



Sinergium Biotech S.A.

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Developing a global vaccine supply

Having established itself as a center of excellence for the development of biotech products, Sinergium Biotech is fast becoming the go-to place for vaccine supplies across Latin America.

Sinergium Biotech specializes in the high-tech manufacturing and supply across Latin America of highly complex biotech products and vaccines. Its innovative production model, which involves partnerships with multinational vaccine companies for cutting-edge technology, enables a rapid response to endemic infectious diseases while fostering autonomy.

It was the realization that Argentina was very vulnerable to pandemic flu that first sparked the concept of Sinergium as a solution. More than 5,000 people were dying every year from respiratory diseases alone, and worldwide vaccine availability at the time could not satisfy the demand that would emerge during a pandemic of flu. The country was continually reliant on imports, with no know-how or vaccine investment.

So in 2009, two Argentine companies, ELEA (the country's third-largest pharma) and Biogénesis Bagó (the world's largest producer of vaccines for foot and mouth disease) formed Sinergium Biotech SA. The idea was that Sinergium would—under a deal with multinational pharmaceutical firm Novartis—manufacture Novartis's influenza vaccine in exchange for full technology transfer to Argentina, including primary production of the antigens by Sinergium and self-sufficiency in the long term. The state later declared this concept, an idea of interest through a presidential decree.

// We believe in collaboration and partnerships—it's our essence

*Fernando Lobos,
director of business development*

The Argentine state put local flu vaccine production out to a public international tender, offering ten years of exclusive purchase in exchange for priority delivery in the event of a pandemic, as well as the construction of a manufacturing facility. It set stiff penalties for failure to deliver the vaccines and for construction delays. Sinergium won the contract and, in 2010, began building a state-of-the-art facility capable of producing vaccines and other biological products under good manufacturing practices (GMP). Production of Novartis's inactivated flu vaccine began in 2013, and today the company produces between 9 million and 12 million doses of trivalent influenza vaccine per year—enough to vaccinate the at-risk population (Fig. 1).



Figure 1: Sinergium Biotech's ViraFlu in production.

"The idea was to leverage the country's government procurement power to bring technology to the country," explained Fernando Lobos, Sinergium's director of business development. "It has worked, and we are building momentum." Sinergium has expanded the model, striking similar deals with Pfizer for a 13-valent pneumococcal conjugate vaccine and with Merck for a human papilloma virus vaccine. "Our manufacturing facility, which meets the highest standards in construction, processes and equipment, has an extra capacity of up to 30 million doses, enabling us to secure these major deals with leading companies. At the same time, we are learning from their huge experience and expertise," added Lobos.

Encouraging vaccine uptake

With a strong public health ethos, Sinergium not only supplies vaccines but also provides bespoke support to increase their uptake, as part of the contracts with the state. With the flu vaccine, for instance, it set up a call center and works with opinion leaders to coordinate promotional strategies and key messages. For the pneumococcal vaccine, Sinergium built cold chambers in each province in Argentina to strengthen cold chain distribution. "Our commitment is with the Argentinean state to improve the immunization results accomplishing the actions requested in the tenders, impacting in uptake rates high," said Lobos.

Results are impressive. Influenza vaccine coverage, for example, is now above 80% in Argentina (in the United Kingdom it is less than 75%, and it is much lower than that in other European countries), and cases of bacterial pneumonia in children above 5 years old have diminished by 50%.

Meanwhile, by using its platform to formulate, fill and package in-licensed products (with or without suppliers' branding), Sinergium is fast becoming the go-to place for access to Latin American markets. Its supply portfolio currently includes vaccines against polio and varicella, the pentavalent vaccine,

Bacillus Calmette-Guérin (BCG) for bladder cancer, and production for third parties of other biologics, such as monoclonal antibodies (e.g., rituximab and bevacizumab) and other recombinant proteins (e.g., erythropoietin).

"We have built a center of excellence in biotech production and have a high reputation with regulatory authorities," said Lobos. "We are capable of fulfilling domestic requirements of the national state for the public market and have significant potential to export regionally, which in turn will benefit the country's trade balance."

The next phase is to export and expand the business in Latin America, Europe and the Middle East, and to tackle other endemic diseases such as Zika virus, chikungunya virus, yellow fever and others. "We are also building a new manufacturing site of 5,000 m² for antigen production, the next necessary step for developing our own, broader portfolio for the longrun," said Lobos.

In April 2016, Sinergium struck a deal with Protein Sciences Corp (USA) to codevelop a vaccine against Zika virus and, together with other companies from Mexico, Japan and Brazil, plus the Mundo Sano Foundation, is expected to start phase 1 clinical trials in August 2017.

Partnering with Sinergium

Sinergium Biotech is interested in establishing tech-transfer agreements for additional vaccines needed for Latin America and the Middle East. Additionally, with its network of sites across these markets, the company is ideally positioned to in-license vaccines and other prequalified World Health Organization or appropriately approved products related to infectious diseases (antivirals, diagnostic kits and so on) for part processing and distribution across the region.

"Latin America and the Middle East are interesting markets but difficult to access for many companies," said Lobos. "We have headquarters in Argentina, are well recognized across the regions and are very flexible with the business model needed in each case. We believe in collaboration and partnerships—it's our essence and a way of bringing much-needed products to this part of the world."

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