

Are you approaching a vaccine project like a pharmaceutical project?

With vaccines and pharmaceutical products occupying a similar place in a country's health strategy, it is easy to assume the industries are more similar than they are in practice. While the industries are more closely related to each other than they are to say, mining, there are significant differences to keep in mind. They are cousins, but not twins.

It is important not to base the chances of success solely from your history with pharmaceutical products. That's not to say that pharma success is a bad start – completing a pharmaceutical tech transfer and bringing a product to market indicates your country's stakeholder alignment, funding, and level of skilled personnel are in great shape. But getting to vaccines from this baseline is not as simple as taking a pharma company and giving it extra funding. In this article, we'll explore what makes these industries so different.

A constrained and competitive market

There are hundreds of pharmaceutical products that help with a wide array of diseases and ailments. In contrast, only roughly 50 diseases have vaccines either licensed for use or in development. The WHO recommends routine immunization of every child against just 13 diseases.

Manufacturers in each industry follow the same pattern. Tens of thousands of companies manufacture pharmaceuticals, while approximately 4-5 dozen make vaccines, with the top dozen accounting for the vast majority of sales volume and value.

In this concentrated market, many vaccines enjoy a monopoly or duopoly. Receiving a tech transfer (TT) from another manufacturer in practice makes you, in some ways, a competitor.

Globally transparent supplier pricing

A pharmaceutical product typically has many purchasers and many suppliers buying and selling on a free and open market, with opaque pricing information. In contrast, the global market for vaccines in LMICs is highly consolidated by UNICEF and PAHO, with these organizations openly providing pricing information. A vaccine manufacturer often sells large volumes of product to a single buyer, resulting in tight margins and fierce competition.

This has implications for tech transfers. Most vaccine TTs take place to gain access to a market where originators can get preferential pricing compared to the import price, a monopoly to sell to the government, or both. However the government – the single source of demand and buyer in the country – has full knowledge of all other potential suppliers and in most cases their pricing. Opportunities to carve out your own profit as the local TT partner can be limited.

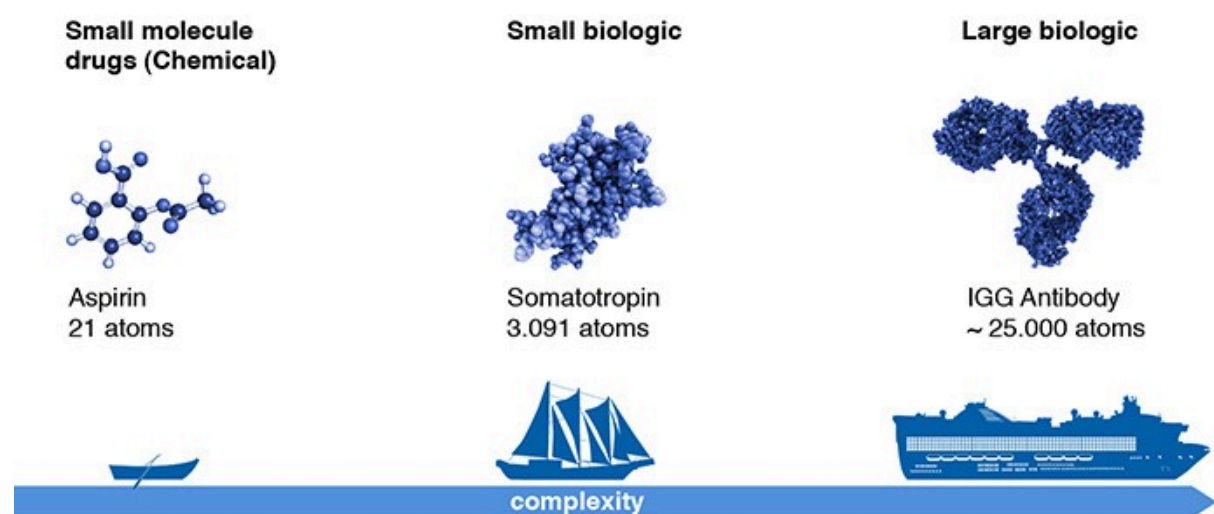
Made differently: Grown, not synthesized

As a 15 year old, my class was able to synthesize aspirin in my high school laboratory. We were not exceptional students, but the process could be explained, drawn on a piece of paper, and carried out with a basic understanding of chemistry and physics. While some pharmaceutical products are much more complex, their synthesis still typically follows concrete steps that can be precisely defined even if they are difficult to control. You could think of a pharmaceutical product like baking a cake – some recipes are more complicated than others, but you can take a fixed list of ingredients, temperatures, and steps to follow and get more or less the same result every time.

Vaccines on the other hand are made in complex biological systems, with the active ingredients, called antigens, typically created by trillions of living cells. You can think of vaccines as growing a garden – small variations in the weather, the soil, and other organisms will affect your crops. You can replicate growing tomatoes year on year, but you won't grow the same tomato plant, or the same tomatoes, even with perfect replication of the initial conditions. It is so difficult to create a vaccine, a product that must be safe and efficacious enough to inject into an infant's body, that only a handful of companies in the world do it.

Innovative Treatments

Biological medicines are produced using living organisms.



Biologics are not medicine like aspirin, which is made with chemicals. To get an idea of the relative size and complexity of molecules in chemical drugs versus biologics, compare a simple rowboat to a schooner and to a cruise liner.

Patents are not enough

Pharmaceutical patents and dossiers typically contain enough information that another company can create the product from that alone. The process might not be maximally efficient, the facility might be too small or large, but you will get the drug that you set out to make. There are countless successful examples of companies in LMICs doing just that. Again we can consider a pharma product like a cake – you can get the expected result just by following the recipe.

In over a decade of carrying out vaccine tech transfers, I never once was shown or needed a patent document. The IP placed on portions of the vaccine manufacturing process are more of a way to ensure royalties are paid correctly or to restrict your competitors from making your product than instructions on how to make the product.

For a successful tech transfer, you will need enormous quantities of explicit knowledge – knowledge written down or stored in databases, SOP, batch records, process descriptions, and more. But you will also need tacit knowledge, the intuitive know-how that comes with context and experience, that can only be learned from repeatedly watching and doing. [Making a vaccine is more like running a Michelin-star restaurant](#) than baking a cake, with the recipes a tiny fraction of the final result.

What does this mean for vaccine tech transfers?

So what does this all mean in practice? Let me give some personal examples.

At 22, I worked on a new facility for Zocor, a small molecule drug. Like many facilities, it was modular for faster construction, and it took just under two years to design, construct, and install. Three engineers from the home facility flew in for the final few months to help me and the project team finalize the process, and we were making a commercial product in under 3 years.

At 23, I worked on a facility for the MMR vaccine. The facility would be form/fill only, and would not be producing any drug substance, which takes years off time to production. This vaccine was originally launched in 1971 as a combination product, but its component parts were developed in the 60s. This facility – also modular – took 5 years from design to commercial production. Dozens of staff from the sending site with MMR experience relocated to the new facility throughout the build to pass on their knowledge and to eventually run the site. Even though MMR was a well-understood older product, the vaccine tech transfer took longer, cost more, and required more people than the pharmaceutical TT.

So this is how two industries that from a distance look very alike have very different products, markets, and timelines to production. Fully exploring and understanding the differences is key to accurately predicting the chances of success of any vaccine project.

Want to explore the differences further? Identify areas where your pharmaceutical experience can help? Contact me for help

For over 20 years, I've helped clients such as Merck, Sharp and Dohme (MSD), InterAmerican Development Bank, the World Health Organization (WHO), Africa Centers for Disease Control and others to evaluate, develop and implement plans to sustainably manufacture life-saving vaccines in Low and Middle-Income Countries (LMICs).

I work with governments, funders, and manufacturers to bring the clarity needed to confidently navigate the decisions and challenges faced while establishing or expanding sustainable local vaccine manufacturing in LMICs. I specialize in supporting:

- Manufacturers looking to establish or expand vaccine production*
- Countries or regions looking to improve health security*
- Investors or donors providing the funding to achieve these.*