
MABION
Your Biologics CDMO
Q3 2023

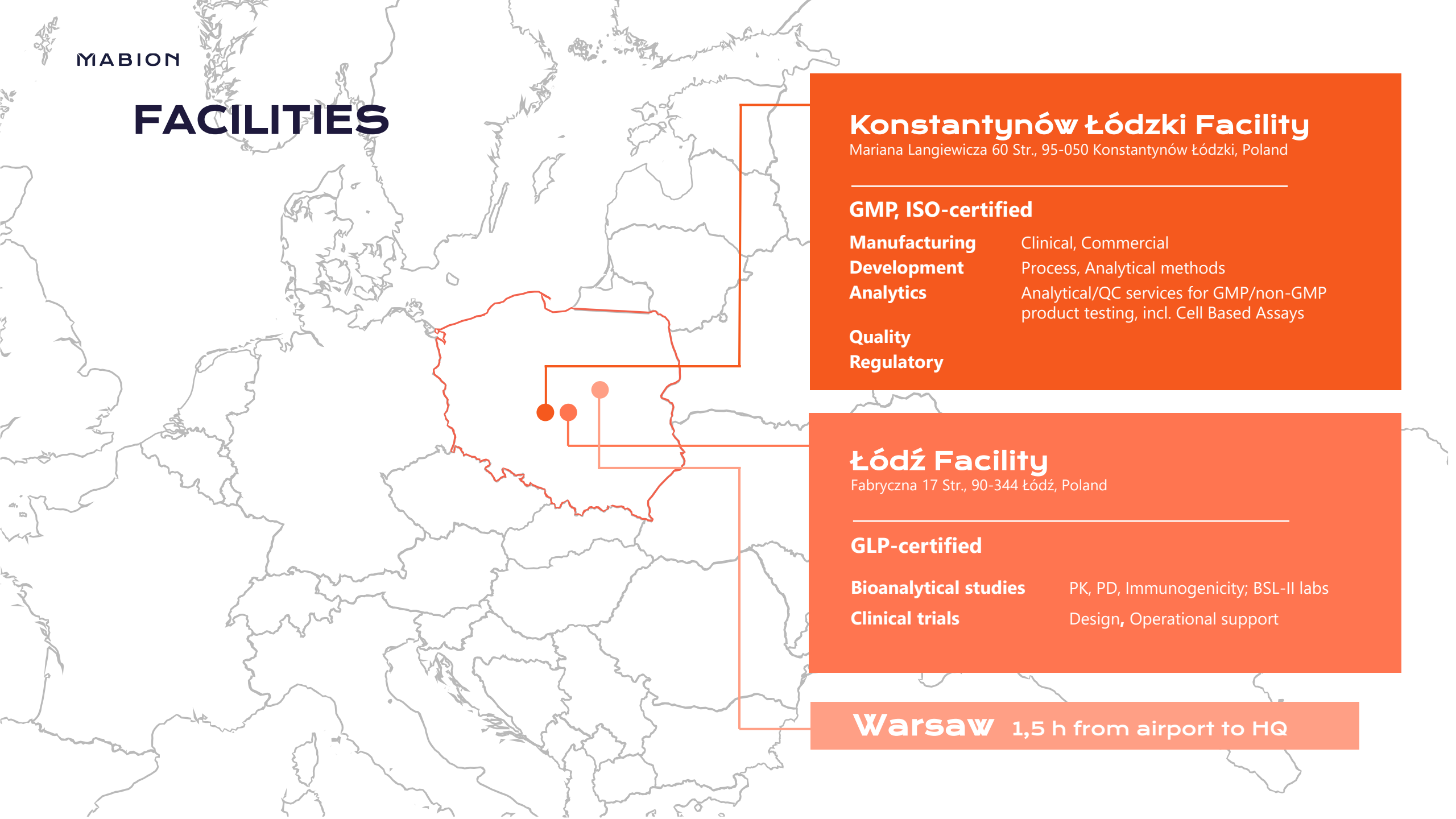
About Us

With a history spanning 17 years, Mabion has a wealth of experience in developing and manufacturing of biologic drugs, allowing us to meet the needs and requirements of the most demanding clients. Along with extensive bioanalytical capabilities and expertise in sterile manufacturing, packaging and serialization, we offer complete, end-to-end CDMO services.

Our Quality Management System, covering GMP, GLP, GCP and ISO, has been inspected by multiple authorities, assuring that services delivered by Mabion satisfy all regulatory requirements.

MABION

FACILITIES



Konstantynów Łódzki Facility

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

GMP, ISO-certified

Manufacturing	Clinical, Commercial
Development	Process, Analytical methods
Analytics	Analytical/QC services for GMP/non-GMP product testing, incl. Cell Based Assays
Quality	
Regulatory	

Łódź Facility

Fabryczna 17 Str., 90-344 Łódź, Poland

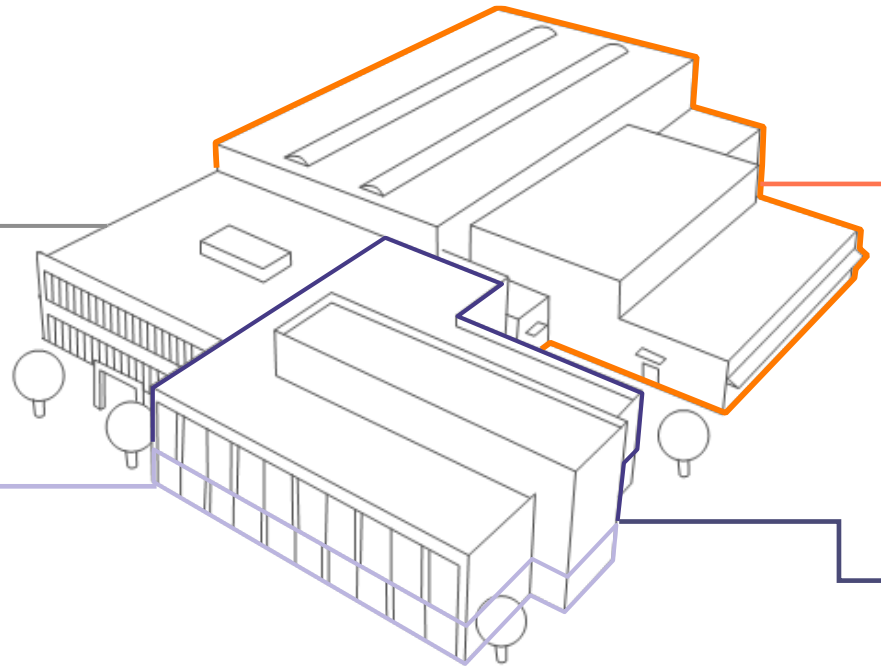
GLP-certified

Bioanalytical studies	PK, PD, Immunogenicity; BSL-II labs
Clinical trials	Design, Operational support

Warsaw 1,5 h from airport to HQ

LAYOUT of Konstantynów Łódzki Facility (HQ)

Office spaces



Manufacturing

Actual area: 2098 m^2

Quality control

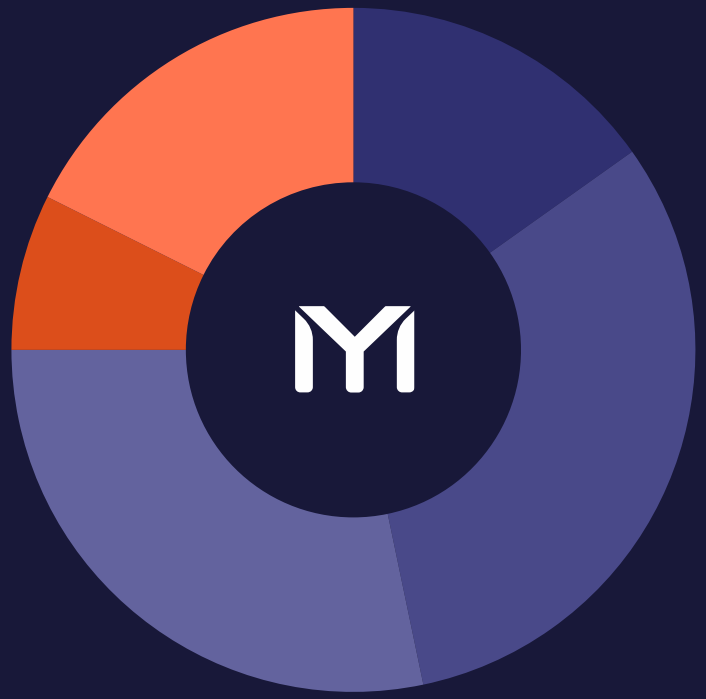
Actual area: 621 m^2

Process Development

Actual area: 566 m^2

MABION

MABION Team 244 FTEs

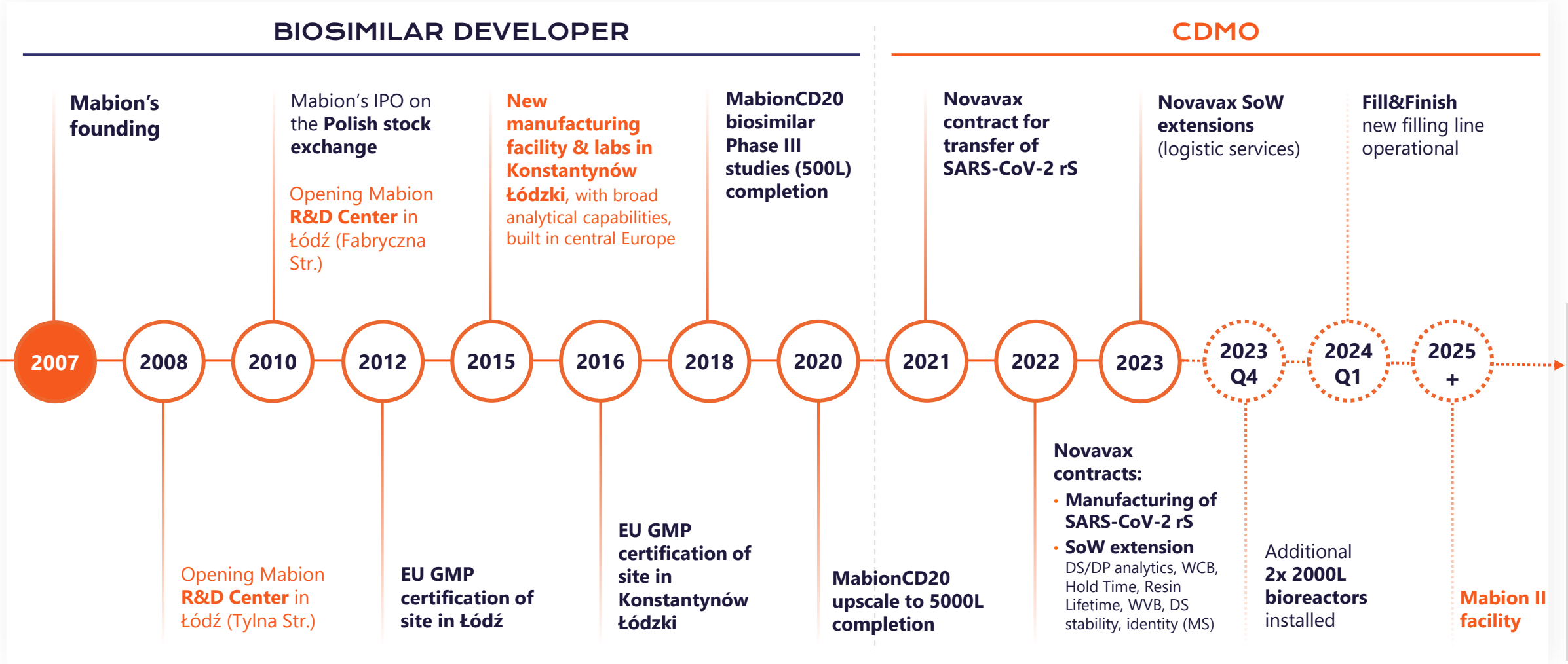


37	Development
77	Quality
69	Manufacturing
18	Maintenance and Qualification
43	Administration/Finance

MABION

History & Transformation into CDMO

History and future of Mabion



MABION

By developing own biosimilar products in the past, Mabion has acquired key competencies and assets, building an integrated biopharmaceutical company

Thanks to these key competencies and assets, Mabion seized a market opportunity and since 2021 has been transforming into a CDMO

We have developed advanced competencies in biologic drug technology using cell lines and monoclonal antibody engineering for **development, manufacture and control of biosimilars**

We have developed effective processes that allow us to systematically obtain products of **high quality** within agreed timelines

We have achieved a high level of integration and we offer a **broad spectrum of services** in the areas of protein development, analytics and manufacturing, as well as consulting and regulatory advisory services

We have a **dynamic team with strong interdisciplinary experience**, competence to operate under GLP/GMP and an open approach ('can do' attitude)

We have **modern analytical and manufacturing assets** located in the EU (Poland)

We operate in compliance with the highest quality standards in the industry: **GMP, GCP, GLP, ISO**

We have validated our competencies and we have begun to monetise the resources we have built through our first commercial collaboration

building competence and resources

transformation into a biologics CDMO

2007 **2021** **2023**

History and transformation


MABION
Biologics CDMO
Quality

Quality systems operating at Mabion include EU-GMP for manufacturing (since 2012), GLP for bioanalytical studies (since 2014) and ISO. Mabion QMS was built following EudraLex vol. 4 principles.

As a result, robust GMP processes have been established, ready to accommodate any Client's quality requirements, including compliance with the US FDA cGMP

Mabion's QMS

Current Mabion facilities regulatory status – GMP, GLP, GCP and ISO compliance

Konstantynów Łódzki

Good Manufacturing Practice (GMP)

- Good Manufacturing Practice (GMP) is a system for ensuring that products are consistently manufactured and controlled according to quality standards
- It is designed to minimize the risks involved in pharmaceutical production that cannot be eliminated through testing the final product
- **GMP certificate was granted in April 2017 for Konstantynów Łódzki facility - Scientific and Industrial Complex of Medical Biotechnology** (Previously, in November 2012, for the Research and Development Centre in Łódź)

ISO

- Mabion holds three **ISO certificates**: **14001**:2015 environmental, ISO **45001**:2018 work safety regulations, ISO **50001**:2018 energy management
- Audits were performed by **independent** certified specialist **SGS Polska / SGS UK / SGS Italy**
- Certificates were issued in 2020 for **3 years period**

Łódź

Good Laboratory Practice (GLP)

- GLP defines a set of rules and criteria for quality system management of research laboratories in order to ensure the trustworthiness of laboratory data, including bioanalytical data from clinical studies and preclinical studies during drug development
- **Mabion was granted GLP certificate in March 2014 and has been continuously re-certified every 2 years (recent GLP certificate is from 2022)**
- Holding this certificate indicates that studies and analyses carried out at Mabion meet high international quality standards

Good Clinical Practice (GCP)

- GCP defines the rules that constitute the international quality standard for clinical trials involving humans
- Compliance with GCP standards guarantees credibility and authenticity of the data collected during clinical trials
- **All trials conducted by Mabion to date have been in accordance with GCP**

Mabion audits and inspections history

- Since its founding in 2007, Mabion has passed multiple inspections and audits demonstrating compliance with **GMP, GLP** and **GCP** practices as well as **ISO 9001** and **ISO 14001/45001/50001** standards.
- Quality assurance is subject to rigorous and continuous improvement through internal and external audits.
- **Mabion is GMP- and GLP-certified since 2011.** No critical findings were ever identified.

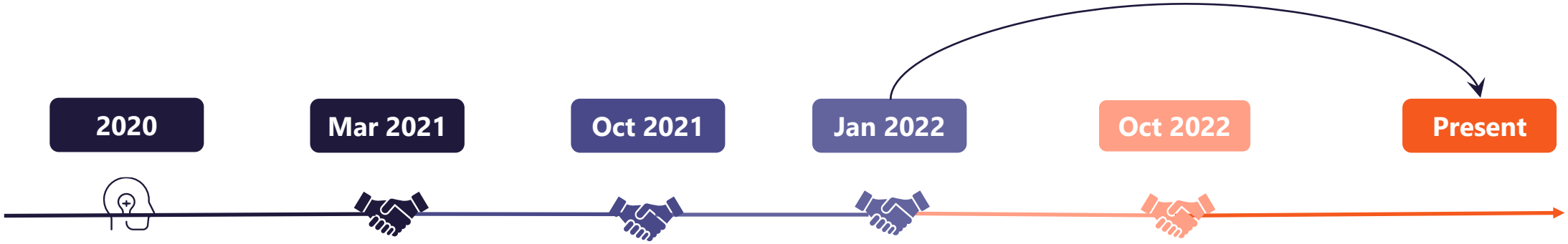
11	8	3	4	9
GMP inspections	**GLP** inspections	**GCP** inspections*	**ISO** inspections	**GMP** audits

14001:2015
50001:2018
45001:2018

* Including 2 inspections performed at sites participating in a clinical study sponsored by Mabion.


MABION
Biologics CDMO
Novavax case study

A path from an idea to becoming a company providing commercial services in diverse biotechnology fields



Mabion as CDMO idea & PMO as a new structure in Mabion

Signing the **first cooperation agreement between Mabion and Novavax** is a breakthrough moment for the company's new strategy

Long-term agreement between Mabion and Novavax for manufacturing of Drug Substance of NVAX vaccine confirms the capabilities of Mabion as a CDMO

Expanding the scope of cooperation with additional scopes of work (analytical, WVB/WCB, additional research, stability or logistics)

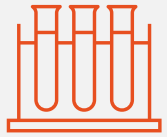
Signing an addendum to the commercial agreement and extending the period of cooperation with the expansion of cooperation with new vaccine variants

Continuous **expansion of cooperation** into new areas

Notable accomplishments in the Novavax lab-scale, analytics and process transfer

Mabion successfully finalized the feasibility phase during which the Novavax protein production process was transferred and scale-up to our facility **within 3 months and ahead of schedule.**

During this period, Mabion has accomplished:



Successful lab-scale batches

Successful full-scale batches

Transfer of DS release testing analytical methods

Generation of >100 documents (SOPs, summary reports, etc.)

The entire process, from agreement signing to the final report and client approval, **took 30 weeks**

Notable accomplishments in the Novavax manufacturing of drug substance for COVID-19 vaccine

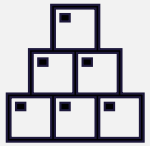
Novavax - Mabion Commercial production is a success with further extension of the scope of cooperation as well as future business development activities. Mabion has been able to adjust the work and schedule for Novavax's needs in short term and jointly solve process and analytical challenges.

Batch success rate and manufacturing schedule adherence per value stream and production suite were assessed on **100% in the KPI Analysis** performed by Novavax.

Until now, Mabion has accomplished:

100% successful engineering and transfer batches

Successfull completion of PPQ batches



GMP production of DS of SARS-CoV-2 in 2,500L scale started

No failed batches and safety events

KPI scorecard review showed no safety events, great batch success rate and schedule adherence

Mabion – A trusted CDMO partner

The best testimony to our quality and reliability as CDMO is the recommendation issued by Novavax based on a 3-year history of successful collaboration on the protein COVID-19 vaccine.

> *„Mabion demonstrated flexibility and a high level of customer focus at the time when the Omicron variant arrived, as they managed to swiftly adapt the manufacturing process to the production of a modified vaccine antigen. This seamless transfer of technology and prompt commencement of the production for a new variant highlighted Mabion's agility and technical prowess."*

> *„(...) based on the outstanding results of our cooperation, we can enthusiastically recommend Mabion as a trusted and reliable CDMO for the development and manufacturing of vaccines. The exceptional capabilities, state-of-the-art technologies and commitment to quality make Mabion an invaluable partner for any company wishing to outsource their key process.*

> *„Mabion is fully capable of delivering this wide panel of services, while continuing to demonstrate a high level of professionalism and unwavering commitment to quality.*

novavax

John Kutney
Vice President, Manufacturing
Novavax, Inc

04 August, 2023

To Whom It May Concern,

I am writing this letter on behalf of Novavax, Inc. to recommend Mabion S.A. as a trusted CDMO for the development and manufacturing of vaccines. This recommendation is based on a track record of cooperation between our company and Mabion, which began amid the COVID pandemic in early 2021. Mabion proved to be a flexible partner in our efforts to combat the COVID-19 pandemic and they have been a valuable part of the manufacturing network for global supply of our COVID-19 vaccine.

Our relationship with Mabion kicked off on March 3rd, 2021, when we concluded a framework agreement for the feasibility and tech transfer for the manufacturing of our COVID-19 vaccine antigen. Initially, Mabion produced the vaccine antigen for the primary variant of the virus (Wuhan strain), demonstrating their capability to meet our stringent quality standards and timelines.

As the pandemic evolved, so did our collaboration. Mabion demonstrated flexibility and a high level of customer focus at the time when the Omicron variant arrived, as they managed to swiftly adapt the manufacturing process to the production of a modified vaccine antigen. This seamless transfer of technology and prompt commencement of the production for a new variant highlighted Mabion's agility and technical prowess.

Following the positive experience with vaccine antigen production, we extended our cooperation with Mabion by signing additional work orders for the development of analytical methods as well as the routine implementation of drug release testing and the preparation of cell banks (MCB/WCB). Mabion is fully capable of delivering this wide panel of services, while continuing to demonstrate a high level of professionalism and unwavering commitment to quality.

The history of our partnership with Mabion outlined above is the best testimony of the high standards, technical expertise, and cooperation skills of our trusted partner. After more than two years of our

Creating tomorrow's vaccines today.

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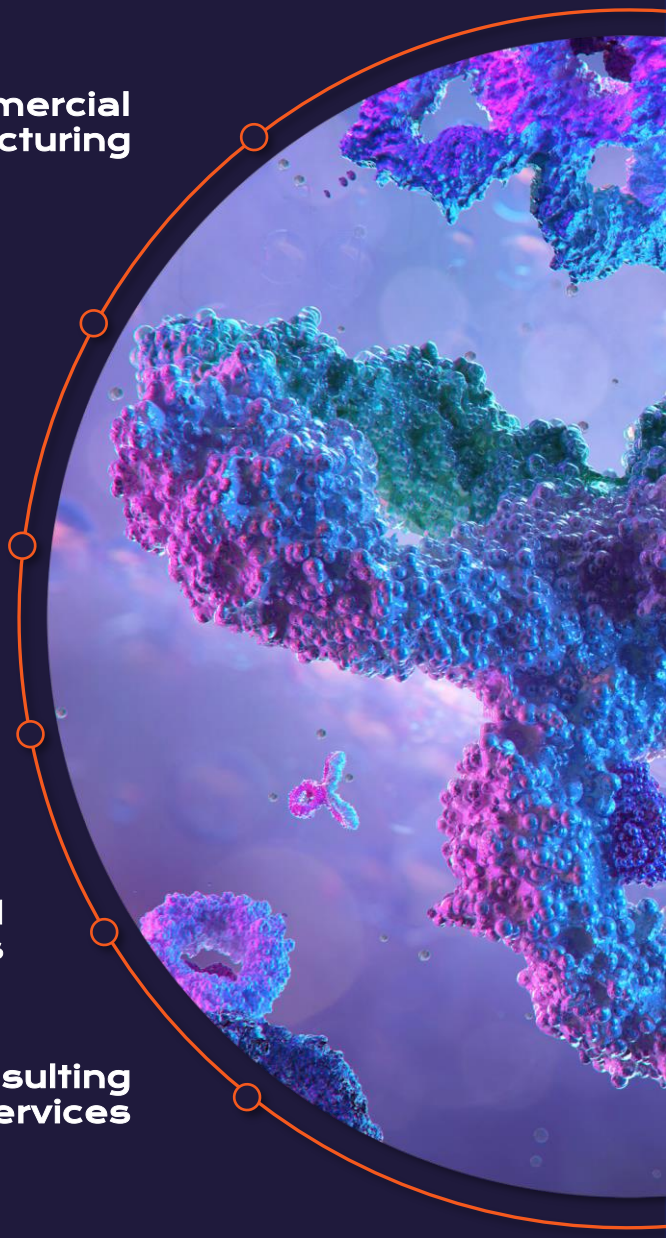
MABION

Biologics CDMO

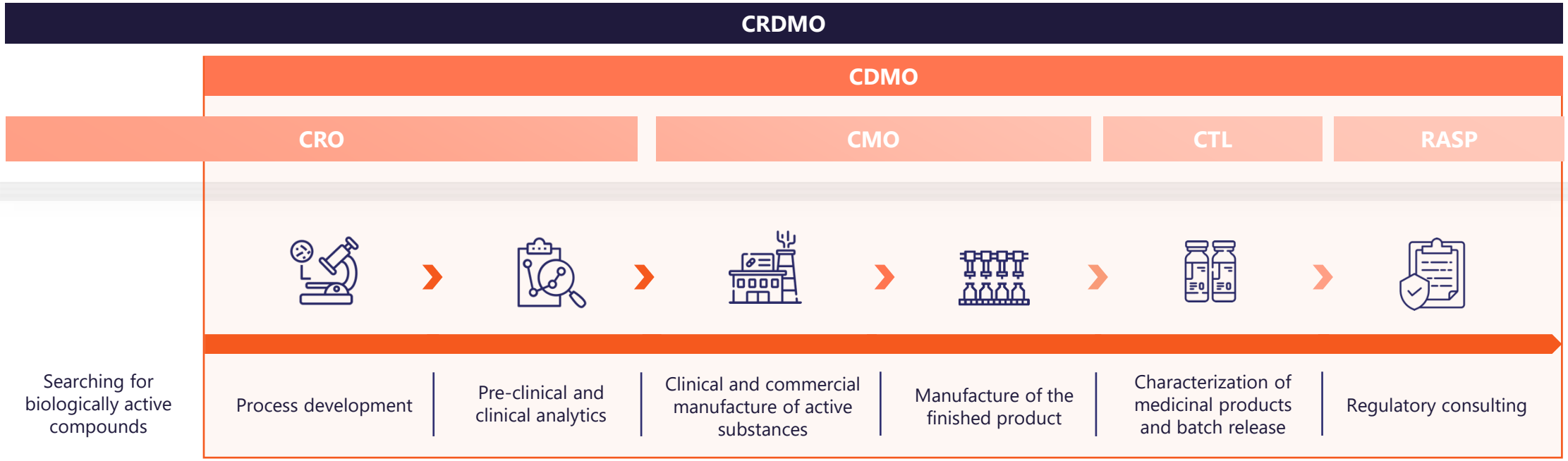
Services

- Clinical & Commercial Manufacturing
- Fill & Finish
- Process Development
- Drug Characterization & Release Testing
- Preclinical & Clinical Analytics
- Regulatory & Consulting Services



Mabion offers a comprehensive portfolio of services for a wide range of biological products

As an integrated CDMO, Mabion offers a full range of services, with a focus on recombinant protein technologies and antibody format, within which Mabion has all needed assets and is ready to execute commercial orders



- Mabion has an offering that addresses a wide range of the CDMO service value chain
- High level of integration and ability to address only selected stages from the entire CDMO service value chain (e.g., CMO, CTL, RASP, part of CRO)

CTL - Contract Testing Laboratory CMO - Contract Manufacturing Organization CDMO - Contract Development & Manufacturing Organization
RASP - Regulatory Affairs Service Provider CRO - Contract Research Organization CRDMO - Contract Research, Development & Manufacturing Organization

Project Management

With every project entrusted to Mabion, comes a dedicated project manager. This committed person ensures that your project is given the utmost attention.

Our approach to **project management** is the key component of Mabion's commitment to provide a world-class, customer-oriented outsourcing experience. By fulfilling this commitment, we are capable of delivering the top-quality services at competitive prices.

Clinical & Commercial Manufacturing

UPSTREAM PROCESS

- Mammalian & insect cell cultures
- 2 x 2000L, 2 x 200L, 2 x 50L and 1 x 10L stirred-tank, single-use bioreactors from Cytivia
- 2 x 2500L and 4 x 250L orbital shaking bioreactors
- Medium & supplements preparation and storage capacity
- GMP MCB&WCB Cell Banks generation and storage

DOWNSTREAM PROCESS

- Separation technologies (depth filtration & centrifugation)
- Affinity chromatographies Ion-exchange chromatographies
- Ultra/diafiltration
- Nanofiltration
- Sterile filtration
- Formulation
- Buffer preparation

CAPACITY EXPANSION IN PROGRESS

Fill & Finish

- Automated filling line
- Automated product inspection
- Secondary packaging
- Product storage and transportation
- Serialization

CAPACITY EXPANSION IN PROGRESS

Process Development

- Upstream process development
- Downstream process development
- Process space & process characteristics
- Process scale up
- Analytical methods development & validation
  - Structural assays
  - Physicochemical assays
  - Biological/functional assays
- Comparability & similarity assessment
- Reference standard establishment
- Clinical and pre-clinical analytics development

Drug Characterization & Release Testing

- Drug Characterization Services
  - Physiochemical Analytics
  - Structural Analytics
  - Biological Analytics
- QC testing of raw materials
- QC testing of intermediate product, drug substance, drug Product, reference product
- Analytical methods optimization and validation
- Characteristics of reference standard
- Long term, accelerated and stress stability study
- Environmental monitoring
- Documentation

Preclinical & Clinical Analytics

- Pharmacokinetics
- Pharmacodynamics
- Immunogenicity
  - Anti-drug antibody
  - Neutralizing antibody testing

Regulatory & Consulting Services

- Setting development strategies
- Supporting pre-clinical and clinical studies: study design, medical writing, literature review etc.
- Designing process and product development pathways
- Review of protocols, outcomes and reports related to studies, projects, processes and analyses
- Defining requirements for manufacture and quality control
- Gap analysis, internal audits, risk analyses
- Consultations with regulatory agencies
- Defining and preparation of the process, analytical and clinical packages necessary for submissions
- Technology and analytical methods transfers
- Dossier writing
- Post-approval regulatory management

Thank you

MABION

SCIENTIFIC AND INDUSTRIAL COMPLEX FOR MEDICAL BIOTECHNOLOGY

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Click here to watch a video presenting Mabion:

Link: https://www.youtube.com/watch?v=2hzQl5ZGyxk&t=2s