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TECH OUTLOOK

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APAC SPECIAL

**CONTRACT
MANUFACTURING
ORGANIZATION**
E D I T I O N

**TOP
CMO
IN CHINA
2023**

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**PHARMA
TECH OUTLOOK**

MabPlex International Co., Ltd.
烟台迈百瑞国际生物医药股份有限公司



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Driving Innovation through CMO Leadership

Quality and reliability are increasingly critical to biopharmaceutical client's when selecting a contract manufacturing organization. MabPlex International embodies these qualities like no other. This global biotechnology powerhouse fuses scientific mastery with a relentless drive to improve lives through quality-driven innovation and consistency.

Founded in 2013, MabPlex established itself as a turn-key solution offering end-to-end services within one organization. The firm provides biologics development and manufacturing services to the biopharmaceutical industry, including monoclonal antibodies (mAbs), recombinant proteins, antibody-drug conjugates (ADC), bi-specifics, tri-specifics, and tetra-specifics. MabPlex is able to assist clients with projects at all stages, from early stage through commercial manufacturing of established programs. MabPlex can enhance early-stage development of products, providing technical expertise and customer-oriented service. From DNA sequence to the finished drug product, all critical steps are conducted in-house.

MabPlex uses proven cell lines and clear licensing terms from the American Type Culture Collection (ATCC), with contract agreements for each stage of a project and strict adherence to FDA guidelines. MabPlex's technology-focused expertise and diverse product experience differentiate us within the industry, providing critical value toward the successful execution of each Client project.


MabPlex's technical team has an average of 20 years in biologics product development experience, with a proven track record assisting a global Client base developing products from pre-clinical stage to commercialization (including global regulatory CMC submissions). Our all-inclusive service is trusted by Clients with a wide variety of backgrounds and products. A recent project involved a particularly complex and unstable multispecific molecule for cGMP production, with problematically low expression and initial product quality. The MabPlex team successfully developed a stable cell line from the sequence with high throughput methodologies. The state-of-the-art design of experiments (DOE) approach in combination with a scale-down bioreactor model helped set the stage for pilot production. The resulting drug substance showed attenuated

aggregation, precipitation, and fragmentation during purification development, all of which were successfully overcome. An effective formulation and analytical process was developed to achieve the highest possible concentration while maintaining monomer percentage and other critical quality attributes (CQAs). Our efforts led to an investigational new drug (IND) filing and acceptance by the U.S. FDA, a testament to MabPlex's commitment to delivering a successful result for even the most challenging programs.

MabPlex has pioneered formulations to effectively manage high-concentration antibodies and proteins, typically plagued by high viscosity, precipitation, and aggregation. Our formulation and fill capacity for ADCs ranks among the top three worldwide.

MabPlex's operations span from the U.S. to multiple locations in Asia, comprising over 200,000 square feet of production space. We maintain dozens of 50-2000 Liter single-use bioreactors, accommodating all client needs from pre-clinical through commercial manufacturing. MabPlex has validated multiple bioreactors from manufacturers including Cytiva, Sartorius, and Thermo-Fisher to accommodate diverse client processes. MabPlex has an annual output of over a million liters, with plans to triple this capacity.

The company prides itself on its unmatched expertise, extensive experience, and large-scale capacity that stands out in the CMO industry. With a sterling global regulatory track record, MabPlex offers comprehensive support for pre-clinical phase projects through global commercial manufacturing supply chains. Adeptness in handling challenging programs is evident in its ability to navigate complex demands, ensuring consistent product delivery to clients worldwide.

MabPlex is a testament to what scientific expertise, combined with a relentless drive for innovation and quality, can achieve. Our record of accomplishment, extensive experience, and distinctive approach to optimizing production places us at the forefront of the CMO industry. MabPlex is not simply an organization; we are a global force committed to improving lives through quality-driven innovation. As we continue to expand capacity, MabPlex is poised to remain a key player in the pharmaceutical industry, driving the development and manufacturing of biologic products that can change lives for the better. 



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The annual listing of 5 companies in China that are at the forefront of manufacturing pharmaceuticals and impacting the Pharma Industry