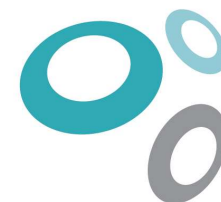




DCVMN AGM 2021 – CEO Forum, Vision 2030

October 2021



World and pandemic scenario

- Vaccination gap still high worldwide
 - Children with zero-dose around 14 MM
 - Coverage rates low in 2nd and 3rd dose schemes
 - Age groups still with low focus (e.g. +65 yo)
- Pandemia lessons learnt
 - High multi-stakeholder collaboration (states, universities, industry, etc.)
 - New proven technologies
 - Change of paradigm in regulatory timelines



DCVM role

- LMIC location increases challenges
 - Higher responsibilities in our own regions
 - Equitable access as a key driver for our organizations
 - Speed-up of technology change: how to keep updated
 - Funding as a key lever

Our challenge: to innovate, to access the new technologies and apply them on time





Our experience



Biogénesis
Bagó



mAbxience

From lab to life



*SINERGIUM
Biotech*

Biotech Hub: 20.000 sqm, 1.500 specialized employees, three companies.
Sinergium and mAbxience for human health
Biogenesis-Bago for animal health

Sinergium Biotech in numbers:

1 70 million doses produced

0 rejected batches

>700 batches manufactured

39% women in our staff

310 direct employees

6 public-private R&D projects

5 agreements with multinational
pharma companies

8 successful vaccine Tech-Transfers



Strong experience with top vaccine companies:

Tech Transfer performed:

- Trivalent seasonal Flu (Seqirus partnership): Tech Transfer finished in 2013, Form&Fill&Pack.
- Tetravalent seasonal flu vaccine (Seqirus Partnership) : Tech Transfer finished 2018.
- Prevenar 13 (Pfizer partnership): Tech Transfer finished in 2015.
- HPV (MSD partnership): Tech transfer finished 2018.
- Rituximab, Bevacizumab, Adalimumab (Mabxience partnership): from 2014, filling and packaging.
- Sars-CoV-2 antigen production (AZ partnership): from 2020, Mabxience facility.

SINERGIUM Biotech





Our capacities and capabilities

Formulation & Filling

PRE-FILLED SYRINGES (PFS)

- Fully automated Groninger filling line
- **Available capacity for 30 MM doses**

VIALS

- Semi-automated line
- **Available capacity for 40 MM doses/year**, in 10-dose vials.

FUTURE PROJECTS

- Fully automated filling and packaging line
- **Capacity projected for 400 MM doses/year**, in 10-dose vials.
- Project ongoing, to be ready by 4Q2023.



FDA/EMA – Best in Class Project

Objective:

Be Ready for “FDA/EMA” like inspection by March 2024

- Project Kick off : November 2021
- Pre Assessment : Nov 2021 – Q1 2022
- Action Plan Definition : March 2021
- Alignment Execution Phase: April 2022 – March 2024
- Interim Mock Audits every 6 month
- **Independent Mock Audit : Q1 2024 - READY FOR INSPECTION**



Sinergium Strategic Vision

We will face new challenges...

- Future local and global competitors
- Current contracts extention
- Improve access of our region to our products



PAHO selects centers in Argentina, Brazil to develop COVID-19 mRNA vaccines

21 Sep 2021



... that will require new strategies

- Foster a stronger partnerships
- Leverage our participation in the local public market (50/50)
- Expand our reach globally
- Expand our portfolio
- Develop new products under different platforms (baculovirus, adenovirus, mRNA)
- Develop a Funding strategy



Thanks

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