
HIPRA
BIOTECH
SERVICES

HIPRA BIOTECH SERVICES

HIPRA GROUP AT A GLANCE

50 years
Experience in a wide range of biologics processes

5th
Global player in biologics for Animal Health

108
Registered products, including BIMERVAX®, of which 21 launched in the last 10 years

300+
Experience with 300+ pathogens, 1,500+ cell lines and 1,300+ virus lines

€500M
Invested in last 8 years in state-of-the-art facilities & equipment

~900
Lots of Drug Substance made each year with >95% success rate

~50M
Vials formulated and filled each year

15%
Of sales reinvested yearly in R&D

100%
Privately owned, with a long-term partnership & investment mindset

2,600
Total employees globally

400
R&D scientists, analysts and biotechnologists (15% of total staff)

1,000
Mfg & QC operators, analysts & process engineers

End-to-end internal capabilities from cell line development to commercial manufacturing

HIPRA BIOTECH SERVICES

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Evolving your biologics through our **expertise**, **excellence** and **engagement**

HIPRA Biotech Services is HIPRA's CDMO division, bringing over 50 years of scientific and technical excellence to pharmaceutical and biotechnology companies, offering comprehensive contract development and manufacturing services in a wide range of biologics technologies and modalities.

ONE HEALTH

Over 50 years of expertise in One Health

Experience with a wide range of technology platforms in highly complex biologics processes

Scientific and technical excellence ensuring flexibility, agility and seamless integration across all stages of the life cycle

Unwavering commitment to quality as demonstrated by GMP certificates and excellent inspection record

State of the art facilities in close proximity, in the European Union

Unlimited optimism to make your project our own and significantly enhance and accelerate your chances of success

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OUR HISTORY

1971
HIPRA established in Amer (Spain)

1991
First exports

2000
Start of Internationalization

2009
Strategic refocus in prevention

2020
Creation of the Human Health division

2023
Approval of BIMERVAX® our recombinant protein vaccine made in CHO cells for Human Health

2024
Launch of HIPRA Biotech Services

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OUR REGULATORY TRACK RECORD

- **EU GMP certified for almost 30 years**
  - First certified in 1997
  - Most recent EU GMP certification July 2022
  - Next inspection in May 2025
- **108 products approved by the EMA, including BIMERVAX®**
- **Ongoing project to achieve FDA readiness by mid-2026**

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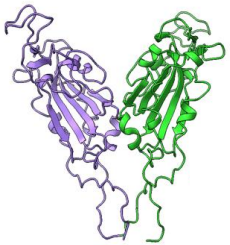
OUR CREDENTIALS IN HUMAN HEALTH



BIMERVAX®, our COVID-19 vaccine

- Bivalent recombinant protein vaccine manufactured in CHO cells
- Unique structure enabling protection against 2 variants in a single molecule
- 100% developed and manufactured by HIPRA (end-to-end)
- Financed entirely with own resources
- Development started May'20, standard Marketing Authorization March'23

EU-FAB, a framework contract setting up a European network for sufficient and agile manufacturing capacities for pandemic preparedness

- HIPRA selected as one of four strategic partners of Health Emergency Preparedness and Response Authority (HERA) for the EU-FAB framework
- Selection valued HIPRA's vast experience in a wide variety of recombinant protein vaccines and state-of-the-art development & manufacturing facilities

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OUR CORPORATE ESG PLAN

GO GREEN

Decarbonization and climate neutrality

Water management

Efficient use of materials and components

GO PEOPLE

Access to health

Fostering talent

Responsible Innovation

Sense of belonging

Safe and healthy work

GO ETHICAL

Regulatory compliance

Responsible sourcing and supply chain

Ethical behaviors towards all stakeholders

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OUR AVAILABILITY AND TIMELINES

We have capacity available *now* to start development and commercial manufacturing projects in mammalian, microbial, and aseptic fill & finish

We are able to hit 12 months from Gene/Strain to Drug Substance as demonstrated by BIMERVAX® and our typical lead times in AH

With an additional 3 months we can get to DP (some of the work would happen in parallel to DS); timelines for just doing DP will depend on amount of development work needed

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OUR SERVICES

Development

From early discovery to clinical manufacturing production, we accelerate each stage of biologics drug development with expertise and flexibility

Development labs feature high-throughput bioreactor systems (Ambr®15 and Ambr®250) for design of experiments, small- and mid-scale benchtop bioreactors, Cobas® analyzers (for clinical chemistry and immunochemistry assays), and advanced tools for cell line development, complemented by a specialized area for process development and a dedicated GMP area for early-phase clinical batch production

Manufacturing

We provide robust and flexible pharmaceutical manufacturing and quality control services at our state-of-the-art GMP certified facilities

DS facilities feature top-of-the-line single-use 500L cell culture bioreactors, 2000L microbial fermentation single-use bioreactors and stainless-steel fermenters, single-use chromatography, tangential flow filtration, and centrifuges.
DP facility features a high-speed isolator liquid vial filling line with 100% IPC.
QC labs feature a wide variety of equipment enabling a wide range of methods; equipment is the same as used in the Analytical Methods development lab

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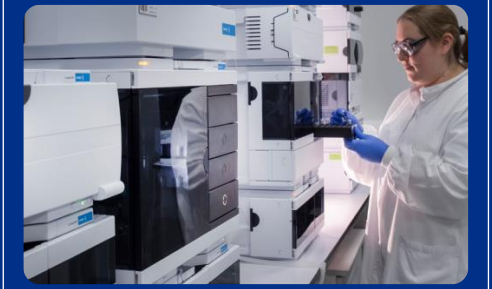
DEVELOPMENT SERVICES OVERVIEW

Cell Line and Strain Development

- **Antigen discovery** including viral and bacterial antigens, recombinant proteins, peptides and monoclonal antibodies
- **Platform development** such as adherent and suspension cell culture (mammalian, avian, or insect) and microbial culture (bacteria or yeast)
- **Accelerated development of cell** lines for recombinant proteins and monoclonal antibodies production, optimizing the timeline from concept to production
- **Stability studies** to assess and ensure the longevity and reliability of biologic products

Process development & scale-up

- **Process development, validation and industrial scale up**, from small-scale and early stages to commercial batch production, covering both Drug Substance and Drug Product
- **Formulation development**, including adjuvant selection where applicable, and scaling these formulations for industrial production
- **Strategic design of protocols for validation process**
- **Technology transfer** of production methods, inbound and outbound, to enable seamless transitions and scaling up of production



Analytical methods development

- **Development and validation of analytical methods** for both drug substance and drug product to ensure consistent product quality in strict compliance with GMP regulations
- **Transfer of analytical methods** to the Quality department, ensuring that all methods are properly implemented and validated for routine quality control
- **Specialized analytical techniques,** such as ELISA, qPCR, peptide mapping, HILIC, sterility and endotoxin testing, SEC-HPLC, and CE-SDS, among others

Preclinical development studies

- **Design and performance of detailed protocols for in-vivo studies**
- **Development and optimization of appropriate animal models** tailored to the specific requirements of the research
- **Development and validation of analytical methods** to assess the immunogenicity and safety of the products
- **Execution of preclinical development studies** in accordance with Good Laboratory Practices
- Preparation of final **reports of in vivo studies**

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DEVELOPMENT

Cell line and strain development

Drug discovery capabilities, including viral and bacterial antigens for vaccine development, recombinant proteins (such as mAbs), peptides, enzymes, and more

Cell line and strain development tailored for both cell culture (mammalian, avian, or insect) and microbial (bacterial and yeast)

Accelerated cell line development pipeline “from gene to manufacturing scale” for the production of recombinant proteins and monoclonal antibodies

Stability studies

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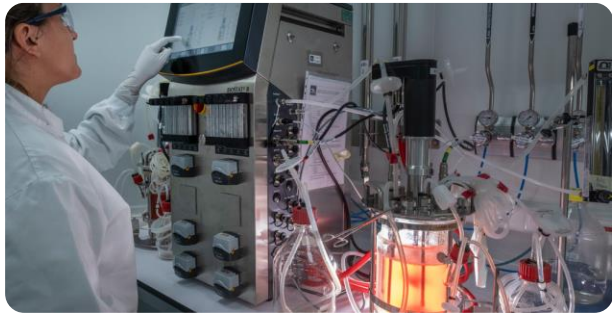
DEVELOPMENT

Process development and scale-up



- Process development, validation and industrial scale-up
- Formulation development
- High-throughput, small-scale bioreactors (e.g., Ambr® system) and robust scale-up methodologies
- Strategic workflow for process characterization and validation
- Efficient technology transfer

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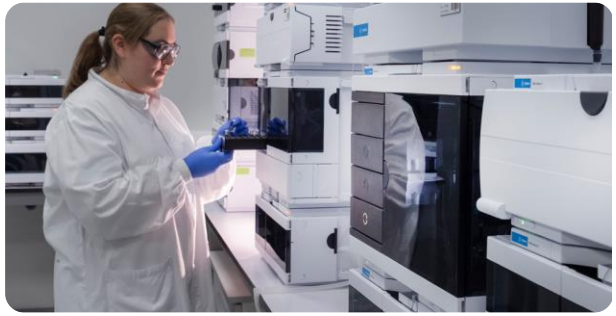
DEVELOPMENT

Analytical methods development



Development and validation of analytical methods

Smooth transfer of analytical methods to commercial QC thanks to identical equipment between R&D and QC

Broad analytical capabilities and expertise to assist in all phases of process development through to manufacturing

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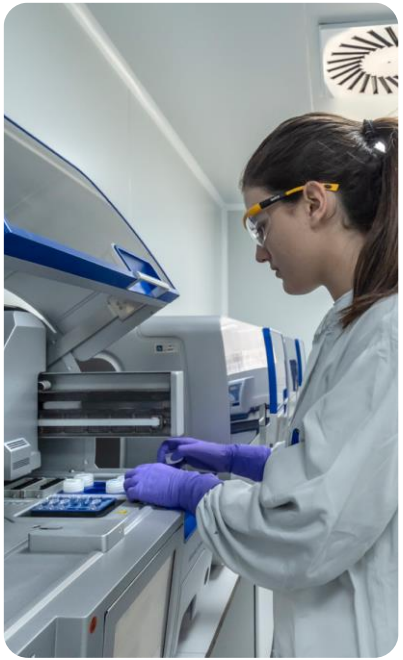
DEVELOPMENT

Preclinical development studies



Design and performance of detailed protocols for *in-vivo* studies, conducted in-house

Development and validation of analytical methods for preclinical studies

Development and optimization of appropriate animal models

Execution of preclinical development studies and reporting

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MANUFACTURING SERVICES OVERVIEW

Cell culture platform

- Adherent and suspension cell lines including production of **recombinant proteins, peptides, monoclonal antibodies, and viral antigens**, using mammalian, avian, or insect cell lines
- GMP master cell bank production

Microbial platform

- *E. coli* and yeast protein expression **systems** including microbial culture, production of **peptides**, and production of **recombinant proteins**
- GMP master cell bank production

Aseptic Fill and Finish

- Comprehensive **formulation services** for sterile injectable drug products
- **Fill-and-finish** operations for **liquid vials**
- **Isolator line with 100% IPC, e**nsuring compliance with stringent sterility and quality standards throughout the process

HIPRA BIOTECH SERVICES

MANUFACTURING

Cell culture platform

Our cell culture manufacturing facilities are designed for large-scale, late-stage, and commercial biopharmaceutical production, offering scalability, efficiency, and high-quality solutions for complex products

Upstream

- 7 x 50L single-use bioreactors
- 13 x 500L single-use bioreactors
- Single-use and stainless-steel complementary equipment

Downstream

- 3 chromatography systems
- 3 tangential flow filtration systems
- Single-use systems for downstream processing

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MANUFACTURING

Microbial platform

Our microbial manufacturing facilities support large-scale, late-stage, and commercial production with the flexibility needed for diverse microbial-based biopharmaceutical processes

Upstream

- 8 x 2,000L single-use bioreactors
- 4 x 200L single-use bioreactors
- 4 x 2,000L stainless-steel fermenters
- 4 x 100L stainless-steel fermenters
- Single-use stainless-steel complementary equipment

Downstream

- 5 CIP-SIP continuous centrifuges
- 2 chromatography systems
- 2 tangential flow filtration systems
- 1 high-pressure homogenizer
- Single-use systems for downstream processing

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MANUFACTURING

Aseptic Fill & Finish

Our aseptic fill and finish facilities are designed for late-stage clinical and commercial production, ensuring the highest standards of product integrity and compliance with global regulations

Formulation

- 4 x 1,200L formulation reactors
- NIRO Soavi high-pressure homogenizer
- 2 x 2,000L single-us mixers
- 4 Hi-shear agitators
- Single-use and stainless-steel complementary equipment

Liquid vials fill & finish

- Skan isolator technology
- High-speed (24,000 u/h) Bausch+ Ströbel filling line with 100% IPC
- From 2R to 10R liquid vials

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FACILITIES LOCATIONS

Our state-of-the-art GMP certified facilities cluster is located in Spain (EU), with biologics development and manufacturing centers close to each other.

This setup allows us to integrate the entire value chain in one location, offering exceptional flexibility and agility in decision-making and manufacturing processes.

Strategically positioned for efficient distribution globally, our facilities benefit from a robust logistics network—encompassing airports, ports, and highways—to ensure smooth and timely deliveries worldwide.

Headquarters (Amer)

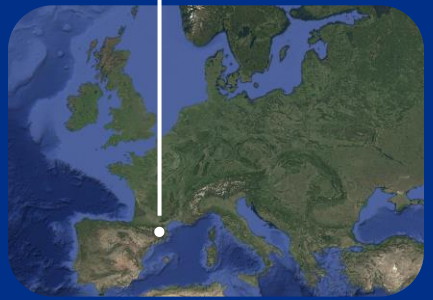
30min from Girona and 1h30 from Barcelona

Headquarters offices
Microbial Manufacturing
Cell Culture Manufacturing
Aseptic Fill and Finish
QC Labs
Preclinical facilities
Warehousing

Campus HIPRA (Aiguaviva)

10min from Girona and 1h from Barcelona

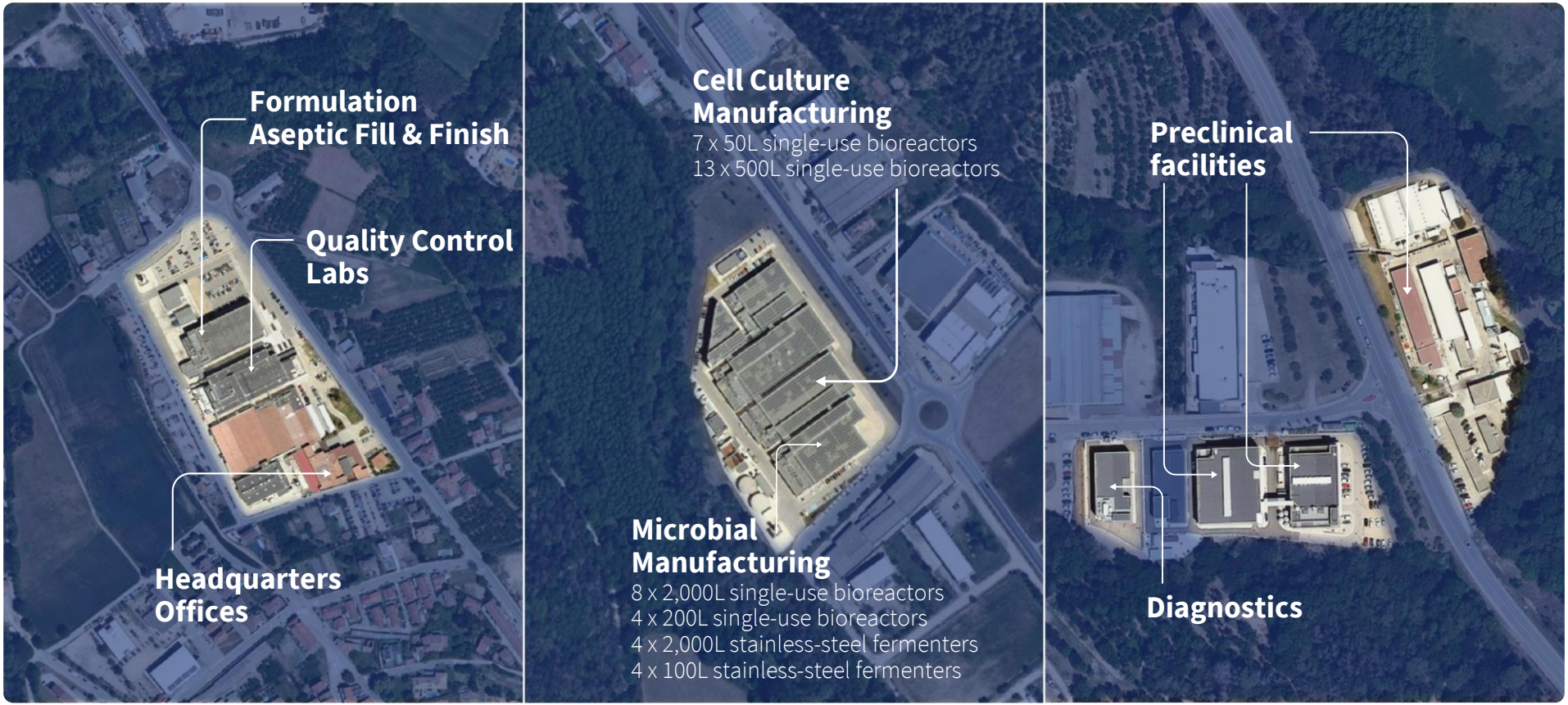
R&D Labs and Pilot Plant
Microbial Expansion
Cell Culture Expansion
QC Labs Expansion
Additional offices



HIPRA BIOTECH SERVICES

Headquarters

Amer, Girona, Spain



HIPRA BIOTECH SERVICES

Headquarters

Amer, Girona, Spain

HIPRA BIOTECH SERVICES

Headquarters

Amer, Girona, Spain

Microbial Manufacturing
8 x 2,000L single-use bioreactors
4 x 200L single-use bioreactors
4 x 2,000L stainless-steel fermenters
4 x 100L stainless-steel fermenters

Cell Culture Manufacturing
7 x 50L single-use bioreactors
13 x 500L single-use bioreactors

Dedicated Facilities for Animal Health

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Headquarters

Amer, Girona, Spain

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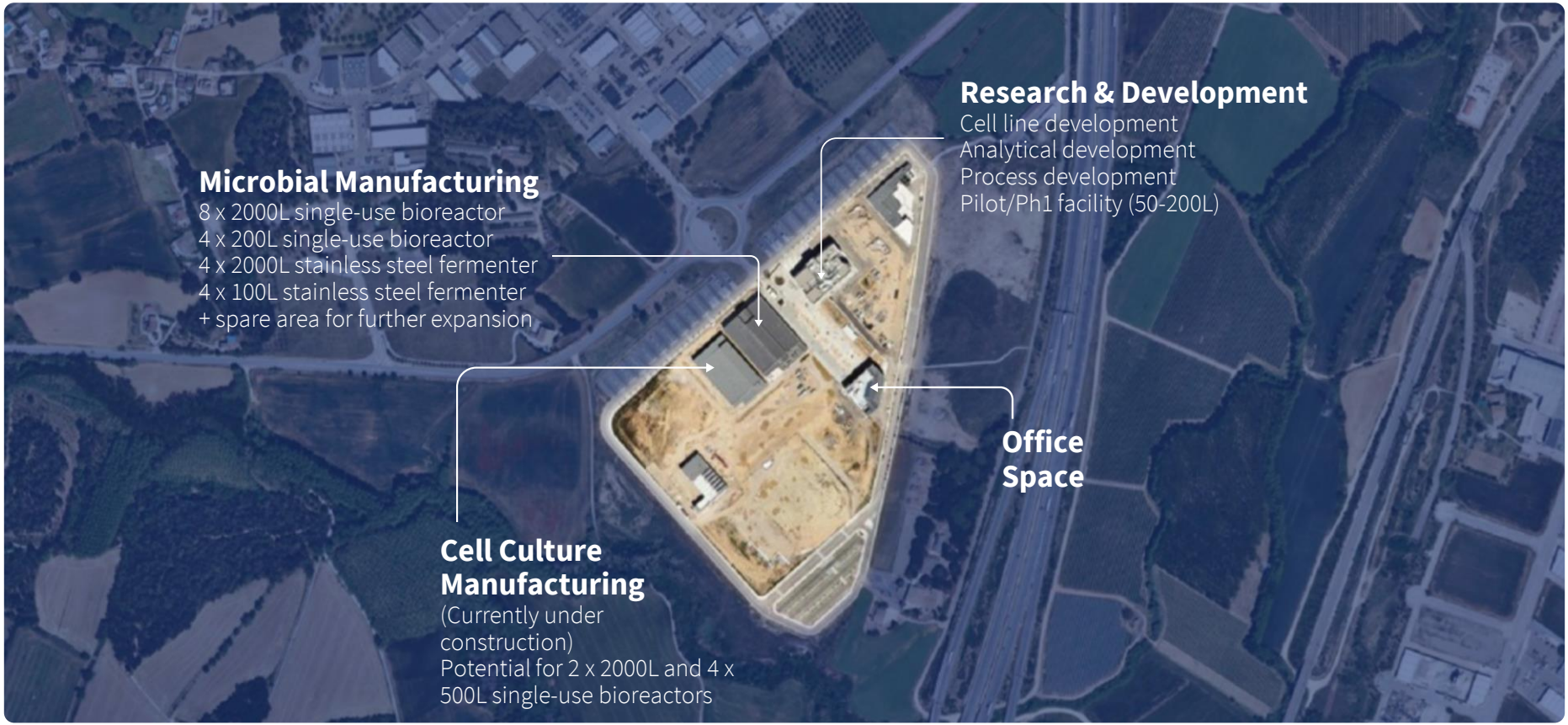
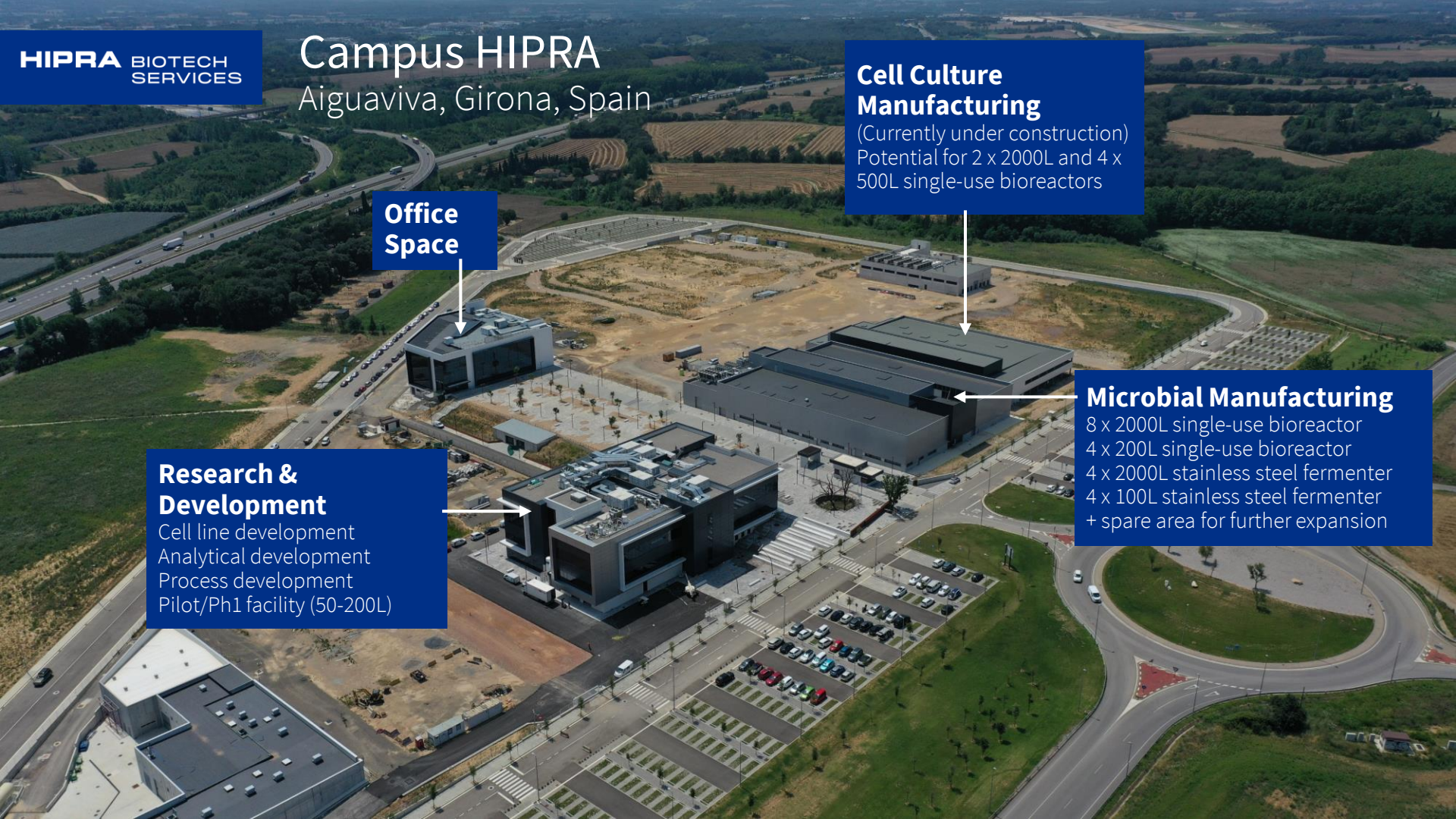
Campus HIPRA

Aiguaviva, Girona, Spain

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Campus HIPRA
Aiguaviva, Girona, Spain
Cell Culture Manufacturing
(Currently under construction)
Potential for 2 x 2000L and 4 x 500L single-use bioreactors
Office Space
Microbial Manufacturing
8 x 2000L single-use bioreactor
4 x 200L single-use bioreactor
4 x 2000L stainless steel fermenter
4 x 100L stainless steel fermenter
+ spare area for further expansion
Research & Development
Cell line development
Analytical development
Process development
Pilot/Ph1 facility (50-200L)

HIPRA BIOTECH SERVICES

Come Visit Us!

Schedule an in-person visit today to meet our team and see our world-class facilities. Meanwhile, click for Virtual Tour.

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