BIO-MANGUINHOS

INNOVATION AND PRODUCTION AT THE SERVICE OF PUBLIC HEALTH

Read more about us.

Instituto de Tecnologia em Imunobiológicos
Bio-Manguinhos

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BIO-MANGUINHOS/FIOCRUZ

Innovation and Production at the service of Public Health

The Institute of Technology on Immunobiologicals (Bio-Manguinhos) is the unit of the Oswaldo Cruz Foundation (Fiocruz) responsible for research, innovation, technological development, and production of vaccines, in vitro diagnostics (IVDs), biopharmaceuticals, and advanced therapies. Its primary aim is to meet the demands of Brazilian public health and provide research services.

With 49 years of existence, Bio-Manguinhos has become the largest federal laboratory in Latin America and has consolidated itself as a strategic agent of public health policies in Brazil. To keep up with the trends and best practices in the pharmaceutical industry, the investment in the expansion and modernization of infrastructure is constant, being part of the innovation process of the Institute.

With its own technological development projects and partnerships, in addition to technology transfer agreements with public and private institutions, Bio-Manguinhos provides a range of products for the Brazilian Public Health System (SUS), through the programs of the Ministry of Health. The result is the annual supply of millions of doses of vaccines, IVDs reactions, vials and syringes of biopharmaceuticals that expand the population's access to high-quality products. The Institute also contributes to the public health of several countries, mainly by the export of the yellow fever vaccine, pre-qualified by WHO.

www.bio.fiocruz.br

Immunological services:

- Development and production of monoclonal antibodies;
- Development of assays: ELISA and liquid microarray;
- Execution of assays: ELISA, liquid microarray, ELISPOT, and flow cytometry;
- Isolation of peripheral blood mononuclear cells (PBMC);
- Encapsulation of molecules in lipid nanoparticles;
- Functionalization of aptamers or antibodies in lipid nanoparticles.

Pilot Plant (available soon)

- Upstream process in bioreactors (up to 200L);
- Downstream process - purification of viruses and proteins, conjugation or chemical modification of proteins at pilot scale.
- Production of non-clinical and clinical batches: under GMP conditions for phase I, II and III studies from production and purification platforms.
- Formulation, aseptic filling, lyophilization, filling, and crimping.

This leading role in the field of public health is the result of the commitment of more than 2,500 employees who make the difference in the lives of millions of people every day.

Pre-clinical services:

- Conducting over 100 experimental techniques in different biomodels, including non-human primates (NHP);
- Performing proof-of-concept studies;
- Conducting immunogenicity assays;
- Executing infection assays for prophylactic and therapeutic evaluation;
- Developing monoclonal and polyclonal antibodies against antigens of different origins;
- Producing hyperimmune serum;
- Performing various techniques for inoculating oncological cells in biomodels;
- Acquiring images through bioluminescence, fluorescence, and X-ray;
- Conducting experimental procedures at Animal Biosafety Level 3.

Immunomolecular services:

- Serum Neutralization Assay (Neutralizing Antibody Dosage – AcN)
  - Methods: Plaque Reduction Neutralization Test (PRNT), microFRNT and Pseudovírus
  - Targets currently analyzed:
    - Respiratory viruses (Ex.: SARS-CoV-2, measles, mumps)
    - Vector-transmitted viruses (Ex.: Arbovirus – Dengue (D1-4); Zika; Yellow fever; Chikungunya).

- Antiviral Assay (Antiviral Activity Dosage)
  - Methods: TCID50 assay
  - Targets currently analyzed: SARS-CoV-2 measles and mumps

Analyses Performed (available soon)

- Endotoxin
- Sterility
- Primary Packaging Identity
- Color Determination
- Clarity and Opalescence
- pH
- Osmolality
- Extractable Volume
- Particle Count
- Identity
- Oligosaccharide Profile
- Content
- Methionine Content
- Oxidized Forms
- Dimers and Related Substances
- Deaminated Forms

GLOBAL HEALTH PERFORMANCE

The importance of Bio-Manguinhos goes beyond the borders of Brazil, with the Institute playing an important role in controlling yellow fever in dozens of countries as well outbreaks through the supply of vaccines and discussions in forums of international agencies related to the subject.

The Institute is also a member of the Developing Countries Vaccine Manufacturers Network (DCVMN), a voluntary public health-driven alliance of vaccine manufacturers from developing countries, firmly engaged in research, development, manufacturing and supply of high-quality vaccines that are accessible to protect people against known and emerging infectious diseases globally.

In 2021, Bio-Manguinhos was selected by WHO as a center for the development and production of vaccines with mRNA technology in Latin America. The selection is the result of a call for expressions of interest launched worldwide, aiming the increase of the production capacity and expanding access to vaccines against Covid-19 in the Americas.
The Institute has already implemented its GMP facility and is about to manufacture the clinical batches.

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