MABION

Your End-to-End Biologics CDMO Partner

Clinical & Commercial Manufacturing

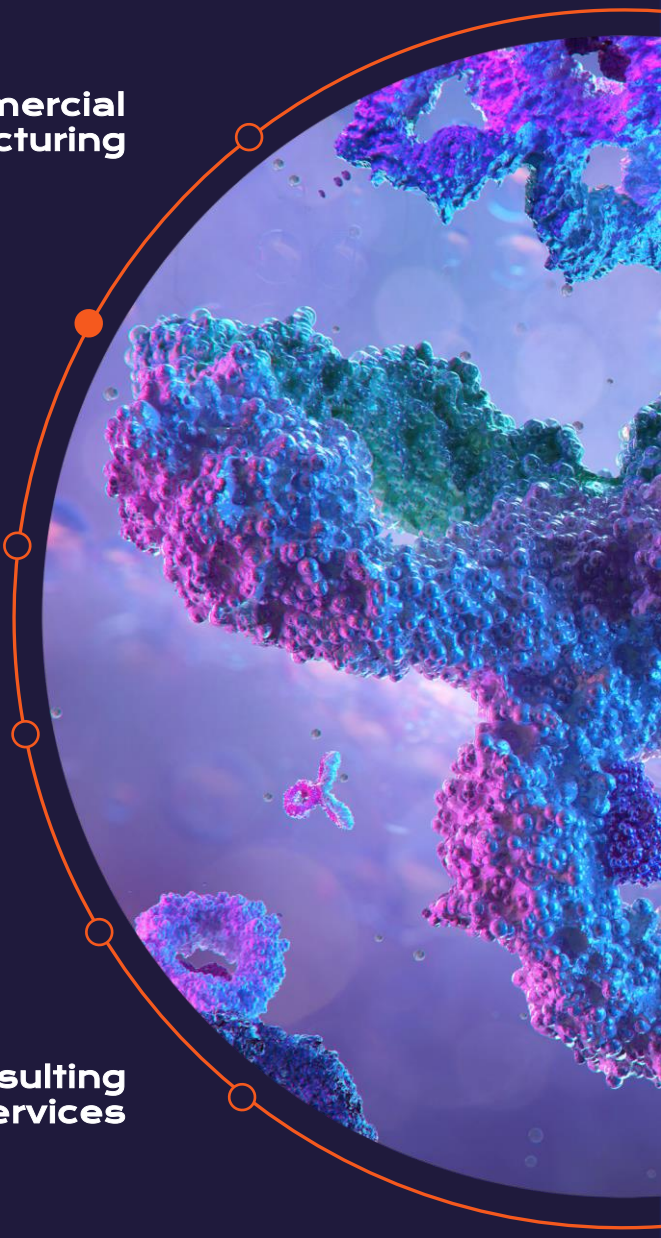
Fill & Finish

Process Development

Drug Characterization & Release Testing

Preclinical & Clinical Analytics

Regulatory & Consulting Services



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Executive Summary

- Our comprehensive list of offered services includes **Fill & Finish of the final drug product, either as a continuation of the integrated manufacturing service or stand-alone**. Fill & Finish entails all elements necessary to obtain a complete biologic drug product, including vials sterilization, filling, stoppering and capping in sterile conditions, product inspection, secondary packaging, and serialization.
- Mabion owns top-notch equipment and well-tested procedures to assure precise filling, sterile conditions, and high quality of the manufactured drug product. A fully **automated isolator-based filling line** along with a disposables system for dosing needles allows us to achieve an efficiency of 6,000 vials per hour (for 10 ml vials).
- We can adjust our filling line and other equipment to fit **various vial formats, spanning from 2 to 100 ml.** Our manufacturing experience includes large-scale production of drug products for two international Phase III clinical trials of a rituximab biosimilar, which together enrolled nearly 1000 patients.
- In addition to customary Fill & Finish services, our large facilities are capable of long-term **GMP-compliant storage** of the produced drug vials as well as **GDP-compliant logistics** throughout Europe. These services include storage and transport under ultra-low and low-temperature conditions.

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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 Fill & Finish Services

- Sterilization
- Filling, Capping and Stoppering
- Product Inspection
- Packaging and Serialization
- Storage and Transport

The philosophy of Mabion is to be an „end-to-end" provider for all key services related to the development and manufacturing of biological drugs, thereby eliminating any need of our clients for additional outsourcing. Fill & Finish service allows our customers to successfully complete the long journey from protein expression to the final drug product with a single trusted partner.

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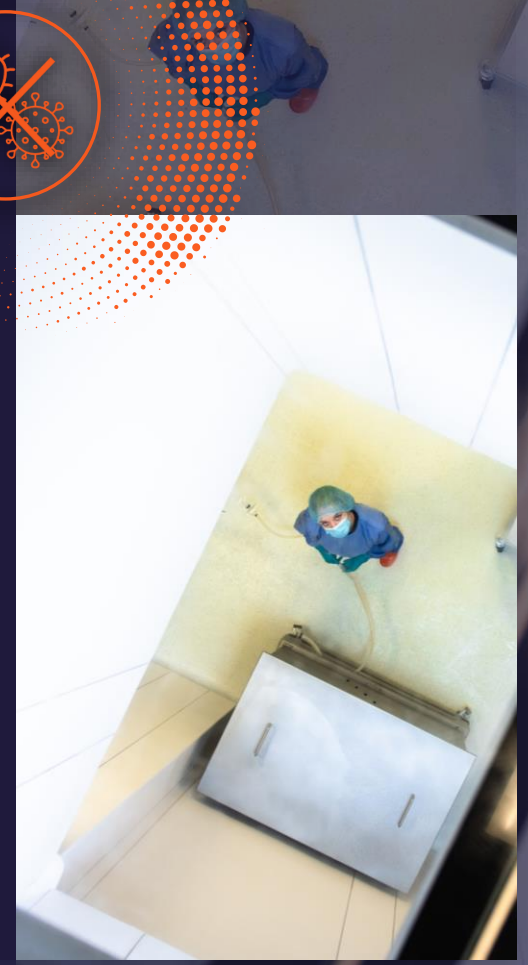
About Our Fill & Finish Services

Sterilization



Assuring sterility of the Fill & Finish process is an important and complex issue that requires purpose-built facilities, specialized equipment, and careful execution by skilled and experienced staff. All these factors are met at Mabion, ensuring a safe and GMP-compliant environment for biological drug production.

Sterilization capabilities at Mabion are summarized in the table below.

Technologies / Description	Room / Equipment
VIALS STERILIZATION **Formats**: 2 – 100 ml vials **Capacity**: 6000 vials per hour (10 ml)	**C-A** class (local) room > Washing machine > Depyrogenation tunnel

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About Our Fill & Finish Services

Filling, Capping and Stoppering

Mabion ensures that the filling, capping, and stoppering of the final drug product is conducted with high efficiency and in a sterile, GMP-compliant environment. This is achieved using a new automatic filling line (with the isolator technology) as well as a disposable system for dosing needles and product-contact parts (incl. feeding). We are capable of filling, capping, and stoppering various vial formats, from 2 to 100 ml.

Technologies / Description	Room / Equipment
STERILE FILLING, CAPPING AND STOPPERING Formats: 2 – 100 ml vials > Disposable system for dosing needles and product-contact parts including feeding	C class room, Local A class - isolator > Fully automated high-capacity filling line

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About Our Fill & Finish Services

Product Inspection

Final quality testing of the manufactured drug product is essential to secure patients' safety. Product inspection at Mabion includes manual or automatic leak detection and visual inspection, with a capacity of 6000 cph. Automatic inspection is performed for all produced containers.

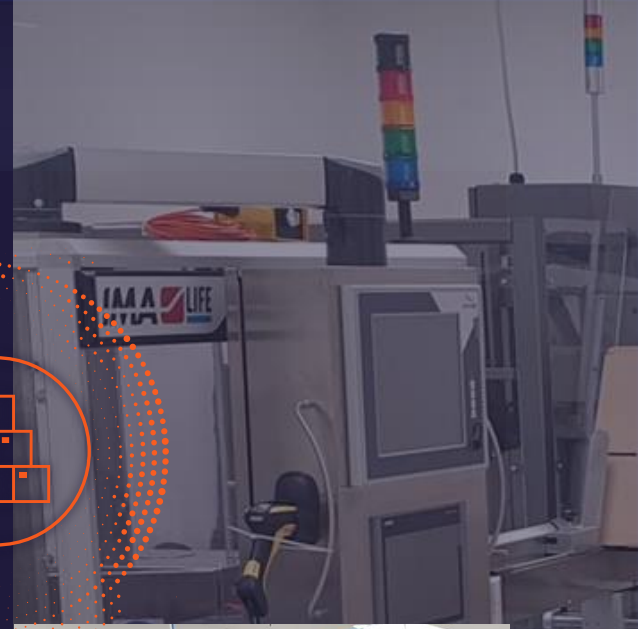
Technologies / Description	Room / Equipment
PRODUCT INSPECTION	C class room > Combined line for Leak and Visual inspection > Fully automated process with 6000 cph capacity (for 10 ml vials)

About Our Fill & Finish Services

Packaging and Serialization

Mabion's offer includes secondary packaging, labelling and serialization of the finished drug product (vials for i.v. use). Detailed overview of the packaging parameters is provided in the table below.

Parameters	50 ml	10 ml	2 x 10 ml
Unit package dimension [mm]	49,50 x 54,50 x 80,00	49,50 x 36,00 x 63,00	49,50 x 36,00 x 63,00
Box dimension [mm]	265,00 x 230,00 x 257,00	212,00 x 193,00 x 200,00	212,00 x 193,00 x 200,00
Quantity in one case (box)	60 (60 vials)	60 (60 vials)	60 (120 vials)
Quantity of layers on pallet	4 layers	4 layers	4 layers
Quantity of cases (boxes) on pallet	36 cases (boxes)	80 cases (boxes)	80 cases (boxes)
Quantity of unit packages on pallet	2160	4800	4800
Quantity of vials on a pallet	2160	4800	9600
Time of packaging + T&T Level 4	50 vials/min	50 vials/min	60 vials/min
Dimensions of pallet [cm]	120,00 x 80,00 x 126,00	120,00 x 80,00 x 104,80	120,00 x 80,00 x 104,80
Gross weight of pallet	258 kg	205 kg	378 kg



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About Our Fill & Finish Services

Storage and Transport

Drug products manufactured at Mabion can be stored in our GMP-compliant warehouses. This includes storage in a cold room, at a temperature of 2°C - 8°C and below -60°C.

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:

< -60°C | < -15°C | 2°C - 8°C | 15°C - 25°C

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

Industry Insights

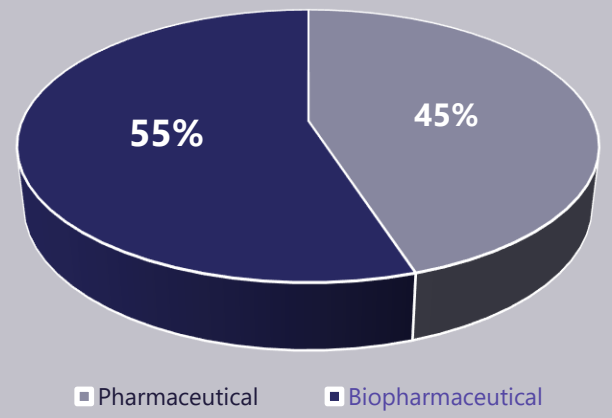
- The size of Fill and Finish CDMO market size is estimated at $9.2 billion in 2022. An annual growth rate of 10.6% is forecasted until 2030. This increase is fueled by the growing overall demand for pharmaceutical manufacturing, which itself is caused by the rising demand for affordable drugs (such as low-cost biosimilars) and widespread automatization of the fill-finish process. As with other branches of the pharma industry, fill & finish services experienced a significant boost during the COVID-19 pandemic owing to the sudden need for mass production of COVID vaccines and anti-viral agents.
- Biopharmaceutical companies are the top customers for Fill-Finish CDMOs, taking 55% of the total market share (2021).
- Geographically, the largest market of fill-finish CDMOs is in North America, covering almost 50% of the total market size. Europe takes the 2nd place, with around 25% of the total share. This proportion is unlikely to change in the nearest future, although Europe is predicted to witness the fastest growth.
- The vials segment of the Fill & Finish market is anticipated to hold the highest market share in the forecasted period (2023-2030). Most vaccines and parenteral drugs are formulated in this way due to the best safety and quality record (decreased probability of leakage).
- An increasing number of small to medium-sized biotech companies are using CDMOs for „end-to-end" manufacturing of their products. The main benefits of such a business model are lower development costs and risk minimization. CDMOs have all required equipment in place and most of all, great technical skills that can help smaller enterprises to reduce the time-to-market and lower the chances for project failure.

Fill & Finish Market

Current and prognosed value of the Fill-Finish market

Attribute	Value
Market size in 2022	$ 9.21 bln
Revenue forecast for 2030	$ 20.61 bln
CAGR (2022-2030)	10.6%

Fill-Finish contract manufacturing 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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