MABION

Your End-to-End Biologics CDMO Partner

Clinical & Commercial Manufacturing

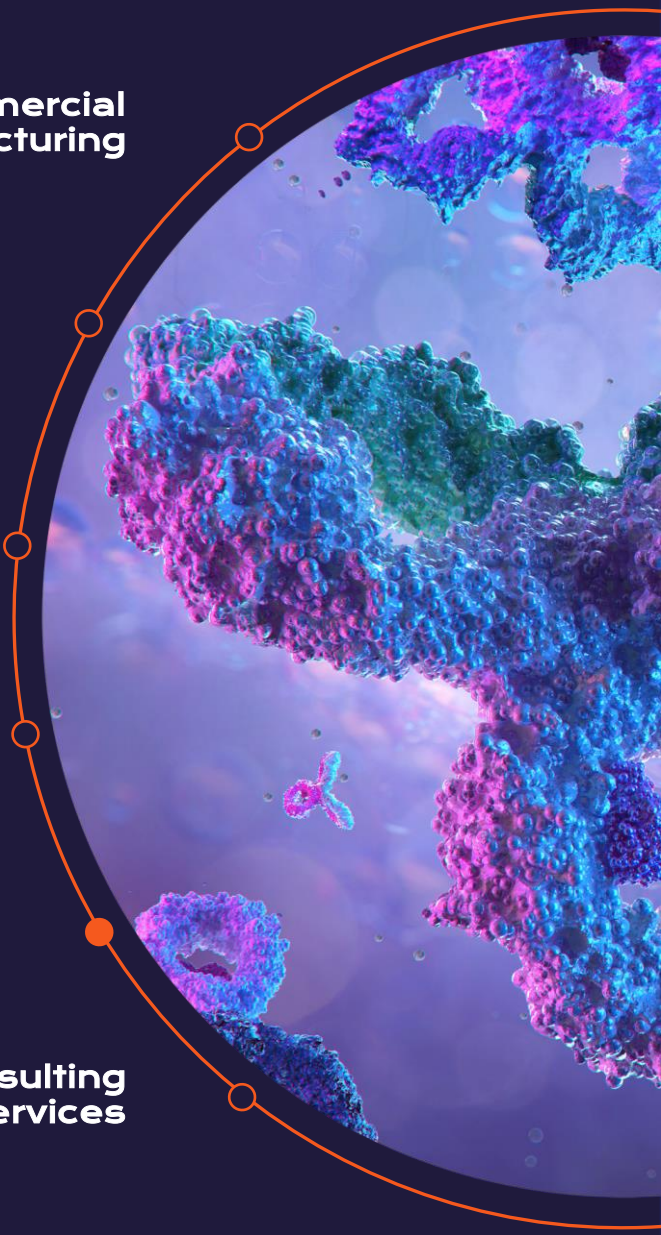
Fill & Finish

Process Development

Drug Characterization & Release Testing

Preclinical & Clinical Analytics

Regulatory & Consulting Services



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Executive Summary

- One of the many services offered by Mabion is **pre-clinical and clinical analytics**, which includes the **development, validation and transfer of bioanalytical methods** as well as the analysis of **pharmacokinetics, pharmacodynamics and immunogenicity** of biologic drugs.
- Mabion possesses dedicated **GLP-certified laboratories** with **world-class equipment** that can work in parallel to provide high-throughput analysis of samples originating from both pre-clinical and clinical studies. We have **developed a set of bioanalytical methods** that can be easily adapted to different classes of biologic medications and study-specific conditions. Our work is fully compliant with the current ICH guidelines and requirements of the EU and US regulatory agencies.
- **Pharmacokinetic analysis** of monoclonal antibodies and other biologics is performed using highly efficient and fully-automated **Gyrolab Platform**. Compared to the classical assays, it allows to **obtain higher quality data, while substantially reducing the time of analysis**.
- **Pharmacodynamics** is assessed using the flow cytometry and immunoassays platforms. The selected methods allow us to accelerate, standardize and achieve better control of the performed tests.
- **Immunogenicity assessment** includes all required analytical stages: Screening, Confirmation and Titer assays followed by the determination of neutralizing antibodies using ADCC cell-based assay.

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About Our Company

- Mabion is an integrated biologic CDMO which is dedicated to the development and manufacturing of monoclonal antibodies, vaccine antigens and other biologics.
- Since its establishment in 2008, Mabion gained recognition as a comprehensive enterprise capable of performing top-quality end-to-end services related to the production of biologic drugs as well as their pre-clinical and clinical evaluation.
- Our key asset is the full-scale manufacturing facility containing multiple bioreactors of 200L and 2000L scale operated by highly skilled personnel with a thorough understanding of biologic drug production, analytics and regulations.
- What sets Mabion apart from most other CDMO's is its multidisciplinary character covering essentially all stages of biologic drug development starting from clone selection, through pre-clinical and clinical research, and ending with the marketing authorization process.

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About Our Company

- Our main GMP and ISO-certified manufacturing facility based in center of Poland, with multiple bioreactor lines of 200L and 2000L scale, is capable of producing biologic drugs and vaccine antigens in both clinical and commercial scale.
- Provided services include process development, transfer, scale-up and optimization as well as analysis and quality testing of the manufactured products.
- Our second facility located 20 minutes away, is dedicated to developing and performing pharmacokinetics, pharmacodynamics and immunogenicity assays for the purpose of pre-clinical and clinical research.

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About Our Pre-Clinical and Clinical Analytics Services

Pharmacokinetics

Pharmacodynamics

Immunogenicity

Our bioanalytics team ensures that all methods used in your studies are well-adapted to the tested products and that analyses are performed efficiently while maintaining high-quality data. By contracting Mabion you receive a partner capable of running all key bioanalytical assessments including PK, PD, and immunogenicity.

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About Our Pre-Clinical and Clinical Analytics Services

Pharmacokinetics

Evaluation of pharmacokinetics of monoclonal antibodies and other biologics within pre-clinical and Phase I-III clinical studies. Analysis is performed utilizing the high-throughput Gyrolab platform.

The use of this fully-automated platform significantly increases the quality of the obtained data while reducing the analysis time compared to the classical assays.

- Nanoliter-scale immunoassay generating high quality data
- High repeatability: ISR >95 % of reanalyzed samples
- High precision: for >95% reported results CV <10%
- High sensitivity, selectivity, specificity and accuracy, with no „carry over" effect
- High throughput

About Our Pre-Clinical and Clinical Analytics Services

Pharmacodynamics

Assessment of pharmacodynamics is performed with the use of flow cytometry and immunoassay platforms. The developed methods are appropriate for any drugs (biologic or not) that work by lowering the concentration of specific cell types and proteins circulating in the blood. They can also be extended to measure the quantity of specific proteins in various body tissues and fluids.

The use of automated flow cytometry and immunoassay platforms allows us to achieve higher speed and better control of performed tests.

- Intra and inter-assay precision <15% of CV
- Accuracy (comparison with reference laboratory) ± 15% Bias
- Sensitivity down to 10 B cells/µL
- Whole blood sample stability extended to 14 days at 2-8°C and to 3 days at RT
- Thermal cycle stability confirmed for 3 cycles

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About Our Pre-Clinical and Clinical Analytics Services

Immunogenicity

End-to-end immunogenicity assessments performed at Mabion include anti-drug antibodies (ADAs) testing with screening, confirmatory and titer assays, followed by neutralizing antibodies testing using ADCC cell-based assays.

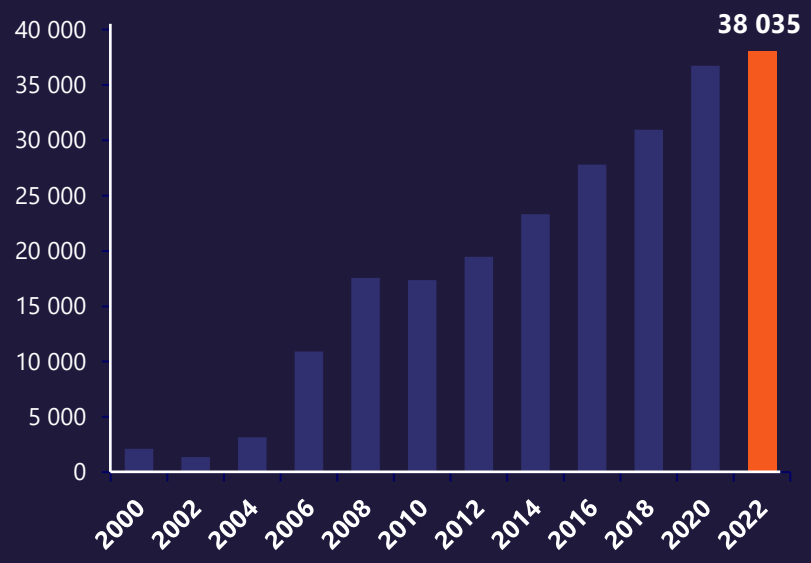
Our assays are recognized for high speed, reproducibility and sensitivity of testing at a level consistent with the expectations of EU and US regulatory authorities.

- Immunobridging assay with acid dissociation performed on Gyrolab™ Platform
- Innovative high throughput Gyrolab™ platform
- High sensitivity (< 100ng/mL)
- High precision (CV < 15%)
- Characterization of neutralizing antibodies and titer with a highly sensitive ADCC cell–based reporter assay
- More reflective of the actual biological activity of neutralizing NAbs

Industry Insights

Bioanalytics

- Pharmacokinetic, pharmacodynamic, and immunogenicity assessments are integral parts of nearly all pre-clinical and clinical studies of biologics. Together they allow us to fully characterize the pharmacologic properties of the developed product, which directly translates into its efficacy and safety profile in future patients. Efficient, reproducible, and sensitive bioanalytical methods are required to ensure high-quality of pharmacology data that is later included in the regulatory dossier. **Mabion is ready to provide a wide panel of such services to any company developing biologic therapeutics, regardless of the development stage and product class.**
- The number of clinical trials performed worldwide is growing steadily, from 2,119 trials registered in 2000 to 437,540 registered trials in 2022 (data from ClinicalTrials.gov). An increasing number of studies is being conducted in more remote locations, aiming to increase the enrolment rate while lowering costs. Such strategies often require the set up of local laboratories, which could handle the ever-increasing number of samples and provide results in a timely manner. In some cases, such as PD assessments, the proximity of a bioanalytical lab is a requirement due to the inherent instability of the samples collected from patients. **Together with its in-house logistics unit, Mabion represents a perfect choice for global trials run in a decentralized model as well as for locally performed pre-clinical and clinical studies.**

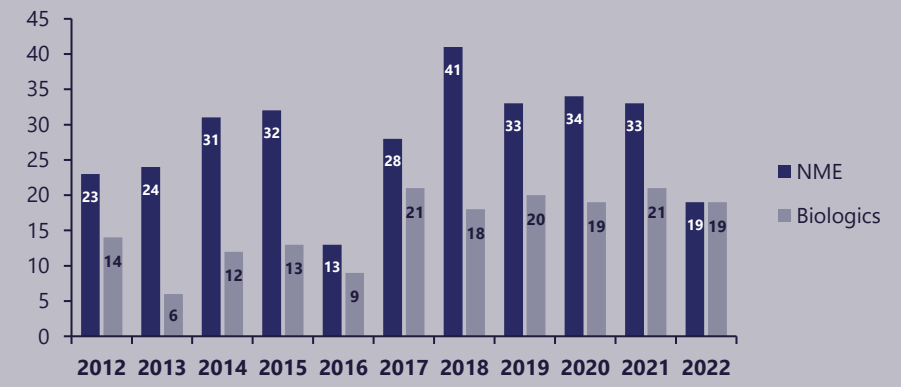


Discovery | **Pre-Clinical** | **PHASE I** PK/PD | **PHASE II** Dose selection | **PHASE III** Efficacy Safety | **PHASE III** Post-marketing

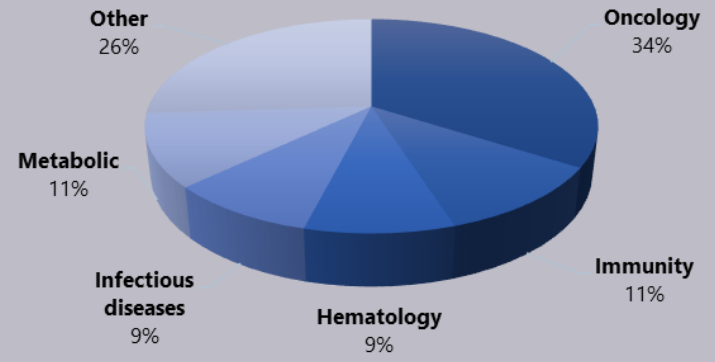
Industry Insights

- Between 2012 and 2021, FDA approved on average 44 drugs per year and the percentage of biologics among all approved drugs has risen steadily over the recent decades. In fact, in 2022, the number of new biologics entering the market has become equal to the number of approved small-molecule drugs. Most recent approvals were for oncology indications (34%) followed by immunity, metabolic, hematology and infectious diseases (9-11%).
- Much attention has been devoted to biosimilar drugs, which can be viewed as „generic" versions of the original biologics. Eighty-eight such products have been approved in the European Union and 40 in the US. Many more biosimilars are anticipated to enter the market within the next few years when more recently developed biologics go off-patent. It is hoped that the widespread use of biosimilars will increase patient access to novel therapies and limit healthcare spending.
- New innovative classes of biologics, such as bispecific antibodies, CAR-T, stem cells and gene therapies, are gaining momentum. Together they accounted for about half of biologic drug approvals in 2022, up from less than one-third in 2021.
- The total biologics market size is estimated at $366.36 billion in 2021 and is expected to rise significantly over the next years fueled by surging demand for new effective therapeutics. The market value in 2030 is predicted to reach $720 billion.
- Major players on biologics market are AbbVie, Johnson & Johnson, Amgen, Sanofi, Hoffmann-La Roche, GlaxoSmithKline, Novartis, Pfizer, Teva and CSL.

Biologic drug market



Number of FDA-approved drugs per year (all New Medical Entities and Biologics only)



Biologics approved by the FDA in 2022 by indication

Thank you for attention

Film presenting Mabion: https://youtu.be/2hzQI5ZGyxk

Mabion S.A.

SCIENTIFIC AND INDUSTRIAL COMPLEX FOR MEDICAL BIOTECHNOLOGY

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