



Drug Substance Manufacturing

Mabion offers advanced Drug Substance Manufacturing services encompassing various types of biologics, antibodies (including multi-specifics and ADC), fusion proteins, enzymes and vaccine antigens. Our state-of-the-art facilities offer 25L – 8000L scale GMP DS batch size for mammalian and insect cell line production are designed to meet the highest quality, consistency and safety standards. Having almost two decades of experience in biologics production from CLD through to commercial supply, we understand what Drug Substance Manufacturing looks like from your perspective.



Fill & Finish

Our aseptic Fill & Finish services, in combination with our other services or as a stand-alone project, provide a seamless transition from Drug Substance Manufacturing to the Final Product release. Our solutions cover every part of the Fill & Finish process, from vial depyrogenation, through automatic vial filling from format 2R to 100R, capping and stoppering to secondary packaging and serialization. Full integration with Mabion's service portfolio allows you to benefit from a streamlined end-to-end service package that includes everything from development, clinical to commercial GMP manufacturing to the final product release.



Gene to Vial: End-to-End Development

With a comprehensive panel of services and fully integrated solutions, Mabion is ready to become your CDMO partner for the entire development journey from pre-clinical to GMP manufacturing. Our end-to-end offer covers every stage of this process, from gene synthesis to the final product release. With Mabion's expertise and comprehensive services, we can bring your biologic to market rapidly and robustly.



Process Development

Our early phase Process Development services focus on bridging the gap between lab scale and GMP manufacturing, ensuring robust scalability and outstanding productivity. In addition, based on our almost 20 years of experience, our late stage Process Development services design and execute process transfer and characterization studies to advance your project from clinical to commercial manufacturing. Mabion's experts will work closely with you to ensure a deep understanding of your molecule and processes and to develop and optimize robust manufacturing processes compliant with relevant regulatory standards. We focus on improving yield, reducing variability, and enhancing product quality as we progress through the consecutive stages of drug development, starting from small-scale production for pre-clinical studies, and ending with commercial-scale manufacturing.



Analytics

Mabion offers a extensive suite of Analytical Services to ensure safety, efficacy and quality of your biologic product. Our portfolio includes development, optimization and validation of analytical methods, as well as stability studies, GMP release testing and in-depth drug characterization. In addition to routine analytics, we also offer our expertise in biosimilarity and comparability studies. With our cutting-edge equipment we provide you with comprehensive tools for analyzing key physicochemical, structural and biological attributes of your molecules. With a focus on precision and compliance, Mabion's analytical capabilities can support your product from early development to commercial release.



Cell Line Development and Cell Banking

Cell Line Development is a key milestone for every biologic. Mabion, together with our renown partners, offers expert CLD and Cell Banking services, establishing robust and stable production platforms to support manufacturing throughout the lifecycle of your biologic. We offer secure, GMP-compliant cell banking services to ensure long-term preservation and traceability of your cell lines.



Warsaw

Konstantynów Łódzki Facility

ul. Mariana Langiewicza 60, 95-050 Konstantynów Łódzki, Poland

GMP, ISO-certified

Manufacturing (Clinical, Commercial)

Development (Process, Analytical)

Analytics (Analytical/QC services for GMP/non-GMP product testing, including Cell Based Assays)

Quality

Łódź Facility

ul. Fabryczna 17, 90-344 Łódź, Poland

GLP-certified

Bioanalytical studies (PK, PD, Immunogenicity; BSL-II labs)

Clinical project management and supporting operations

Your Contact at Mabion

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Check out [www](http://www.mabion.eu) and find us on LinkedIn:

www.mabion.eu

www.linkedin.com/company/mabion-s.a.



About Mabion

With a history that spans 17 years, Mabion has a wealth of experience in Biologic development and manufacturing, making us well-positioned to deliver on client's needs and requirements. We offer an end to end service with extensive bioanalytical capabilities and expertise in sterile manufacturing, including packaging and serialisation.

MABION

Your End-to-End Biologics CDMO Partner

Drug Substance
Manufacturing

Fill & Finish

Gene to Vial:
End-to-End
Development

Process
Development

Analytics

Cell Line
Development
and Cell Banking