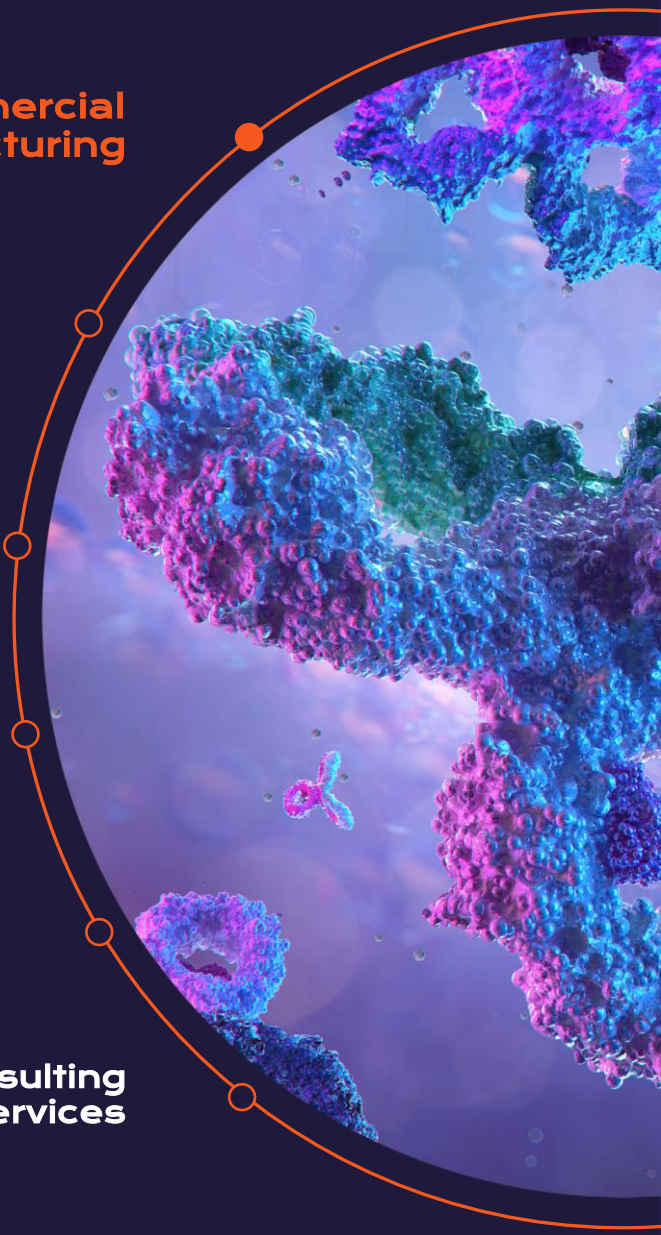
MABION

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 offers high-quality **end-to-end manufacturing services** of biologic drugs and vaccine antigens. These services encompass **upstream and downstream processes** as well as **fill & finish of drug vials.** We can address nearly all needs of a biologic DS and DP development program from the earliest stage of **protein expression** up to **commercial-scale manufacturing**.
- Our main manufacturing plant contains **multiple bioreactors of 200L and 2000L scale.** The availability of different sizes of bioreactors allows us to tailor the process to the specific requirements of a given molecule and achieve **outstanding manufacturing performance**.
- By partnering with Mabion, you will have access to an efficient **GMP-certified manufacturing** site and a skilled and enthusiastic **team of over 250 specialists** who assist you in developing and streamlining the entire production process.
- The **constant collaboration between all of Mabion's units** including Quality Control and Regulatory, results in a well-controlled and GMP-compliant manufacturing process that can **meet the most demanding deadlines**.

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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.

About Our Manufacturing Services

- Upstream Processing 
- Downstream Processing 
- Process Validation and Documentation 
- Logistics and Supply 
- Preparation and Storage of Cell and Viral Banks 

Our facilities operated by experienced and well-trained staff will ensure that optimal parameters are applied to your manufacturing process allowing it to proceed at optimal throughput while maintaining full compliance with international quality standards. The finished product can then be safely stored in our warehouses before being quickly dispatched to your chosen localizations.

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About Our Manufacturing Services

Upstream Processing

Upstream processing at Mabion is characterized by a high degree of expertise with the use of specialized equipment ensuring optimal cell growth and productivity.

Our upstream processing offer includes:

- our manufacturing plant contains 4 x 200L and 4 x 2000L bioreactors, which may be utilized back-to-back obtaining large product quantities for clinical testing or commercial purposes
- protein pharmaceuticals production including monoclonal antibodies, protein vaccine antigens, and novel modalities such as bispecific antibodies, antibodies for ADCs, fusion proteins, and others
- culturing mammalian and insect cell lines under tightly controlled conditions, with in-depth analysis of culture parameters both in terms of physiological characteristics as well as gas and metabolite content
- inoculum cell cultures in local A-class rooms
- preparation and storage of media and supplements

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About Our Manufacturing Services

Downstream Processing

Downstream processing at Mabion, being a critical part of biologics manufacturing, involves a series of carefully executed steps designed to purify the therapeutic protein and remove impurities.

Our downstream processing offer includes:

- cell harvest and separation from cells/culture medium via depth filtration and/or centrifugation
- protein purification via a multitude of methods including:
  - affinity chromatographies (incl. Protein A, Lentil Lectin)
  - ion-exchange chromatographies (incl. CEX and TMAE)
  - ultra/diafiltration
  - Tangential Flow Filtration
  - nanofiltration and sterile filtration
- virus inactivation
- formulation into final drug product
- preparation and storage of buffers
- storage of prepared drug substance

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About Our Manufacturing Services

Downstream Processing

Technologies / Description	Room / Equipment
CELL HARVEST	**D** class room › Depth filtration FlexAct system with pressure sensors, magnetic mixer, peristaltic pump and scale › Product collection, weighing and transportation system › Disc stack centrifuge
VIRUS INACTIVATION Low pH	**D** class room › FlexAct system with pH and temperature sensors, magnetic mixer, peristaltic pump and scale › Product collection, weighing and transportation system
AFFINITY CHROMATOGRAPHY Protein A with 25L column Lentil Lectin with 26L column	**D** class room › AKTA Ready system › Product collection, weighing and transportation system
ION-EXCHANGE CHROMATOGRAPHY Cation-exchange chromatography (CEX) with 63L column TMAE chromatography with 150L column	**D** class room › AKTA Ready system › Product collection, weighing and transportation system
ION-EXCHANGE CHROMATOGRAPHY Anion-exchange chromatography in flow-through mode with single-use columns	**D** class room › FlexAct system with pH and temperature sensors, magnetic mixer, peristaltic pump and scale › Product collection, weighing and transportation system

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About Our Manufacturing Services

Process Validation and Documentation

At Mabion, we understand the critical nature of process validation and therefore we produce top-quality documentation certifying the adherence to predetermined product specifications and quality characteristics.

Let our high-class specialists take care of:

- design and preliminary evaluation of the manufacturing process
- qualification of the manufacturing process
- continued monitoring through regular testing, analysis, and review of the manufacturing process
- validation after introducing changes to the manufacturing process
- documentation of the process validation in line with ICH guidelines; preparation of the Validation Master Plan (VMP), Validation Protocols and Reports

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About Our Manufacturing Services

Logistics and Supply

Mabion's in-house Logistics Unit with its own fleet of vehicles and qualified equipment offers validated logistics services under environmentally controlled conditions throughout Europe.

Mabion's Logistics services entail:

- transport of pharmaceutical products and materials under controlled conditions within four temperature ranges:

< -60ºC | < -15ºC | 2ºC - 8ºC | 15ºC - 25ºC

- monitoring and recording temperature data
- protection of shipment from temperature deviations using innovative solutions
- supply chain planning (including clinical trial logistics)

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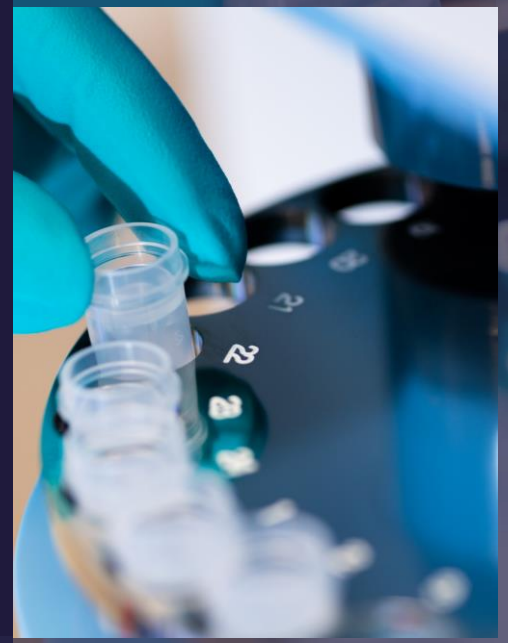
About Our Manufacturing Services

Preparation and Storage of Cell and Viral Banks

In addition to antibody and vaccine antigen manufacturing, Mabion is able to produce cells and virus banks, including the generation of MCB/WCB and MVB/WVB cell banks. Their preparation and storage is performed with the use of modern freezing systems.

Our offer includes:

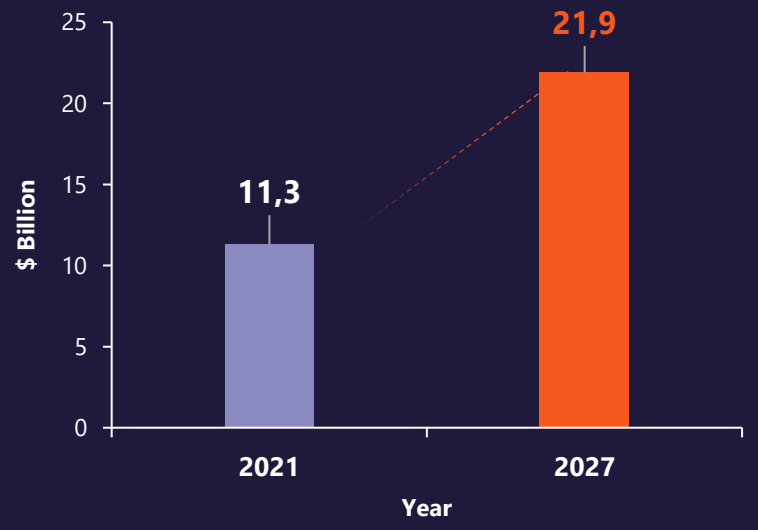
- cGMP-compliant operations under a cleanroom environment to assure the highest quality, uniformity, and purity
- <-150°C liquid nitrogen storage tanks and ultra-low-temperature freezers with a 24-hour monitoring system
- Growth, sterility, and mycoplasma (PCR) testing available on site
- Research Cell Banks for development purposes



Industry Insights

- Biologic drugs, which encompass multiple different classes of recombinant therapeutic proteins such as monoclonal antibodies and fusion proteins, have revolutionized modern medicine and turned many previously untreatable and often fatal diseases into manageable conditions. Thanks to their high specificity and low toxicity, these modern therapeutics were able to outcompete small-molecule drugs in several areas. Ever since the advent of genetic engineering and the introduction of the first biologic drug, insulin Humulin in 1982, there has been a growing demand for new biotherapeutics and increased productivity in the biologics manufacturing sector. The existence of comprehensive CDMO companies such as Mabion helps to meet this growing demand by offering high-quality end-to-end services to various biotech companies regardless of whether their molecule is in the early research phase or already approved by the regulators.
- Driven by global economic growth, the aging population, and a continuous threat from emerging infectious diseases, the biological drug market is growing year-to-year and is currently valued at $366.36 billion[a]. The biological CDMO market, being closely associated with the expansion of the global pharmaceutical industry, has also seen a major increase and is now valued at $11.3 billion.
- The importance of the CDMO sector has been recently exemplified by the emergence of the COVID-19 pandemic and the subsequent rush to discover, test and distribute vaccines to billions of people around the world. Without the existence of multiple CDMO sites, this goal could not have been reached within a reasonable timeframe potentially resulting in millions of unnecessary deaths. Mabion contributed to this endeavor by partnering with Novavax, the manufacturer of a protein-based COVID-19 vaccine - Nuvaxovid™. This partnership initially entailed only the manufacturing of the protein antigen but as the cooperation grew, it was subsequently expanded to also include other services such as quality testing.

Biologics Manufacturing Market



Current and prognosed value of biologics CDMO market

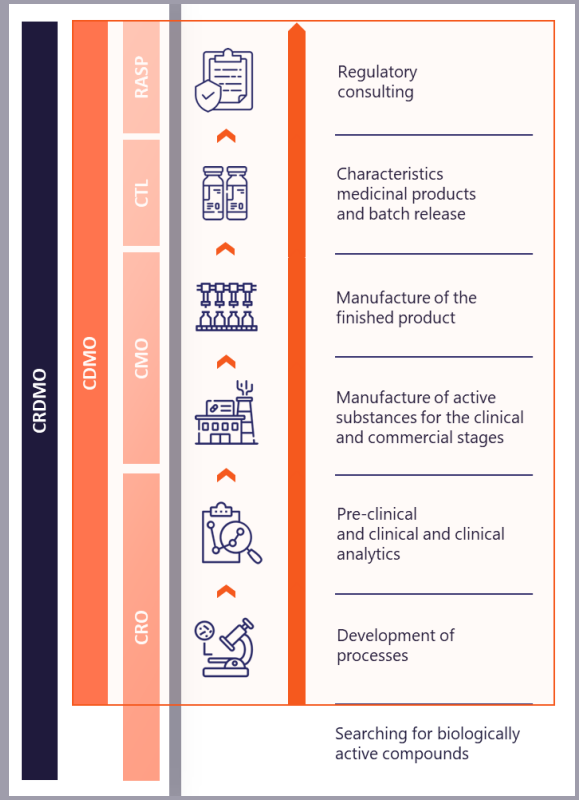
[a] Source: *https://www.precedenceresearch.com/biologics-market*

Industry Insights

- Manufacturing of monoclonal antibodies dominates the CDMO market, with over 50% being attributed to this class of biologics. However, the recent emergence of gene therapies, CAR-T technology, and antibody-drug conjugates are becoming an important segment of the market.
- The pharmaceutical industry is progressively embracing the outsourcing of drug substance and drug product manufacturing. This can be traced not only to the enormous market growth but also to the high cost-effectiveness of the CDMO model. Our qualified staff armed with deep knowledge of the underlying manufacturing processes as well as an elastic approach and a "can-do" attitude considering the numerous challenges constitute a perfect solution for both small and big pharma enterprises.
- Many CDMOs concentrate only on selected parts of the manufacturing process without a holistic consideration of biological drug production. Mabion surely does not belong to this group – our manufacturing unit is closely connected with other departments and other services. Our complex approach also includes development, regulatory, and quality control services, which help to reduce product development time and cut down total costs.

CDMOs play a critical role in the biopharmaceutical ecosystem. They allow pharma companies to focus on drug discovery and early development, while taking over the laborious tasks of process development and manufacturing.

Biologics Manufacturing Market



Typical division of roles between the pharmaceutical companies, CDMOs and CROs

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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