Starting with product gene cloning into BI HEX® vectors, material for toxicological studies from monoclonal cell lines can be supplied in just 13 months. Specific productivities up to 100 pg per cell and day for monoclonal antibodies have been achieved and successfully translated into product titers up to 6 g/L in an 11-day fed-batch process without compromising product quality characteristics or bioactivity.

Cell line development projects deliver titers of 2,5 g/L in average with minimal process development after clone screening.

Speed by Automation

The BI HEX® fast-track cell line generation concept gives a production cell line with the potential for high-titer processes. A well-characterized media platform minimizes product changes throughout process optimization.



Royalty Free Access

A range of development packages is available, from cell line only to cell line generation followed by process development for preclinical and clinical supply.

Our extended CHO host cell portfolio gives you the opportunity to select between different glyco-profiles which fit best to your product – A perfect match for your 2nd generation!

The BI HEX® system is royalty-free for Boehringer Ingelheim's contract manufacturing customers.

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