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)

- Pandemic 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
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:

- **170** million doses produced
- **0** rejected batches
- **>700** batches manufactured
- **310** direct employees
- **39%** women in our staff
- **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.
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 extension
• Improve access of our region to our products

... 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