MABION

Your End-to-End Biologics CDMO Partner

Clinical & Commercial Manufacturing

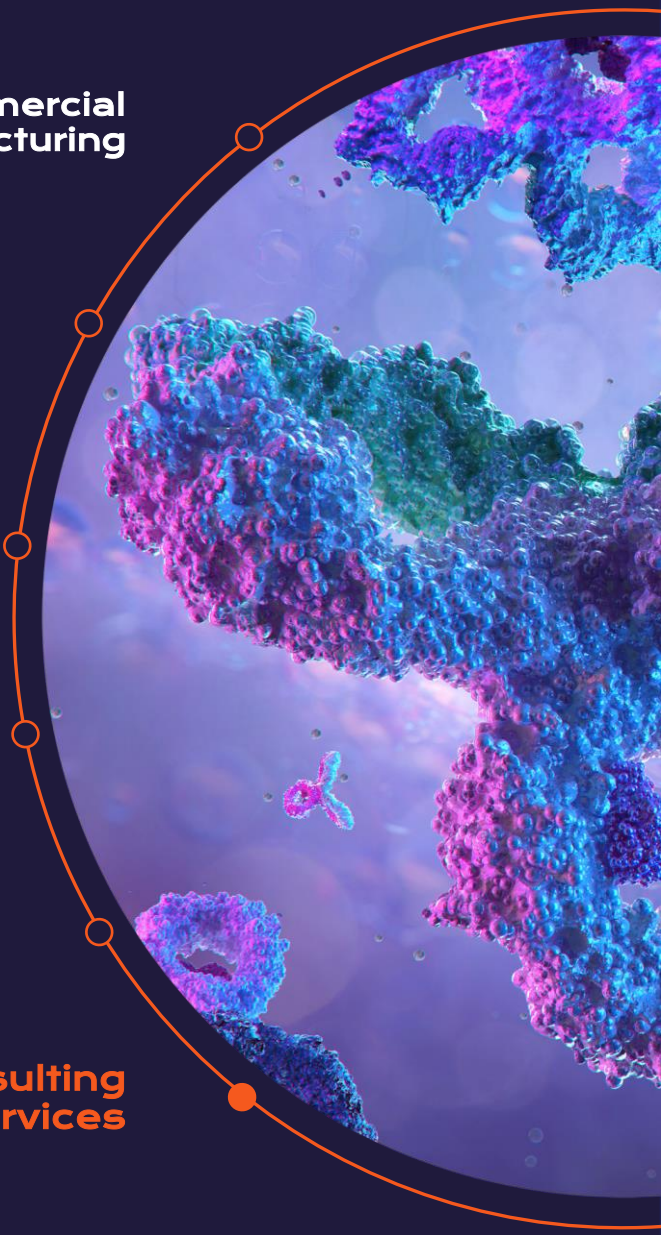
Fill & Finish

Process Development

Drug Characterization & Release Testing

Preclinical & Clinical Analytics

Regulatory & Consulting Services



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Executive Summary

- Mabion's Regulatory team offers **broad and comprehensive regulatory services** to any company developing biologic therapeutics or vaccines and planning their registration on the EU and/or US market.
- Our services include **building regulatory and development strategies,** assisting with manufacturing and quality control, supporting pre-clinical and clinical research, writing and submitting regulatory documentation, as well as handling interactions with drug agencies such as EMA and FDA.
- Mabion team can seamlessly guide you to the successful drug approval of your project starting from the pre-clinical research stage or as late as in the finalizing of the regulatory dossier stage.
- Together with our manufacturing and quality control capabilities, Mabion team represents the best option for accelerating development and ensuring top quality of the manufactured biologics.

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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 Regulatory and Consulting Services

- Building Regulatory and Development Strategy 
- Supporting Process Development, Manufacturing and Quality Control 
- Supporting Pre-Clinical and Clinical Development 
- Medical and Regulatory Writing 
- Regulatory Interactions and Submissions 

Our expert team provides continuous regulatory support throughout the entire process of biologic drug development. We are your partner from the first stage of strategic planning up to the dossier preparation.

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About Our Regulatory and Consulting Services

Building Regulatory and Development Strategy

Ensure regulatory compliance from the start by designing a successful regulatory strategy with Mabion.

Our specialist team can offer the following services:

- Preparing the optimal pathway for drug development to meet the EMA and FDA requirements
- Planning, preparing and leading the meetings with regulatory agencies (including Scientific Advice meetings, Oral Explanations at EMA as well as BPD Type I-III and pre-IND meetings at FDA)
- Benchmarking and market analysis
- Reviewing and performing gap analysis of the existing CMC, pre-clinical and clinical data/documentation
- Providing scientific and regulatory support to all teams participating in the biological drug development
- Development of Target Product Profile

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About Our Regulatory and Consulting Services

Supporting Process Development, Manufacturing and Quality Control

Understanding the uniqueness and inherent complexity of biologics, our expert team will help you to address any challenges you may encounter on the pathway to drug commercialization.

Mabion team is ready to support your company in the following activities:

- Defining regulatory requirements for process development and transfers, in terms of manufacturing and quality control
- Defining the content of analytical and quality control package required for clinical trials and MAA submission
- Performing gap analyses within the drug manufacturing and quality control process
- Support in the development, qualification and validation of analytical methods
- Support in scale down models development and qualification
- Support in manufacturing process development from lab scale to full scale and the validation of the final process as well as process transfers
- Preparing regulatory documentation related to drug manufacturing and quality control
- Support in contract manufacturing of biologic drugs and vaccine components for research and commercial purposes
- Performing audits of manufacturing sites and bioanalytical laboratories

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About Our Regulatory and Consulting Services

Supporting Pre-Clinical and Clinical Research

Mabion Regulatory and Development Consulting team offers multilevel support in design, supervision and analysis of clinical studies of biologics/biosimilars and vaccines across all development phases (phase I-IV).
Our expertise includes, but is not limited to: rheumatology, oncology, hematology and rare autoimmune disorders.

Our dedicated team of experts would be happy to support you in the following activities:

- Planning the conduct of pre-clinical and clinical studies to satisfy the regulatory requirements and business needs
- Tailoring the clinical development program to address the issues emerging from pre-clinical studies
- Designing pre-clinical and phase I-IV clinical studies (protocol writing)
- Preparing and submitting clinical study documentation from the study inception to regulatory filing (protocol. SAP, ICF, IMPD/IB and CSR)
- Managing regulatory interactions post CTA submission
- Review and analysis of clinical trial data to optimize regulatory approach and facilitate drug approval
- Auditing the clinical sites and units involved in clinical research to ensure ethical and regulatory compliance (GCP, GLP and GMP)
- Supporting pharmacovigilance and safety management activities
- Managing and acting as a point-of-contact to clinical study CROs

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About Our Regulatory and Consulting Services

Medical and Regulatory Writing

Our medical and regulatory writing skills will ensure the top quality of your dossier.

Specific services connected with Medical and Regulatory writing include:

- Writing and/or reviewing the reports from pre-clinical pharmacology and toxicology studies
- Preparing and reviewing the clinical study documentation from the study inception to regulatory filing (protocol. SAP, ICF, IMPD/IB and CSR)
- Preparing all documentation required for the regulatory dossier
- Preparing documentation for regulatory meetings with EMA and FDA: developing questions, company's positions and background materials
- Reviewing and submitting regulatory documentation (including meeting requests, meeting packages and briefing documents)
- Writing and managing the responses to health authorities
- Performing regulatory gap analysis and risk management
- Preparing the Orphan Drug Designations (ODDs)

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About Our Regulatory and Consulting Services

Regulatory Interactions and Submissions

Building a positive relationship with drug agencies based on desire to learn and understand regulatory requirements.

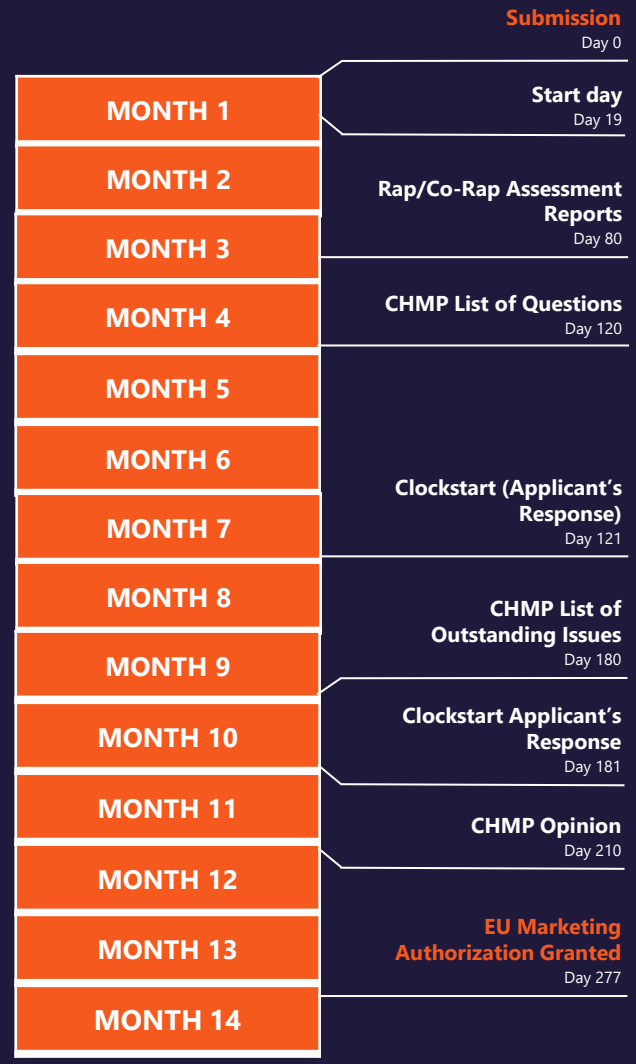
We can assist you in this endeavor by:

- Planning, managing and compiling the regulatory dossier in compliance with eCTD format
- Interpreting and implementing the latest regulatory guidances
- Supporting the companies during the meetings with regulatory agencies
- Submitting dossier and other regulatory documents to the EMA, FDA and national authorities
- Managing communication with EMA, FDA and national authorities on an everyday and/or project-specific basis

Our Experience in Regulatory Interactions

- Mabion's Regulatory and Consulting team has large experience in almost all stages of marketing authorization of biologic drug products. This includes:
  - Preparing and filing the regulatory dossier for biologic drugs
  - Leading the marketing authorization process in the EU, including the supplementary submissions and responses to EMA's queries
  - Participating in Oral Explanation with CHMP
  - Preparing Briefing Documents for EU and US agencies
  - Preparing clinical trial documentation required for trial approval by the competent authorities and later for successful drug registration (protocols, CSRs, IMPD. IB and other)
  - Organizing and attending the Scientific Advice meetings with EMA
  - Organizing and attending BPD Type 2 and Type 3 meetings with FDA
  - Preparing Orphan Drug Designation applications

Right: Timeline of MAA review by EMA



Industry Insights

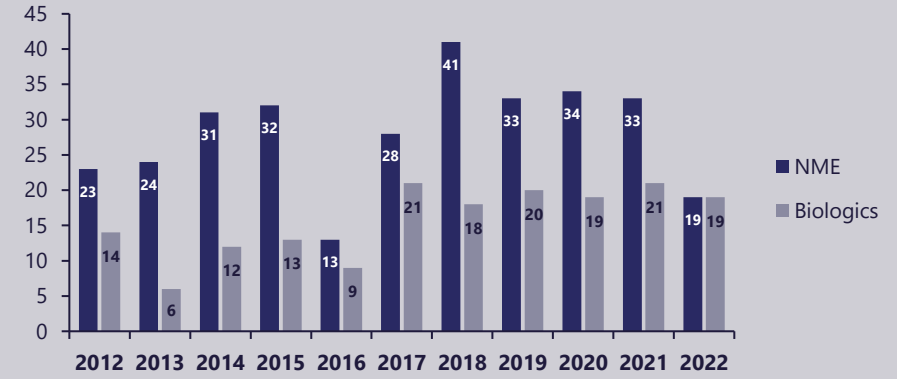
Overview of Biologic Drug Regulations

- Although biological drugs are regulated similarly to standard medications, several important differences do exist and must be considered when planning the development program or preparing the regulatory dossier. Mabion understands the nuances of biological drug development and can turn this knowledge into a successful outcome.
- Specific guidelines applicable to biological drugs have been issued by both EMA and FDA. Knowledge of these guidelines and their practical implications is essential to the successful registration of a candidate product. Specialists from Mabion are there to help you with interpreting the most recent regulations and introducing them into your development framework.
- Pre-clinical and clinical development of biologics requires sophisticated bioanalytical methods that can reliably measure drug concentrations, pharmacodynamic profiles, and immunogenic potential of the developed molecule. Immunogenicity is an important parameter specific to biological drugs and vaccines, that receives particular attention from regulatory agencies. Pharmacologic characterization of your drug product will proceed with outstanding performance thanks to our well-equipped bioanalytical unit which cooperates closely with regulatory specialists.
- Biologics are much more sensitive to manufacturing process changes that frequently occur during drug development. Often, regulatory agencies expect additional evidence proving that these changes have not introduced any unintended effects into the molecule that could impact efficacy, safety or immunogenicity. Mabion Regulatory team can support you in identifying the need for additional data, discussing the comparability issues with regulators, and performing the required studies.

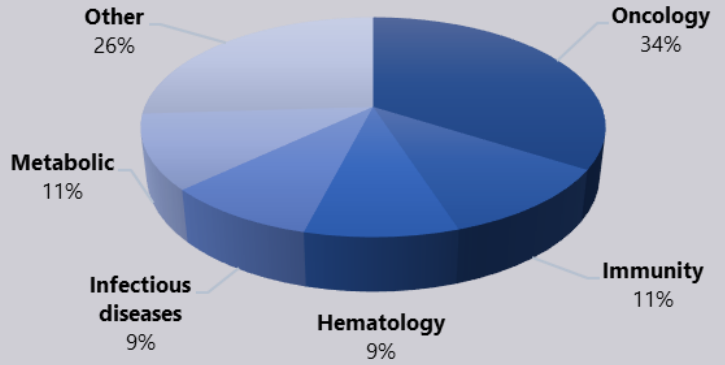
Industry Insights

- 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[a] 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

[a] Source: *https://www.precedenceresearch.com/biologics-market*

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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