MABION
Biologics CDMO

Your End-to-end Biologics CDMO partner

Presentation of Mabion's services

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MABION
Biologics CDMO

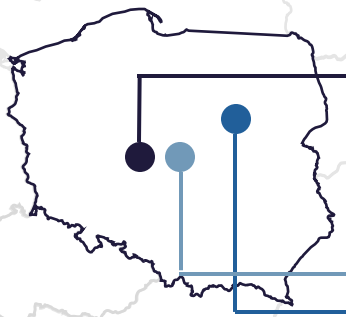
About us

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.

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

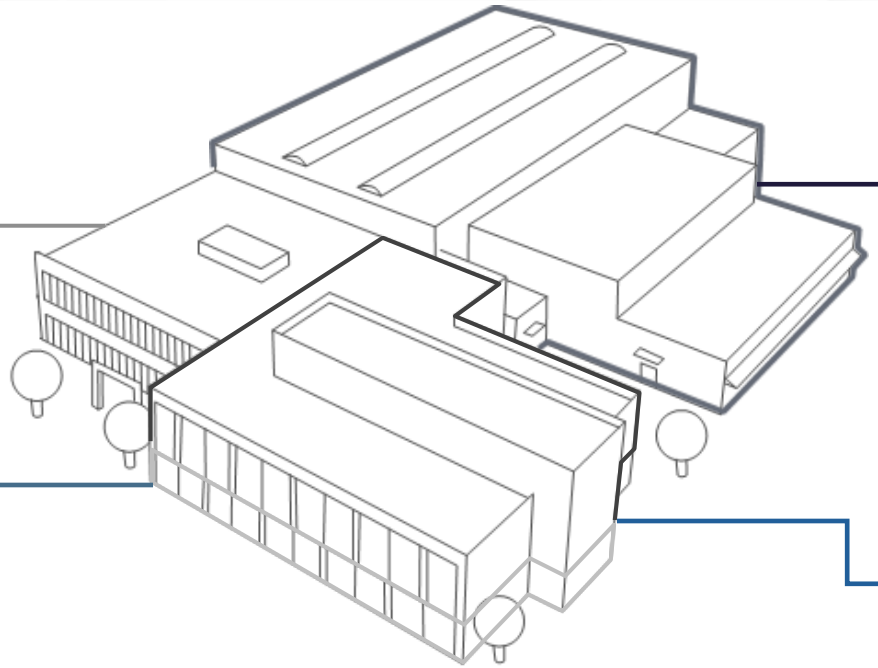
Bioanalytical studies	PK, PD, Immunogenicity; BSL-II labs
Clinical trials	Design, Operational support

Warsaw 1,5 h from airport to HQ

Main manufacturing facility

Konstantynow Lodzki

Office spaces



MANUFACTURING

Actual area: 2098 m^2

QUALITY CONTROL

Actual area: 621 m^2

PROCESS DEVELOPMENT

Actual area: 566 m^2

MABION
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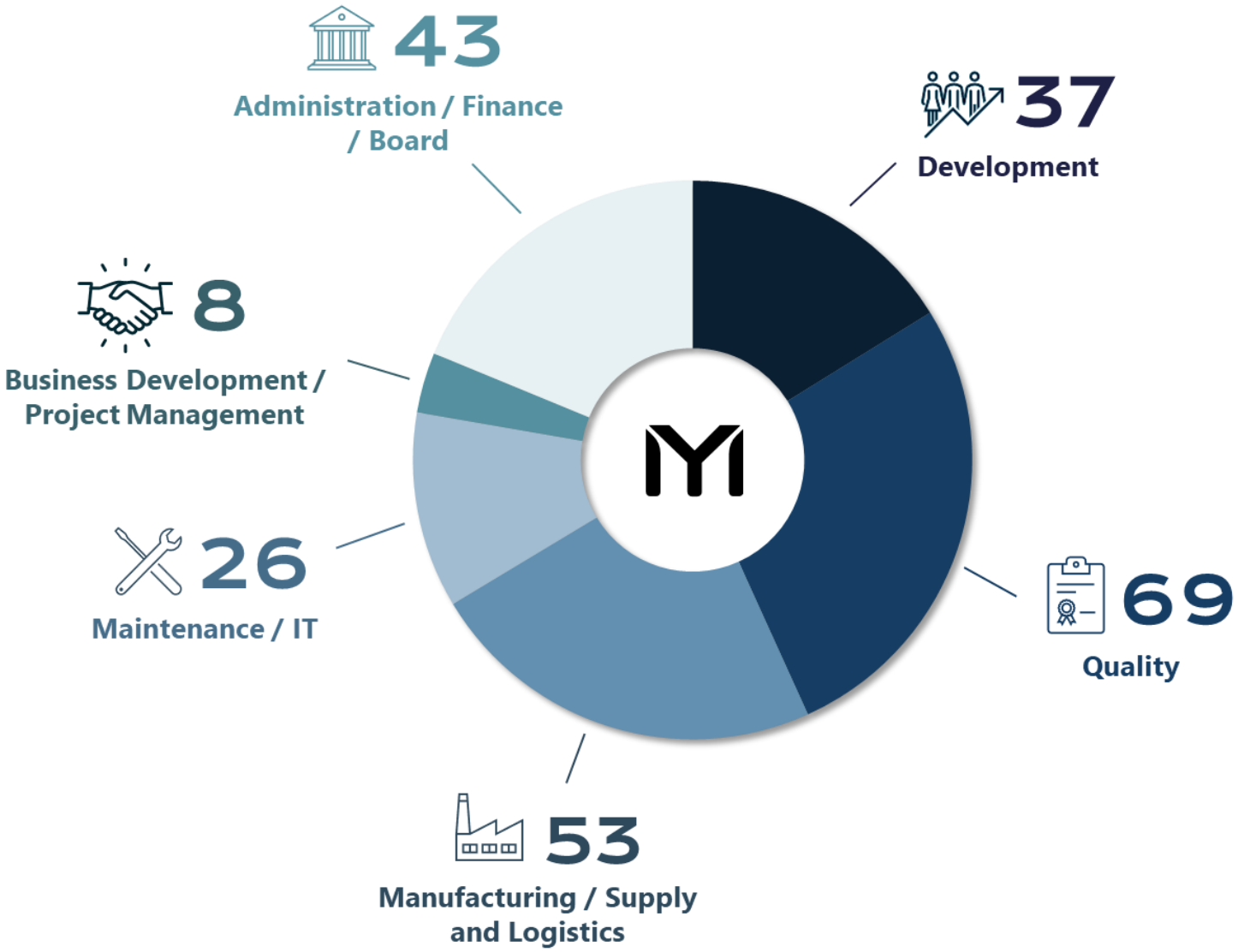
Our team

Our team

FULL-TIME EMPLOYEES

229



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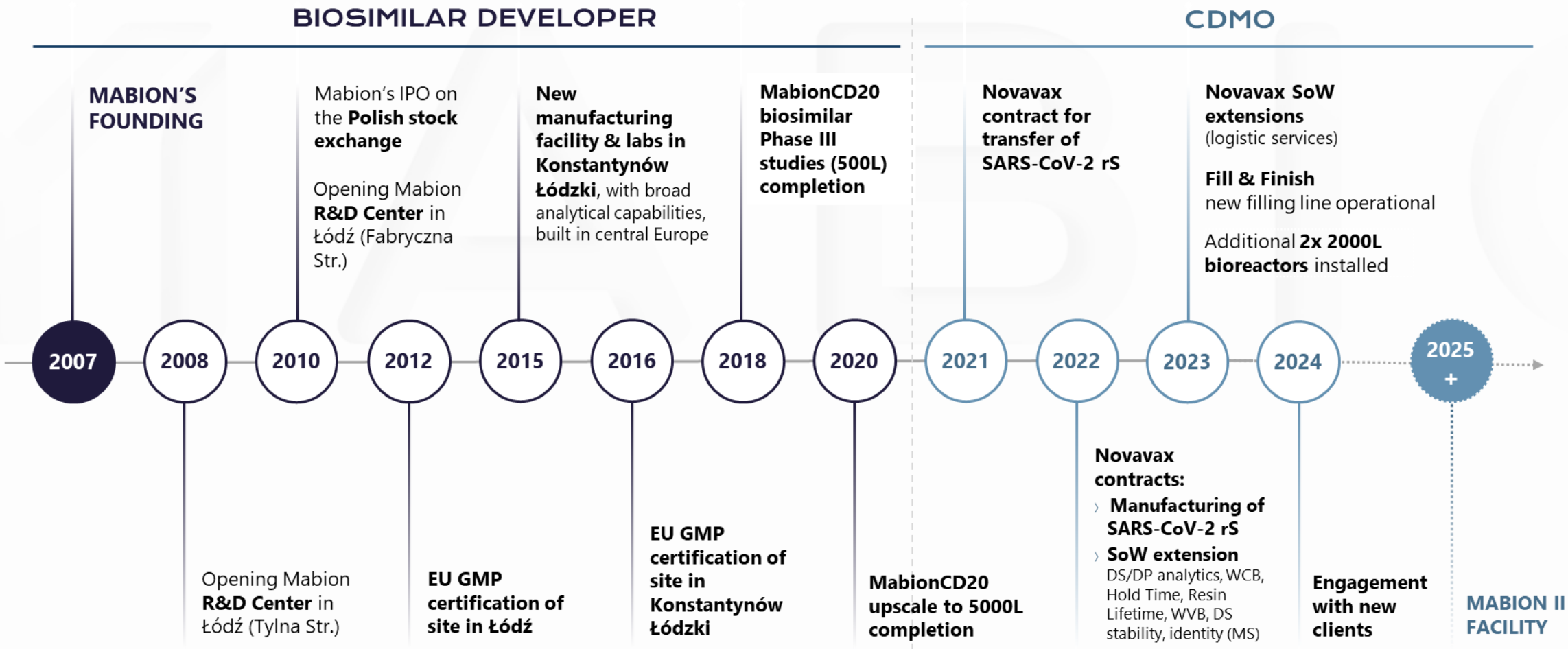
History and transformation into CDMO

History and future of Mabion



Integrated biopharmaceutical company built on experience with developing own biosimilar products

Thanks to the key competencies and assets acquired by developing own biosimilars, Mabion seized a market opportunity and in 2021 began its transformation into a full-service CDMO that it is today.

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 monetize the resources we have built through our first commercial collaboration

BUILDING COMPETENCE AND RESOURCES

TRANSFORMATION INTO A BIOLOGICS CDMO

2007

2021

History and transformation

MABION
Biologics CDMO

Quality

Mabion’s Quality Management System (QMS)

Quality systems operating at Mabion include **EU-GMP** for manufacturing (since 2012), **GLP** for bioanalytical studies (since 2012) 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**.

Compliance with GMP, GLP and ISO

KONSTANTYNÓW ŁÓDZKI

Good Manufacturing Practice

- 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 can't 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).

International Organization for Standardization

- 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 2023 for **3 years period.**

ŁÓDŹ

Good Laboratory Practice

- 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 2012 and has been continuously re-certified every 2 years (recent GLP certificate is from 2024).**
- Holding this certificate indicates that studies and analyses carried out at Mabion meet high international quality standards.

Audit and inspection records

- 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 became GMP and GLP compliant in 2012.** No critical findings were ever identified.

11	8	5	9
GMP inspections	GLP inspections	ISO audits	GMP audits

Quality

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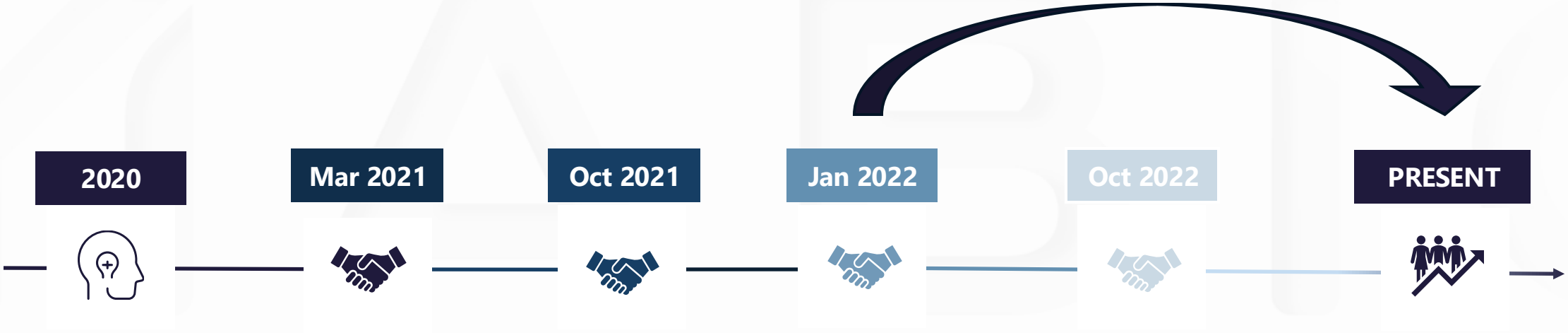
Case study: cooperation with Novavax

Our path to becoming a CDMO

From an idea to a company providing 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

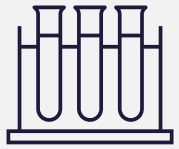
Novavax case study

Cooperation with Novavax

Notable accomplishments in 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**

Novavax case study

Cooperation with Novavax

Notable accomplishments in manufacturing of DS for COVID-19 vaccine

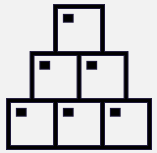
Novavax - Mabion Commercial production is a success with further extension of the scope of cooperation as well as future business development activities. Mabion has been able to adjust the work and schedule for Novavax's needs in short term and jointly solve process and analytical challenges.

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

Successful 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

Novavax case study

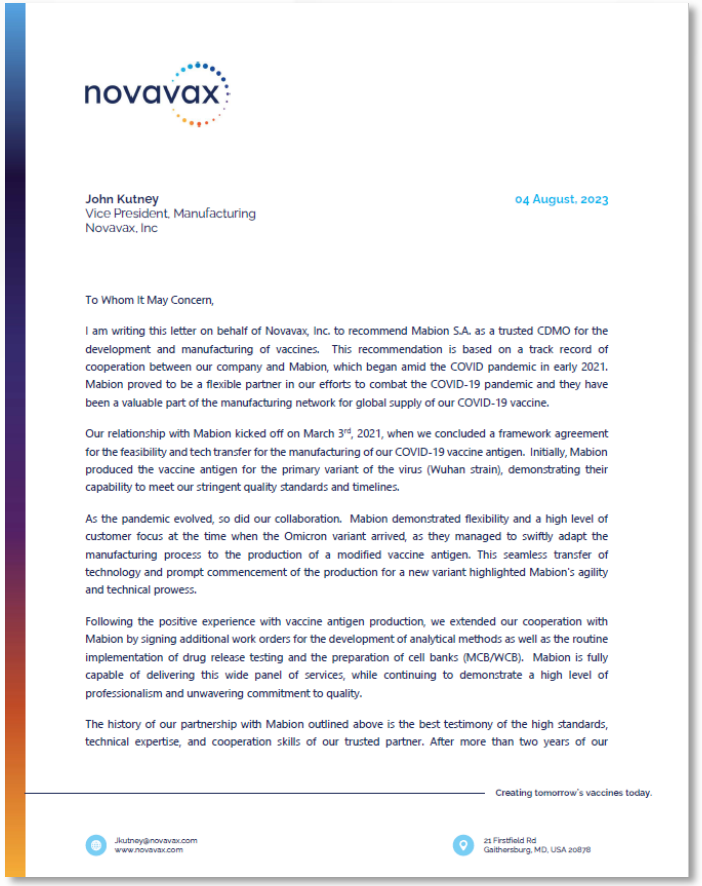
Mabion as a trusted CDMO partner

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.

Jkutney@novavax.com
www.novavax.com

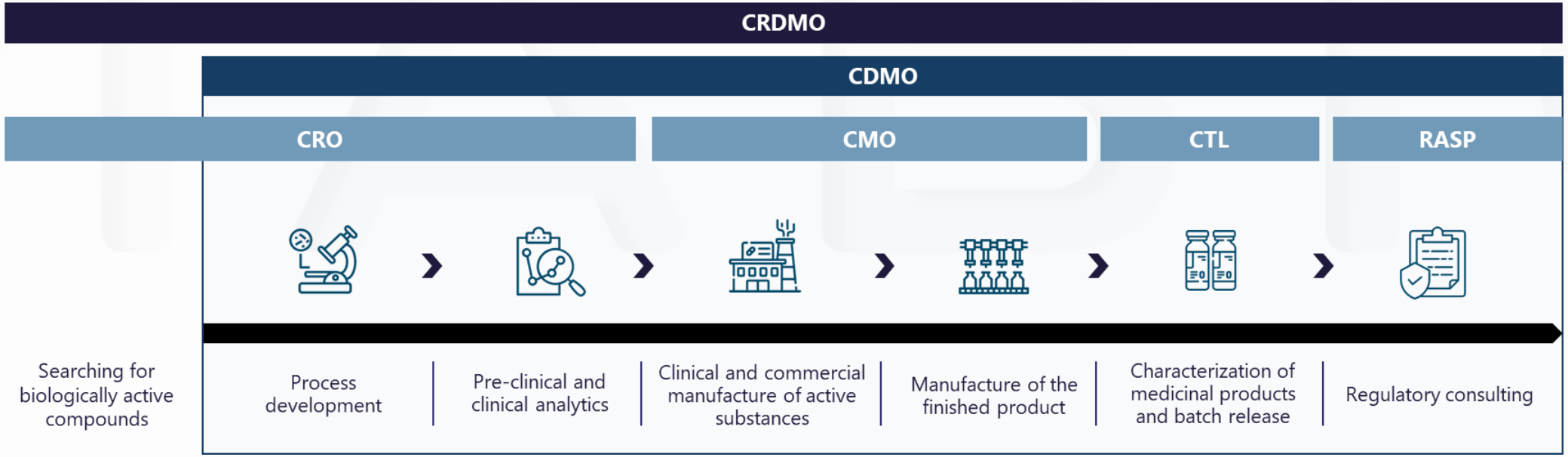
21 Firstfield Rd
Gaithersburg, MD, USA 20878

Novavax case study

Our 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.



- 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.**

Drug Substance Manufacturing

UPSTREAM PROCESS

- Mammalian & insect cell cultures
- 2 x 2000 L, 2 x 200 L, 2 x 50 L stirred-tank, single-use bioreactors from Cytiva
- 2 x 2500 L and 4 x 250 L orbital shaking bioreactors
- Medium & supplements preparation and storage capacity

DOWNSTREAM PROCESS

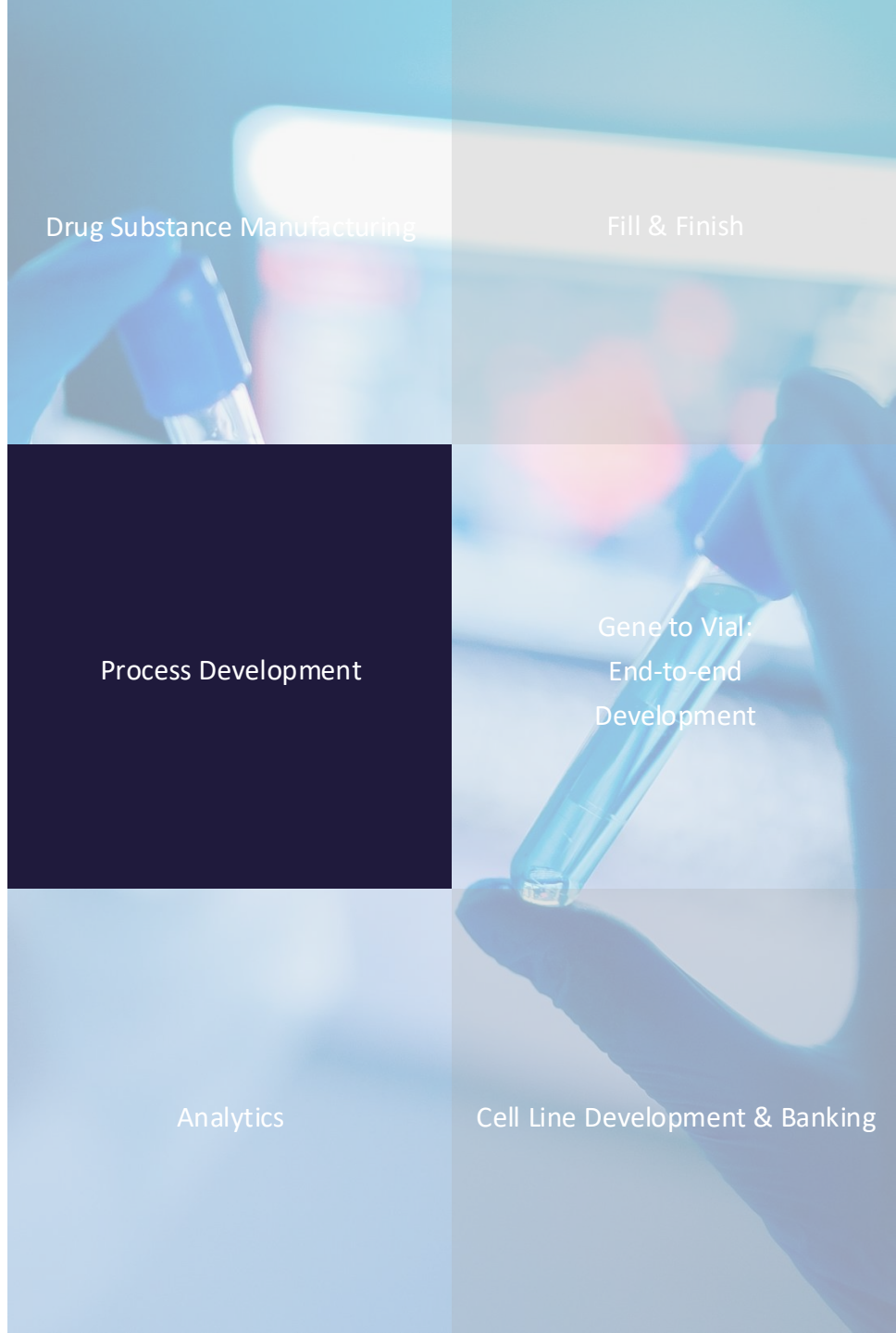
- Separation technologies (depth filtration & centrifugation)
- Affinity chromatographies Ion-exchange chromatographies
- Ultra/diafiltration
- Nanofiltration
- Sterile filtration
- Formulation
- Buffer preparation

Fill & Finish

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

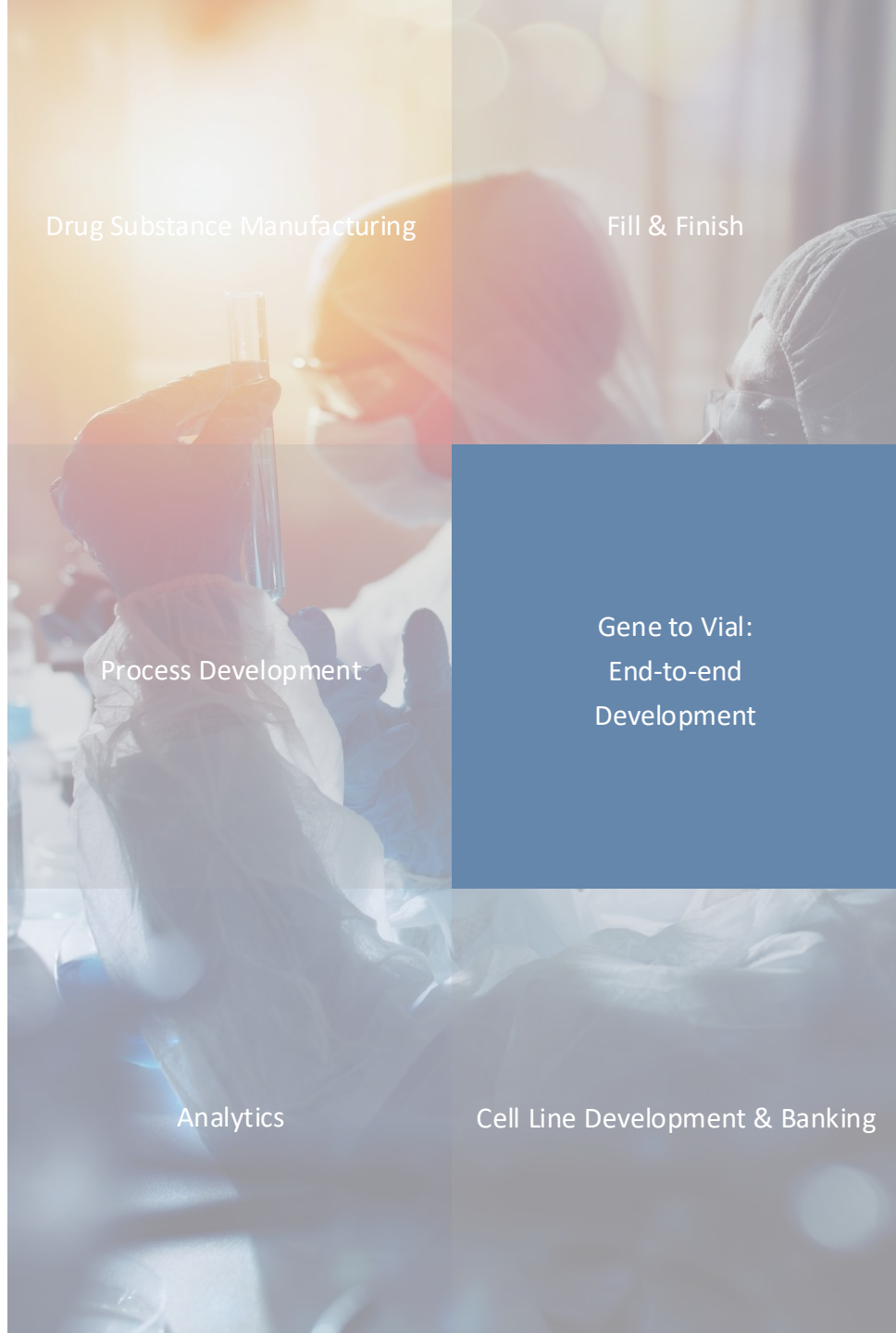
Process Development

- 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



Gene to Vial: End-to-End Development

- Cell banking
- Process development
- Analytical development
- Drug Substance manufacturing
- Fill & Finish
- Suite of services specifically tailored to the project

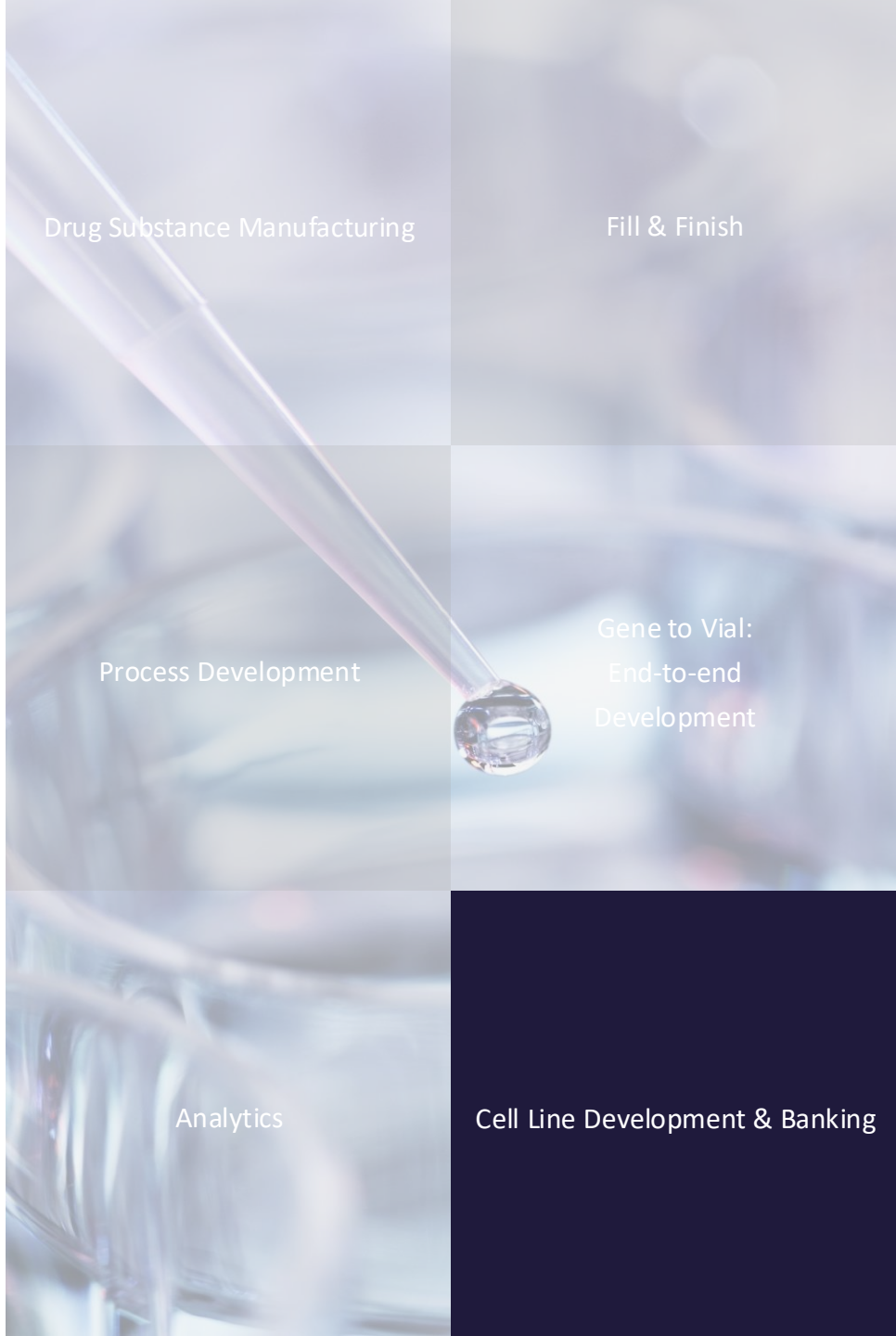


Analytics

- Drug characterization services
  - Physiochemical analytics
  - Structural analytics
  - Biological analytics
  - Clinical and pre-clinical analytics
- GMP release testing
- QC testing of intermediate product, Drug Substance, Drug Product, reference product
- Analytical methods development and validation
- Comparability and similarity studies
- Characteristics of reference standard
- Long-term, accelerated and stress stability study
- Environmental monitoring

Cell Line Development & Banking

- Cell line development:
  - Clone selection
  - Stable and highly productive monoclonal cell line
  - Culture medium optimization
- Non-GMP Research Cell Banks (RCB)
- cGMP Master Cell Banks (MCB)
- cGMP Working Cell Banks (WCB)



Thank you

MABION
Biologics CDMO

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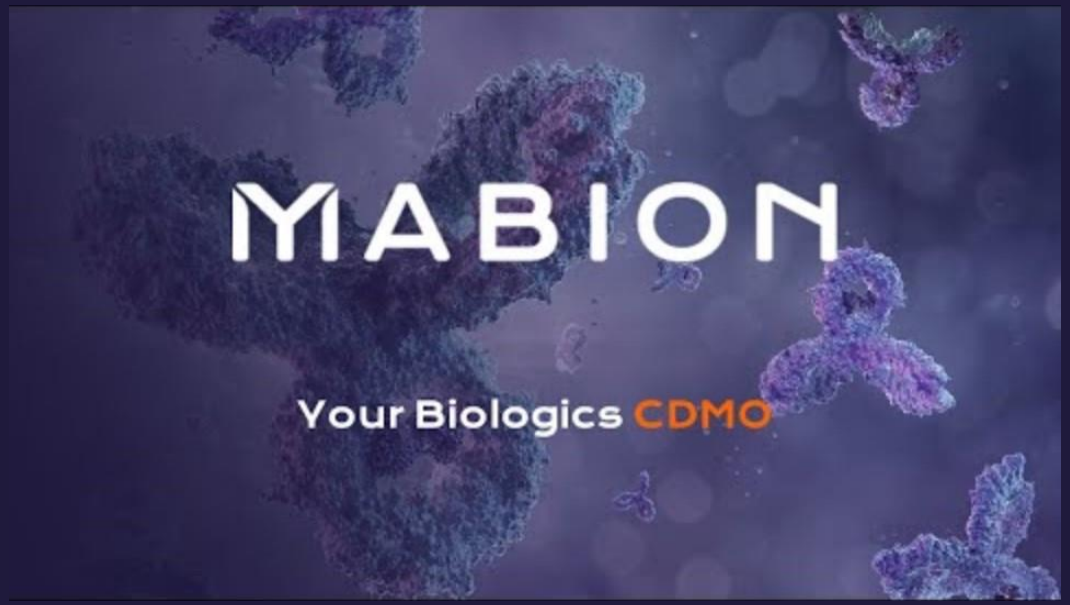
Watch a video presenting Mabion:



Link: https://www.youtube.com/watch?v=qhkeojtEdW8&t=10s

For more information about our services please visit our new website:

https://www.mabion.eu/