



**Genedata Biologics saves valuable research time and money**

Markus Enzelberger, Ph.D., Chief Scientific Officer, MorphoSys

**INDUSTRY**

Biopharma

**GENEDATA CUSTOMER SINCE**

2011

**ABOUT MORPHOSYS**

MorphoSys, a pioneer in antibody-based therapies, uses its proprietary technology platforms with partners including Bayer, Merck, Boehringer Ingelheim, Novartis, Janssen Pfizer, Daiichi Sankyo, and Roche to develop innovative therapies.

**KEY CHALLENGES**

Increase R&D efficiency and throughput in a quickly growing organization.

**RESULTS**

Up to more than 50% efficiency gains, enabling a significant scale-up of MorphoSys' R&D operations.

**GENEDATA SOLUTION**



**BIOLOGICS**

# MorphoSys Accelerates Antibody R&D with Genedata Biologics

## Biotherapeutic Discovery

### Background & Challenges

MorphoSys is a late-stage biopharmaceutical company devoted to the development of innovative and differentiated therapies for patients suffering from serious diseases. Based on its proprietary technology platforms and leadership in the field of therapeutic antibodies, MorphoSys, together with its partners, has participated in the development of more than 100 therapeutic product candidates currently in R&D. The company has one of the broadest pipelines in the biotechnology industry, including unique approaches for patients with conditions such as cancer, Alzheimer's disease, infectious diseases, cardiovascular dysfunction, and inflammation.

The MorphoSys pipeline is based on a combination of strong business partnerships and proprietary development activities. MorphoSys has partnered with major biopharmaceutical companies including Astellas, Bayer, Merck & Co., Boehringer Ingelheim, Novartis, Janssen, Pfizer, Daiichi Sankyo, F. Hoffmann-La Roche, and Shionogi. Using MorphoSys' proprietary synthetic antibody libraries and their phage display screening technologies HuCAL, Ylanthia, and Slonomics, MorphoSys enables faster, more flexible and, ultimately, better-quality access to drug candidates.

The rapid growth of MorphoSys has led to a significant increase in molecule and sample throughput, which has made it challenging to capture, process, and interpret the huge amount of resulting R&D data.



“The scale and throughput of our operations necessitated the use of an enterprise workflow platform to manage and streamline the growing number of our discovery programs,” said Markus Enzelberger, Ph.D., Chief Scientific Officer at MorphoSys.

To cope with this data avalanche, MorphoSys decided to implement a corporate workflow platform as a “data backbone” to capture and process all data generated by their R&D programs.



The MorphoSys implementation of Genedata Biologics® as their end-to-end workflow platform has resulted in a significant increase of efficiency across all R&D functions, including library generation, screening and selection, molecular biology, antibody screening, protein engineering, expression, purification, and analytics. Images: © MorphoSys

The goal of the new system was to make MorphoSys’ sophisticated R&D processes more efficient and to facilitate handovers between various R&D teams and functions, including screening, molecular biology, engineering, expression, purification, and analytics. The

new system also needed to be able to handle the increasing amount of data and samples produced by external partners, such as CROs, which had to be integrated into MorphoSys’ R&D process.

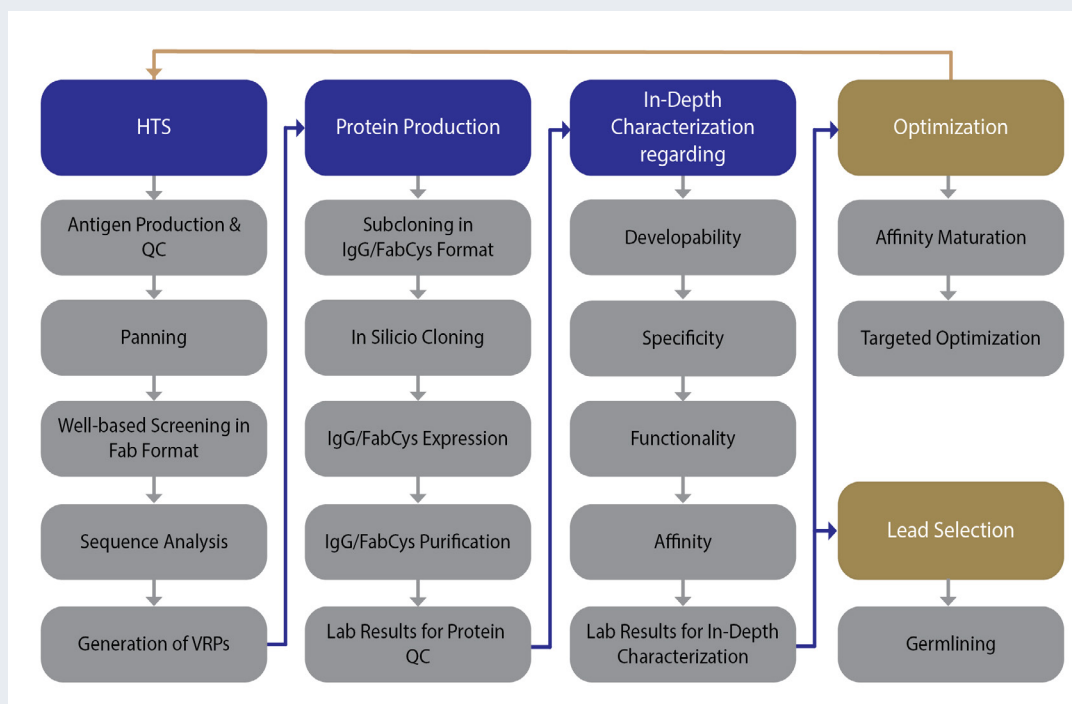
Flexibility and scalability of the new solution was of utmost importance. “Our biopharma R&D operations required an integrated and scalable informatics infrastructure that can be tailored to support our biologics discovery processes,” continued Enzelberger. MorphoSys required a solution that could be flexibly adapted to future R&D processes.

### Solution

After a formal selection process, MorphoSys decided to implement Genedata Biologics® as their new enterprise workflow platform, which they internally refer to as “Ybase”.

A key reason for this decision was the fact that Genedata Biologics is the only turnkey system available in the antibody R&D space. This allowed for rapid deployment and gave MorphoSys full process coverage right from the start. “Genedata Biologics provides the flexibility needed to support our proprietary antibody discovery processes and technology portfolio,” noted Enzelberger. “More importantly, Genedata Biologics provides all these functionalities out-of-the-box, which saves valuable research time and money,” he added.

High-level overview of one of the MorphoSys R&D workflows. Due to the flexibility of the Genedata Biologics® platform, MorphoSys’ proprietary technologies are fully supported. Shown here is MorphoSys’ Ylanthia technology, comprised of over 100 billion distinct, fully human antibodies, which translates into a huge amount of structurally diverse entities that need to be systematically screened for therapeutic candidates. This approach simultaneously pre-selects based on expression levels, increased shelf life, serum stability, and solubility, as well as improved aggregation behavior. Resulting candidates from the Ylanthia library screens are then optimized with unprecedented speed and flexibility using MorphoSys’ proprietary Slonomics technology.



Genedata Biologics was deployed as MorphoSys' end-to-end workflow platform across all discovery and development units. As part of the deployment project, the platform was integrated with all relevant laboratory equipment and IT systems, ensuring smooth and efficient data exchange between different systems and groups.

Today, Genedata Biologics is MorphoSys' enterprise workflow system for 150 users, including scientists, program managers, engineers, technicians, IT, and management. In addition, the system has become the central "mission-control center" for all their partnered and proprietary development programs.

### Efficiency Gains & Cost Savings

Using Genedata Biologics as their central workflow platform, the MorphoSys R&D teams can now access all project information in real time. The ability to immediately see the status of any project at any time allows for more informed and rapid decision-making at all levels – from corporate leaders to scientists, engineers, and technical staff.

This access to R&D information has transformed how MorphoSys operates today. In dedicated project dashboards, all teams can look up project information such as molecule characteristics (e.g., sequences, assay data, analytics data), as well as operational key performance indicators (KPIs) that help them more effectively

make decisions. Using a shared workflow platform also encourages all collaborators to review, comment on, and use the same data and planning information. This improves accuracy and quality of critical project data, and effectively cuts down on redundancies and inconsistencies.



Genedata Biologics® has become MorphoSys' central "mission-control center" for all R&D programs. All R&D teams have immediate access to comprehensive status information on all projects at any time, which allows for effective decision-making at all levels. At MorphoSys, 150 users, including scientists, program managers, engineers, technicians, IT, and management benefit on a daily basis from the shared platform. *Image: © MorphoSys.*

As an additional plus, teams no longer need to create manual reports, as reporting is now the result of day-to-day operations. After each step in the R&D workflow, such as for an antibody optimization campaign, the responsible scientists register all

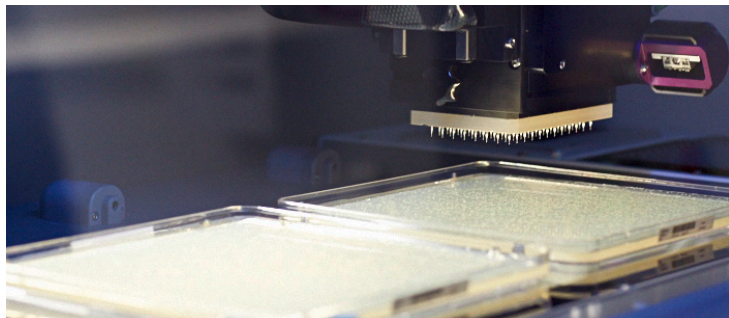
Laboratory Results for 4 Protein Purification Batches											
Protein Purification Batch	Parent Protein Expression Batch	Freeze-Thaw Stability	High-Concentration Stability (Solubility)	High-Temperature Stability	Homogeneity/Charge heterogeneity (IEX/cIEF/SEC)	Low-Temperature Stability	Low-pH Stability	MS Analytics (mAbs)	N-linked Glycan Analytics	Purity and aggregates (SEC-MALS, SDS-PAGE, cGE)	Thermal Stability (DSC)
Target Product Protein ID	Cell Line ID	Outcome	Outcome	Outcome	Outcome	Outcome	Outcome	Outcome	Outcome	Outcome	Outcome
TPP-84	CLI-37	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed
TPP-85	CLI-36	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Ambiguous	Passed	Passed
TPP-86	CLI-35	Not Passed	Passed	Passed	Passed	Not Passed	Passed	Passed	Passed	Passed	Passed
TPP-87	CLI-38	Ambiguous	Ambiguous	Passed	Passed	Ambiguous	Passed	Passed	Passed	Passed	Ambiguous

Genedata Biologics® provides MorphoSys' R&D teams access to all project information in real time. The upper image shows a central dashboard for a developability risk assessment of four different antibody development candidates, integrating multiple critical quality attribute (CQA) data generated by different analytics teams. An intuitive traffic light system enables the identification of superior development candidates based on systematic and objective developability and manufacturability criteria. Color-coded fields indicate whether developability assessment results do (green) or do not (red) meet the developability criteria – or are ambiguous (yellow). The lower image shows another project dashboard example, with a drill-down to individual clones from an affinity maturation and optimization campaign, together with decision-relevant SPR binding and neutralization assay data. The system automatically integrates and evaluates all sequence and assay data, and highlights clones carrying binding relevant mutations (red cells = unexpected mutation, blue cells = expected mutation).

Assay Results for 20 Antibody Clones filtered by sequence optimized Antibody Clones derived from CL-17765 (0151MGT-M021-F01-1791)																				
Antibody Clone	Parent Antibody Clone			Mutation Validation VL							Mutation Validation VH					Biacore AR-65 (Biacore (hTNFa)) AG-40 (hTNFa)		Neutralization Assay AR-67 (L929 Assay)		
	ID	Relationship Type	Relationship Status	21	27	31	51	52	89	90	29	30	97	108	109	K <sub>D</sub> [pM]	k <sub>on</sub> [1/(M*s)]	k <sub>off</sub> [1/s]	ND <sub>50</sub> [pM]	Neutralization Level
CL-28809	CL-17765	Sequence Optimized	Mismatch	I	Q	I	G	S	Y	S	H	S	K	Q	A	6.88	4.79E06	3.30E-05	61.831	++
CL-28808	CL-17765	Sequence Optimized	Mismatch	L	Q	L	S	Y	D	K	G	H	K	Q	Q	5.16	5.36E06	2.77E-05	34.747	++
CL-28807	CL-17765	Sequence Optimized	Verified	I	Y	L	G	Y	Y	S	Q	S	K	D	S	4.93	3.78E06	1.86E-05	73.606	++
CL-28806	CL-17765	Sequence Optimized	Mismatch	I	R	I	G	Y	D	K	G	P	K	Q	Y	2.94	1.77E06	5.20E-06	7.482	+++
CL-28805	CL-17765	Sequence Optimized	Verified	I	Q	L	G	Y	D	S	Q	S	A	Q	S	1.98	4.29E06	8.48E-06	7.797	+++
CL-28804	CL-17765	Sequence Optimized	Verified	I	Q	I	Y	S	Y	K	Y	H	K	Q	Y	5.91	1.79E06	1.06E-05	9.736	+++



relevant data (e.g., binding, activity data) and the drug candidate information is automatically updated for the next step in the workflow. Furthermore, all contextual and collaborative data are tracked and can be verified, providing a vital history of all drug candidates and samples.



*MorphoSys has integrated their high-throughput robotic platforms to directly interact with Genedata Biologics®. This enables full automation of the overall process for antibody library screening, including isolate tracking, from automated picking of bacterial colonies, primary screening of thousands of single clones in robust 96/384 well assays (ELISA, FACS, Biacore, etc.), fully automated transfer of a pre-defined selection of positive clones for further validation, cross-assay hit selection, including cross-reactivity and quality control of positive clones, and automating the iterative affinity maturation processes. Open interfaces enable a transparent integration via APIs (RESTful webservice).*

Images: © MorphoSys

The biggest impact, however, has been on the agility of the R&D teams. MorphoSys recently surveyed its R&D teams and found that time spent on administrative tasks had been reduced by about 25% – and for some standard tasks by even more than 50%. This has freed up valuable time for the R&D teams to focus on critical scientific tasks, such as analyzing a candidate’s efficacy and safety profile along with developability and manufacturability data, to make earlier informed decisions on the best drug candidates to move forward. Genedata Biologics helps MorphoSys’ scientists to spend their time on science rather than on cumbersome manual IT housekeeping tasks, reporting, or data management.

By standardizing and automating the underlying workflows, R&D

processes have become more efficient and robust, which in turn has enabled a scale-up of MorphoSys’ R&D operations. Plus the speed and accuracy of the drug discovery and development process has improved.

## Future

MorphoSys is now well prepared to address new large-molecule R&D requirements as they benefit from having an evolving system, with multiple upgrades per year. “We are pleased to see the steady and continuous evolution of the Genedata Biologics platform and how it addresses our constantly emerging new technology and workflow requirements,” said Enzelberger.

Since deployment of the platform, MorphoSys has come to rely on this ability of Genedata Biologics to adapt to new R&D processes and objectives, such as MorphoSys’ new Ylanthia and Slonomics library technologies. Furthermore, as an open and flexible system, Genedata Biologics is future-proof as it can quickly and cost-effectively be integrated with any novel laboratory instrument or robotics equipment.

Finally, MorphoSys values the ongoing support Genedata provides. “We appreciate the collaborative approach with Genedata, and their unique expertise in biopharma discovery and process optimization,” continued Enzelberger. With offices around the globe, MorphoSys is pleased to have local support available when and where they need it.

Enzelberger summarized, “We made a decision early on to use Genedata Biologics as MorphoSys’ workflow backbone to accelerate our drug discovery efforts and have watched as Genedata Biologics has become the global industry standard for biopharma discovery organizations.”

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GENEDATA SOLUTION



Genedata Biologics® is part of the Genedata portfolio of advanced software solutions that serve the evolving needs of drug discovery, industrial biotechnology, and other life sciences.

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