

How to think about vaccine costs

Often, the first questions newcomers to the industry have is “How much will my project cost?” and “How much money can I save?”. Unfortunately, these are some of the most complex questions to answer.

Pricing spans from cents to over a hundred dollars per dose. Small volume differences and facility utilization can dramatically change unit costs. Procurement is global and sensitive to many sources of competition and funding. On top of this, most stakeholders lack access to the experience or data that could help them make informed decisions.

While there is no substitute for working out a detailed cost plan for a vaccine project, doing so for every potential opportunity is likely to waste your time and resources. In this article, I will show you how to develop frameworks of vaccine costs, which you can then apply to potential projects to filter the strong prospects from the likely failures.

Costs do not scale linearly with volume

Frameworks will naturally focus on two areas – keeping costs down, or getting high prices. First, let's focus on costs and how they scale.

Your costs will not scale with your volume, and doubling your output will not cut your unit costs in half. Vaccine manufacturing includes fixed, stepwise, and variable costs, and overall costs per project can jump in unpredictable steps.

- **Fixed costs** remain unchanged regardless of output. These include facility overhead, regulatory approval, QA headcount, and more.
- **Stepwise costs** jump at thresholds. Examples include installing a lyophilizer or larger filler.
- **Variable costs** scale linearly, such as labor-hours, stoppers, excipients. The least complicated type of cost.

A project's fixed and stepwise costs, compared with total output units, have enormous impacts on the profitability and thus viability of any project.

Sharing infrastructure lowers costs

One way of increasing facility utilization and thus lowering your cost per dose is looking for projects where you can share infrastructure. For example, while producing drug substance for multiple products requires basically a facility's worth of investment for each product, fill/finish for multiple products often lets you share much of the same equipment, support staff, QA systems, and regulatory approval. Investing in a lyophilizer makes more sense if you have three products, with three sources of demand, to keep it running year-round.

Remember that vaccine production doesn't need to be start to finish – there are opportunities along the production chain from formulation, filling, quality control, packaging, and distribution that can be added to a potential facility.

Under-utilized facilities make expensive doses

Following on from our last frameworks, it's essential to think of a project in terms of facility utilization and cost per unit dose. A facility itself represents an enormous fixed cost, with every piece of equipment a significant stepwise cost. A project that requires a lyophilizer without the demand to keep it full and running most of the year is likely to be a poor use of your funds.

By sharing infrastructure and selecting step-wise costs wisely, you can take a project from poorly utilized and unviable to something much more interesting. As with most vaccine manufacturing questions, there are no hard and fast rules about how much utilization is enough, however, I can give some relevant examples.

Contract manufacturing organizations (CMOs) typically aim for very high levels of utilization, 80-90% or above. On the other hand, a large multinational with an existing facility and equipment could make do with just 20% utilization. For a new facility, you are probably looking at utilization between 40% and 60%, depending on how much you can share production infrastructure.

Margin matters more than volume

Now we've spent some time considering the costs, it's time to look at the other end of the equation – prices. Any facility is likely to be constrained both by the amount of product that can be manufactured per year, as well as a relatively fixed level of demand for a product year by year. In this scenario, every dose should earn the highest margin possible. Relatively small price premiums per dose can significantly increase overall profits.

An important consideration here is that high-priced, novel vaccines such as HPV and PCV can tolerate price premiums in a way that low-priced, well-established vaccines cannot. Adding 20 cents to a 20 cent vaccine doubles the price, and few buyers will be inclined to double their costs here. On the other hand, adding 20 cents to a \$3 vaccine is a 6-7% increase, which is much easier to absorb. As a smaller producer, you simply will not have the ability to lower costs with high volumes like Merck or other multinationals – focusing on opportunities that allow for price premiums and more profit is beneficial for local production.

Too many cooks spoil the profits

Many newcomers to the industry look at local production as a way to lower their costs. However, this framework is flawed. Vaccine demand, locally and globally, is mostly fixed – if we add more suppliers, we're not expanding the pie, we're just dividing it into thinner slices. On the other hand, too few suppliers may lock newcomers out completely, especially if just one supplier can create a monopoly for a single vaccine product.

This increases the difficulty for a new producer to find a niche. An invaluable resource is the GAVI Healthy Markets Framework (HMF), which examines supply and demand for each available vaccine by highlighting gaps, surpluses, and market stability indicators.

Bringing the pieces together

With these cost and profit frameworks in mind, you can screen for opportunities that align with your strengths and marketing, rather than wasting time evaluating dead ends. As you explore more potential projects, you will increase your confidence and decisiveness.

Facility costs are very important, but not the be-all and end-all of local production. Remember, you do not have the same facilities and economies of scale of multinationals. You should be keenly aware of how these frameworks affect your costs, but also remember that there are benefits to local production aside from cost-savings. For example, you might want to increase the amount of high-tech, high-skill industry in your country, or create a more secure medical supply chain. Be clear-eyed about your expectations and potential trade-offs.

*Want to evaluate potential opportunities? Determine which products can share facilities?
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.*