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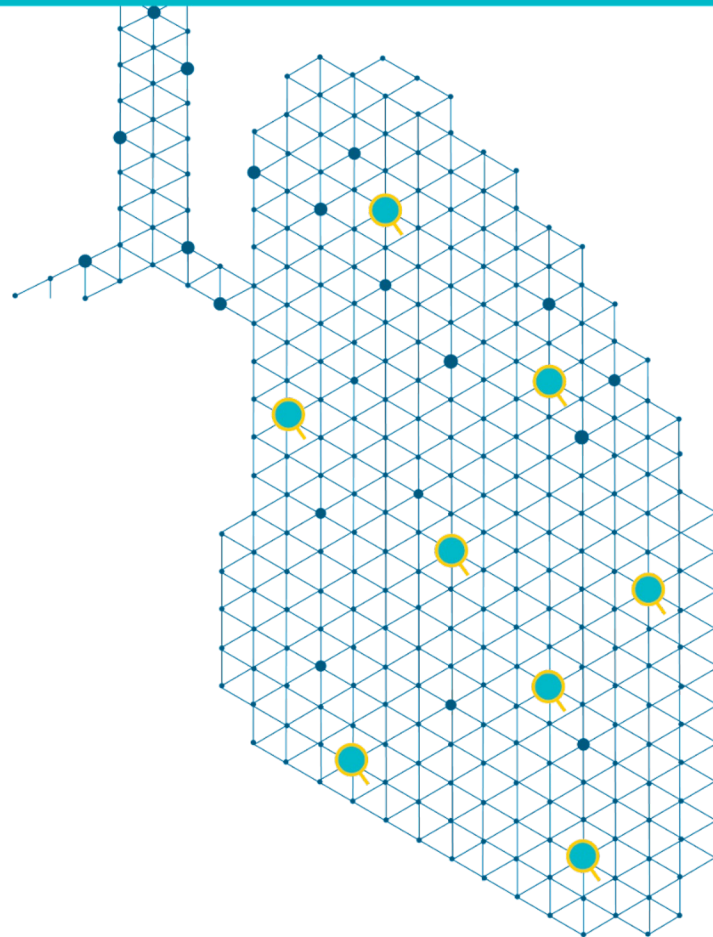



FORO DE POLÍTICAS PÚBLICAS EN VRS



Alliances with an impact in Public Health

**Fernanda Boulos- Chief Medical
Officer at InstitutoButantan**



We at Instituto Butantan work tirelessly at the service of life



Founded in 1901, it is a public entity **currently associated with the Health Secretary of São Paulo**. It is the main producer of immunobiologicals in the country and one of the main suppliers of sera and vaccines for the Brazilian Ministry of Health.



Founded in 1989, it is a non-profit civil and private entity to support the Butantan Institute. Its role is to ensure dynamism, maintaining, facilitating and accelerating the scientific development and production of immunobiologicals.

Our core business is

- R&D
- Manufacturing
- Culture and Education

4000
collaborators

We are in São Paulo, Brazil

- Population of 15 million people
- The largest city of Latin America
- 17^o wealthiest city in the world

122
years



PRODUCTION OF SERA AND VACCINES

VACCINES



* Product from Tech Transfer

ANTITOXINS AND ANTIVENOMS



**12 types of sera against
toxins from venomous
animals and microorganisms**



RESEARCH AND DEVELOPMENT

150

Researchers



44

Scientific
Initiation
Scholarships



119

Graduate
Scholarships



140

Research
Projects



132

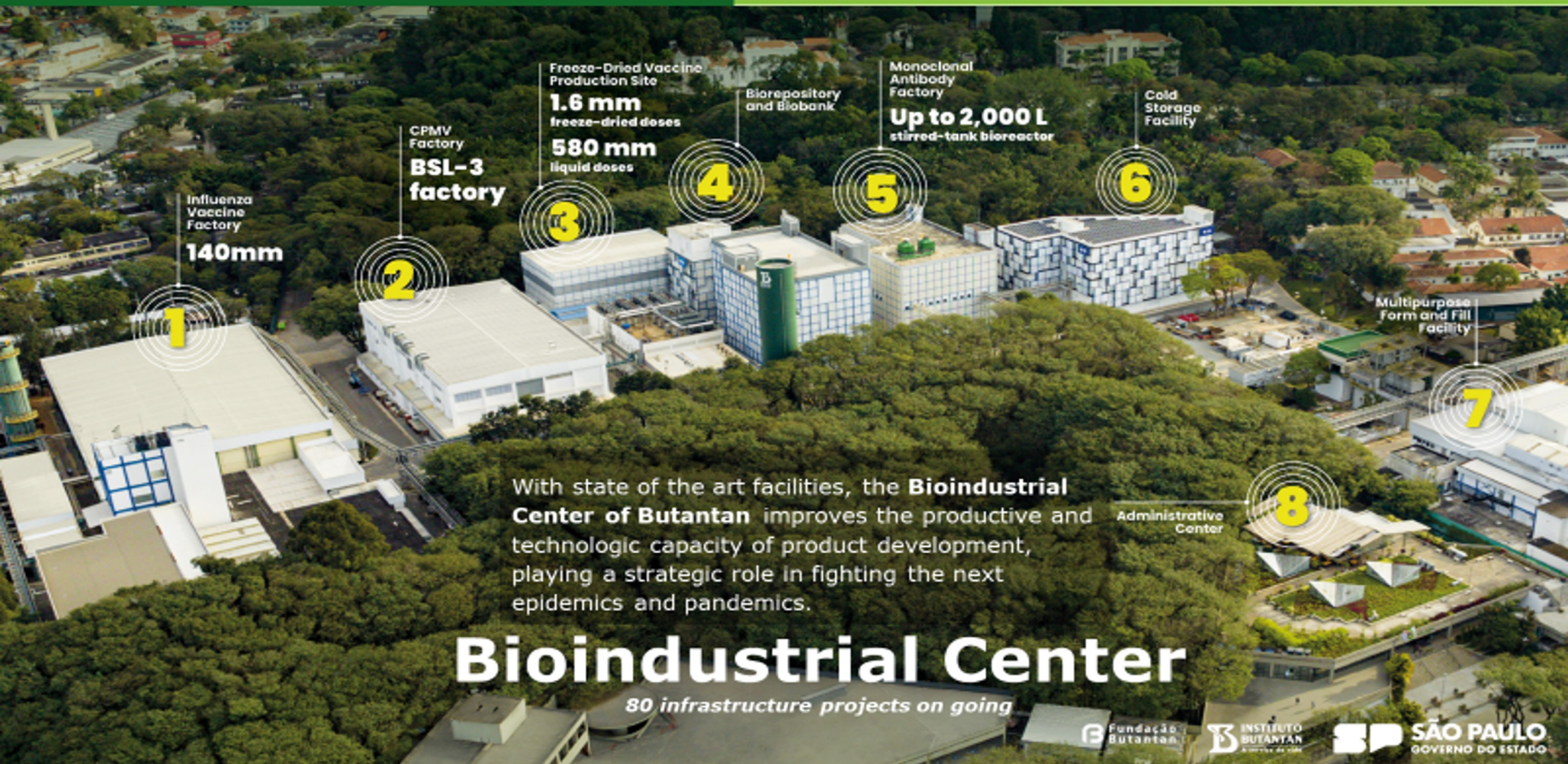
Lines of
Research



275

Published
Articles





Influenza Vaccine Factory
140mm

CPMV Factory
BSL-3 factory

Freeze-Dried Vaccine Production Site
1.6 mm freeze-dried doses
580 mm liquid doses

Biorepository and Biobank

Monoclonal Antibody Factory
Up to 2,000 L stirred-tank bioreactor

Cold Storage Facility

Multipurpose Form and Fill Facility

Administrative Center

With state of the art facilities, the **Bioindustrial Center of Butantan** improves the productive and technologic capacity of product development, playing a strategic role in fighting the next epidemics and pandemics.

Bioindustrial Center

80 infrastructure projects on going



CLINICAL DEVELOPMENT

- **Clinical trials** since 2003
- **Over 40 studies**, ~half in the past 6 years
- Sponsoring from **Phase I to IV**
- All regions in Brazil
- Ongoing:

Dengue, Chikungunya, Influenza, COVID-19

~57,000
participants
enrolled

+60
clinical
sites across Brazil



STRATEGIC PARTNERSHIPS

Strategic Alliances

- Technology Transfer
- R&D Co-development Agreement
- Licencing Agreement
- Produc. Registration and Commercialization Agreements
- Clinical Co-Development Agreement

Influenza, HepB, Dengue, Chick, COVID-19 and others

Following a premise that a public institution has waiver of bidding process and can supply directly to MoH



MINISTÉRIO DA SAÚDE



Partnerships for Productive Development (PDPs)

– For existing products –



Currently supplying 4 products under PDP

Pre-Commercial Procurement (ETEC)

*A special type of public purchase, which does **not** require bidding, where the objective is to **develop a solution that is not yet available and requires a formal R&D effort.***

- Need for R&D
- Presence of Technological Risk
- Absence of a market solution
- Must be a MoH's real problem



CO-DEVELOPMENT AGREEMENTS

- COVID-19 VACCINE (CORONAVAC)

SINOVAC

Ph I and Ph II

Licensing in



Pivotal Ph III Trial

Form & Fill



Commercialization



- Butantan was the solely **sponsor of the pivotal Phase III trial** in healthcare workers
- Study involved **13,000 volunteers** in Brazil
- Several vaccine effectiveness study in different populations
- Butantan **supplied 120M doses in Brazil**



CO-DEVELOPMENT AGREEMENTS

- COVID-19 VACCINE – BUTANVAC (NDV-HXP-S)



- Recombinant **Newcastle Disease Virus (NDV)** expressing the **Prefusion** Spike Protein
- Currently on Ph II Clinical Trials (400 volunteers) – Ph III will involved 4,000 volunteers
- NDV is harmless to humans and grew in embryonated eggs and further inactivated
- Manufacturing Process is similar to the flu vaccine.

CO-DEVELOPMENT AGREEMENTS

- CHIKUNGUNYA VACCINE



LMIC

- **Live attenuated** vaccine developed by **Valneva** and supported by **CEPI**
- Single Dose, lyophilized vaccine
- Adolescent Study in Brazil (Endemic Area) with Butantan as Co-Sponsor **~750 volunteers**
- Butantan **will launch the product in Brazil and LMIC** (co-development and licensing agreement)
- Valneva remains with Travelers Market



CO-DEVELOPMENT AGREEMENTS

- DENGUE VACCINE**



- **Single dose** live attenuated vaccine against 4 serotypes of **Dengue virus**
- Ongoing **PHASE III** clinical development - more than 16.000 volunteers
- Expected **launch in 2025** by Butantan in Brazil and MSD worldwide
- Partial results from 2-year follow-up show **79.6% overall efficacy** to prevent the disease
- It will be provided in Brazil through Public Health System and Private Market

BUTANTAN WITHOUT BORDERS



Examples of partnerships that resulted in products over the years

Strategic objectives

- Expand partnerships portfolio
- Diversify products within existing platforms
- Platforms diversification (mRNA is a target)
- Offer cost-effective products to Brazil and abroad
- End-to-end R&D and manufacturing pathway
- Improve R&D output into new products
- Disseminate culture, Education and Teaching



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