

Can you really build a vaccine manufacturing facility in 14-16 months?

An estimated timeline that keeps coming up when discussing vaccine manufacturing with newcomers to the industry is 14-16 months. How do people come to this number in the first place, and why can it be misleading?

This timeline can cover one project stage in some situations, but it far from covers what it takes to establish a vaccine manufacturing facility ready to make commercial products. In this article, we'll explore the full story, some common pitfalls, and why comparing your project to what happened during the Covid-19 pandemic is a bad idea. As most industry newcomers start with a tech transfer into their new formulation and filling facility, we will focus on this scenario.

Where does the 14-16 month figure come from?

The 14-16 month figure is not a lie, but it isn't the whole story. This is often the timeline quoted to design and erect **modular facilities**, but often leaves out what comes before and after that. Furthermore, rushing to design a "generic" facility is likely to require expensive, time-consuming changes later on.

The problem is that building the facility is just a fraction of what needs to happen between deciding to produce vaccines and manufacturing products that are ready to sell commercially. Think about a Michelin-star restaurant – simply building a kitchen will not plan recipes, test dishes, hire and train staff, and the million other things you need to do before opening.

And of course, until you know what dishes or type of cuisine you will make, how can you even design your kitchen? Do you need a brick wood-fired pizza oven, clay tandoor or 2000 gallon stainless steel smoker?

Before you can start designing and building your facility, you need to at least know what products you want to make, and the specific manufacturing process your tech transfer partner uses. After your facility is built, you will still need to receive your tech transfer, successfully make test batches of your product, possibly carry out clinical studies, and get regulatory approval. Let's examine before and after facility construction in more detail.

Modular facilities are built off-site and assembled later. They can be built quickly, with predictable construction timelines and costs. They are usually more expensive than stick-built. They are less reliant on finding skilled construction locally, but still require local labor to assemble.

Stick-built facilities are built on-site by a construction crew. They have more variance in timelines and costs, but have a greater degree of design flexibility. They rely on finding skilled construction locally.

[Learn more in my white paper](#)

Why does it take so long to start building?

Carpenters are often told “measure twice, cut once” – this cautious approach is exponentially more important when planning a vaccine facility. There is no one-size-fits-all facility which will be able to make any type or quantity of vaccine. This might be because:

- Live virus vaccines can't share facilities with non-live products
- Some equipment, such as a lyophilizer (for freeze-drying) take up a lot of space and must produce large quantities to be cost-effective
- Products with different fill volumes (biologics vs vaccine) or administration method (vial vs syringe vs autoinjector) might need different filling machinery
- And more!

Many are eager to believe that their facilities can accommodate any vaccine of a certain type, but in practice, this is very unlikely. Even vaccines against the same disease from two different manufacturers can be made differently enough that you will require different facility attributes. More than one company I've worked with has had to make costly, time-consuming changes to their initial design to work with their tech transfer. In the worst-case scenario, the product simply cannot be transferred to the facility at all.

With this in mind, you need to know what products you are going to make, how much of each you are planning to produce, and ideally have your tech transfer deal signed and sealed before you design your facility. Your originator partner will be able to explain their manufacturing process and ensure the facility design fits their product, and that you can order the right specifications for critical equipment (some, like fillers, have lead times of 12-18 months!). A typical timeline to go from the start of design to ready to receive a tech transfer is 2-3 years, assuming your tech transfer partner is onboard early in the process to guide you on their design needs.

Why does it take so long after building?

Finishing construction of your facility is an important milestone, but still a long way from producing commercial vaccine batches. Next, you will need to receive the tech transfer from your partner. There are plenty of ways this can go off-track.

Perhaps your facility needs extra adjustments, and if your design firm has already left, you need to locate consultant experts who have the right knowledge to do this. Perhaps it takes you a long time to find appropriately skilled staff who can operate the facility correctly. From the originator side, this transfer might be low on your partner's priority list compared to their other business interests, or you could face cultural or language barriers.

Once the product has been transferred successfully, you'll then need to look at product registration and approval and in some cases clinical studies. A realistic timeline for this stage would be 2-3 years, assuming the tech transfer is successful. To keep things in perspective, when I worked for Merck, we had to make a “copy” of an existing facility, placed right next to the original. We had the resources of an experienced multinational company, full knowledge of the production processes, \$20B in annual sales demand for the products, and no cultural or physical distances to overcome. However, it still took us over 4 years to go from design to commercial readiness.

We made Covid vaccines quickly, why can't we repeat that?

During the Covid-19 pandemic, governments, health organizations, regulators, and vaccine manufacturers performed incredible feats of collaboration to bring effective vaccines to market in record time. It's tempting to think that these timelines can be replicated, but in reality, these were driven by very unusual circumstances that we will likely not see again.

First, the pandemic and the associated shutdown were costing the world trillions of dollars a year according to IMF, OECD, and WB estimates. Spending a few hundreds of millions or even billions to fast track projects to alleviate the shutdown was a great return on investment.

Second, manufacturers knew the potential market for such a vaccine was enormous. In 2021 alone, WHO estimated Covid-19 vaccines to account for \$99B of sales, compared to \$42B for all other vaccines put together. That much money on the table is a powerful motivator to get production online, and to get it online fast. The potential reward was great enough that the cost of failures could be absorbed.

Thirdly, many of these tech transfers were being placed into repurposed existing facilities, a much shorter process than building a new facility from scratch.

Vaccine manufacturing is a complicated undertaking with a large information asymmetry that exists between industry veterans, novice vaccine manufacturers, and the non-technical political and funding stakeholders involved. Understanding realistic timelines before, during, and after production will let you make better decisions for budgeting and hiring, and increase your chances of success.

Want to evaluate likely timelines for your region? Understand more about the barriers to successful tech transfers? 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.*

