COGs process economics for autologous cell therapy

Process economics: the means of understanding cost distribution across a manufacturing process. With the insights provided by process economics, we're enabled to make data-driven decisions regarding process development and optimization.

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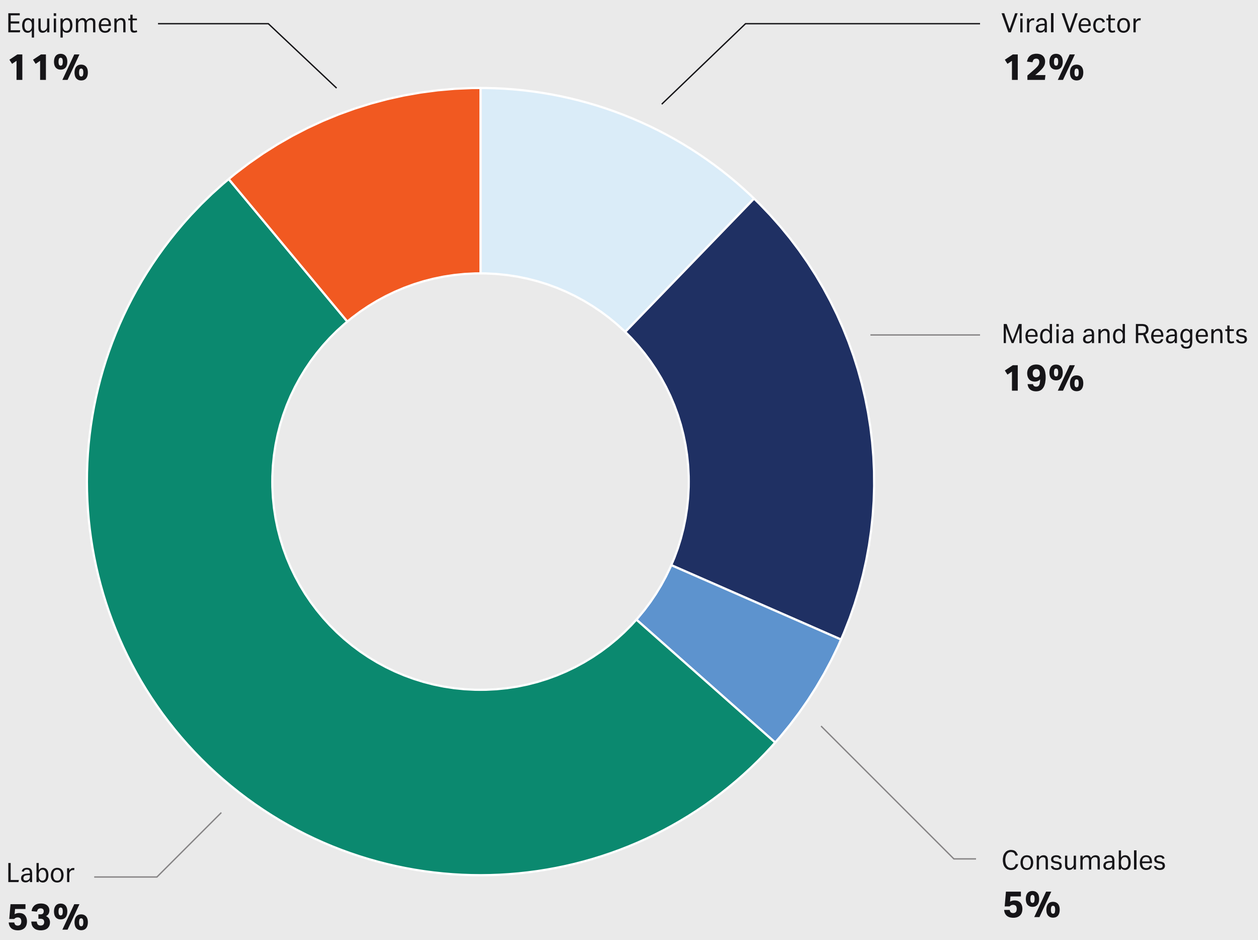
Using the principles of process economics — coupled with insights from scientists and R&D — we're able to evaluate this generic, autologous CAR T therapy manufacturing process*, for example. The manufacturer has a target throughput of 10 therapeutic doses per year, which is typical of very early clinical development.

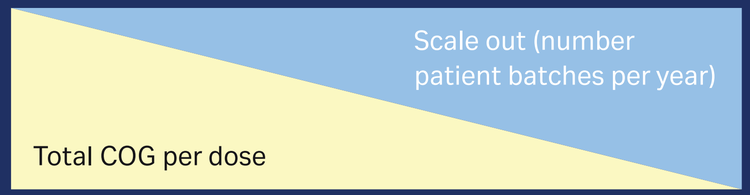
As we dive into the cost of goods (COGs) breakdown, we see that at such a small production scale, the labor costs dominate other CAR T manufacturing costs by more than double.

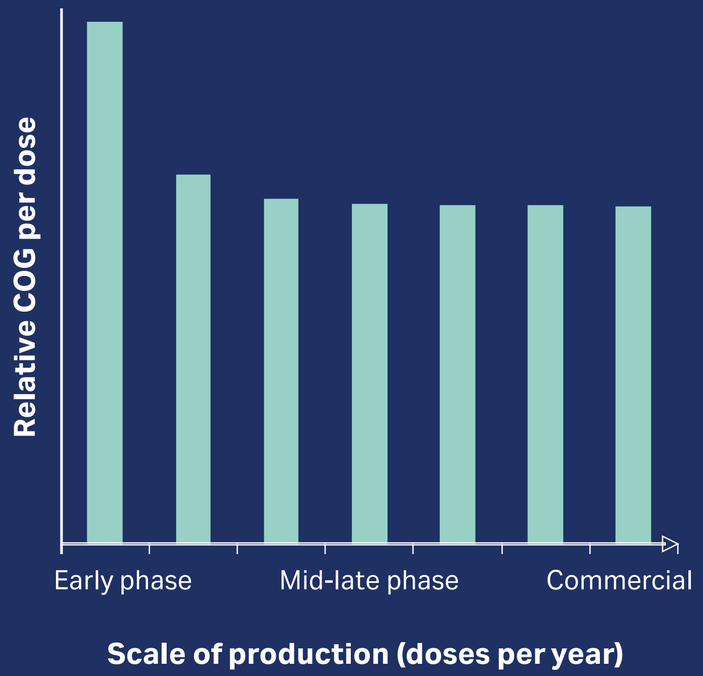


* Costs for equipment, viral vector, media and reagents, and consumables include only those used directly for the manufacturing process. Materials and equipment used for analytical purposes are not included in this analysis.

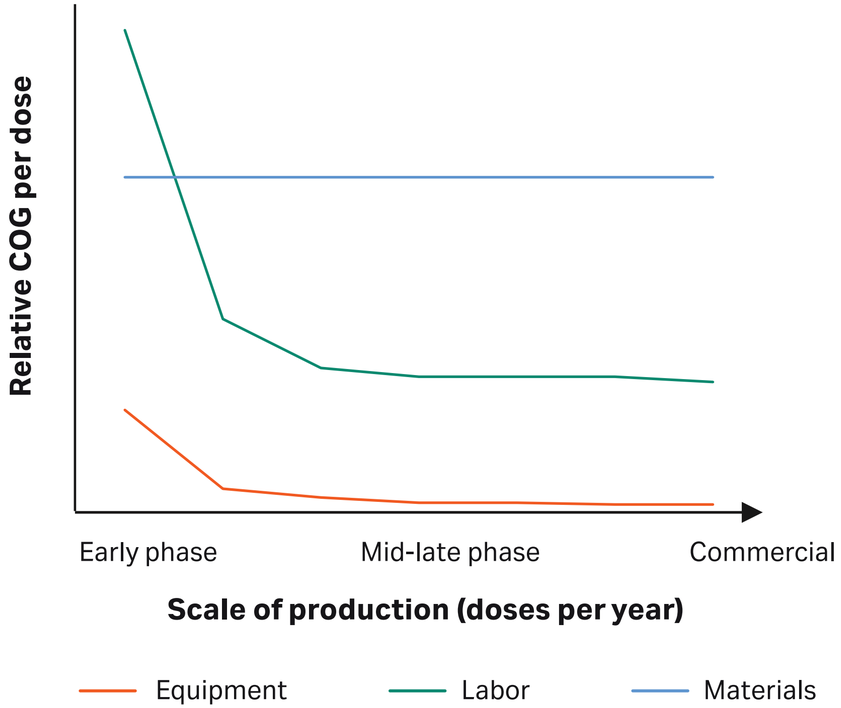
So, how can cell therapy manufacturers like the one above combat such high labor costs?

One way is to take a systematic approach to scale-out and parallel processing (manufacturing more than one batch at a time). Optimizing batch scheduling can help drive economies of scale, as shown below.





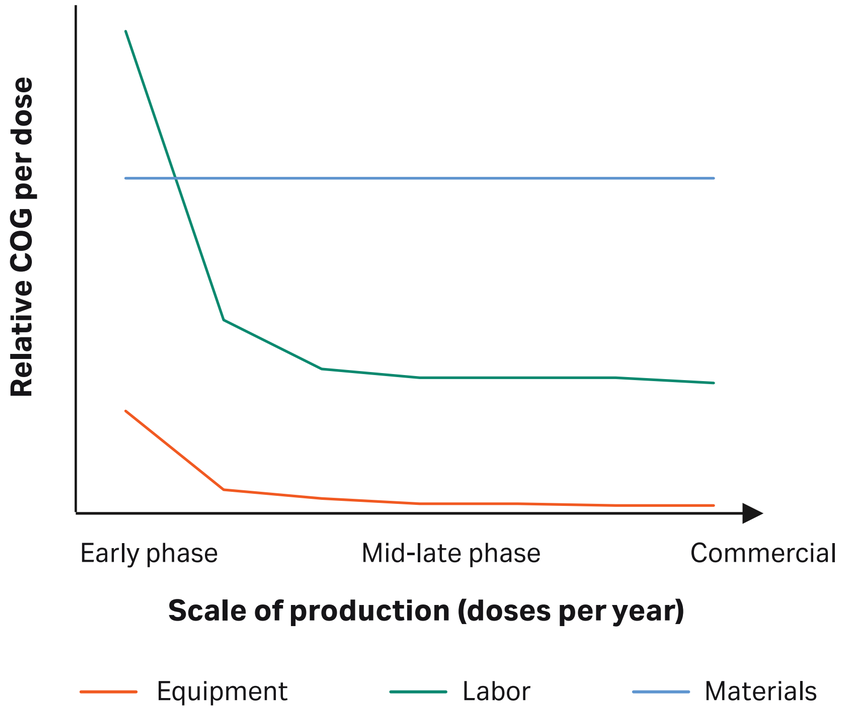
With parallel processing, the cost of materials*, or direct costs, remain constant on a per-patient basis, regardless of scale for autologous cell therapy manufacturing.



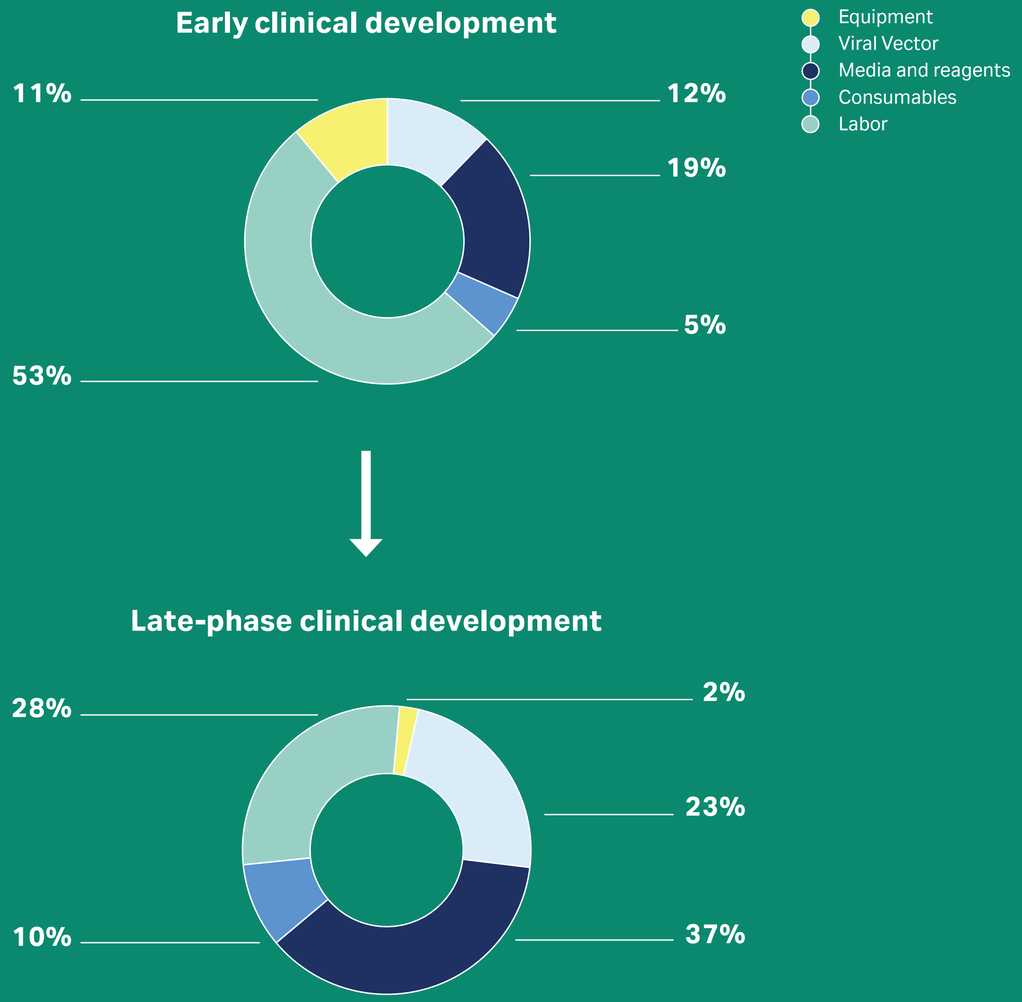
However, optimizing batch scheduling (planning and scheduling manufacturing processes) can make for more efficient utilization of equipment and labor resources. Examples of this would be operators working on multiple batches during their shift, thereby reducing labor costs, or hardware being able to support more than one production line, bringing about reductions in equipment costs. This can therefore lead to economies of scale — or reduced cost per dose — in labor and capital expenditure cost centers.

* Materials refer to the aggregated cost of consumables, media, reagents, and viral vectors used throughout the manufacturing process.

It's important to note that the absolute value of material costs per dose remains constant — regardless of scale.

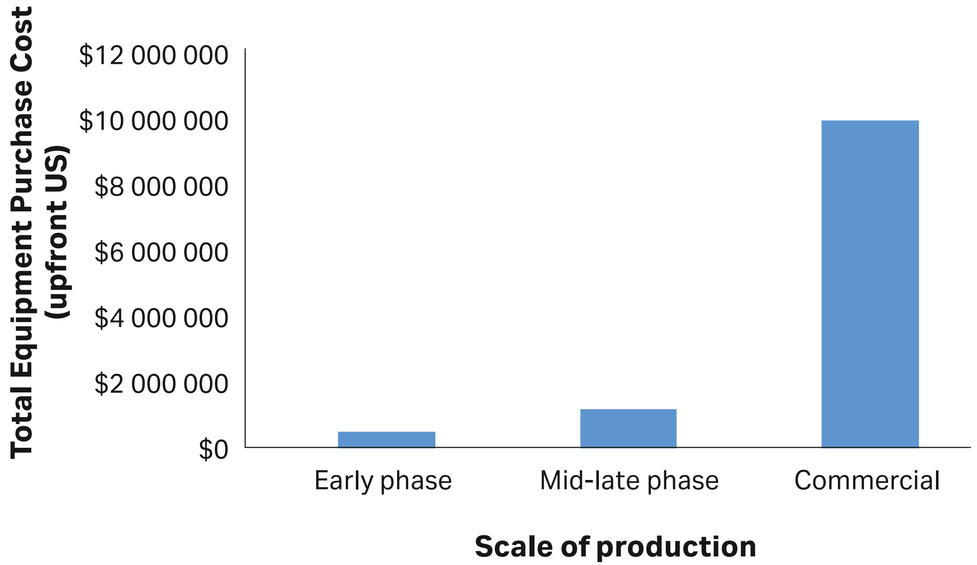


However, the cost of materials — including media and reagents, consumables, and viral vectors — as a percentage of the total cost of goods increases with scale. This is due to economies of scale being realized with capex and labor costs

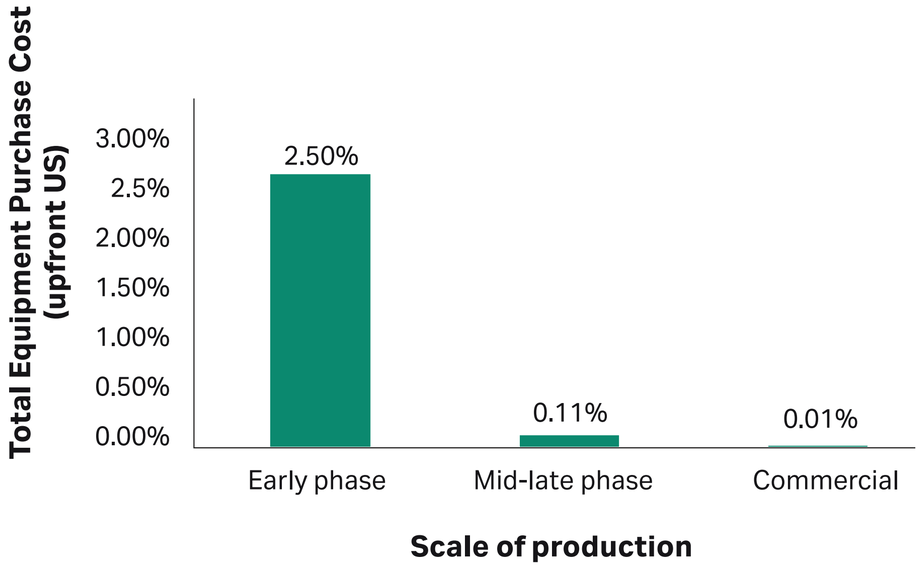


In it for the long haul

Commonly, upfront equipment costs* can appear to be a major cost center. This is due to the capital investment required for the purchase of advanced manufacturing equipment for cell therapies.

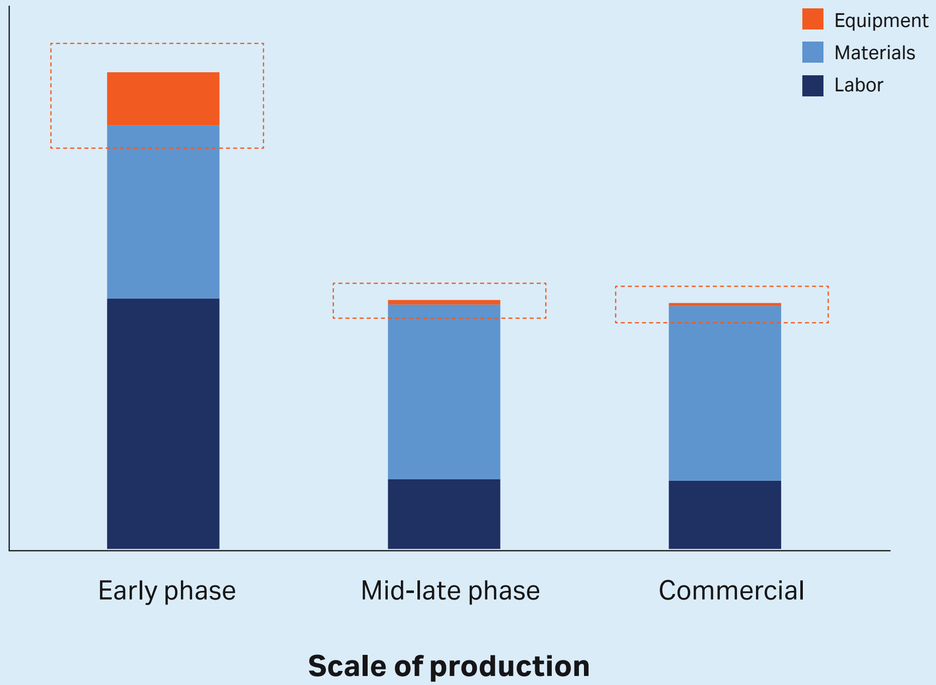


However, once equipment costs are amortized (over an assumed 5-year lifespan) and spread out over the number of doses produced annually at a facility, the cost per dose for equipment is a small percentage of equipment purchase costs.



* Includes processing equipment only — excludes analytical equipment and extraneous support hardware

Plus, once amortized and spread over the annual facility demand (doses per year), the cost of equipment encompasses only a small percentage of cell therapy manufacturing costs.



Therefore, process improvements should focus on labor and material cost reductions in order to drive down autologous cell therapy manufacturing COGs.

* Amortization period of 5 years has been assumed

The bottom line

1. Upfront costs for cell therapy equipment that can support large-scale manufacturing can appear to be expensive.
2. However, when considered alongside other long-term costs — such as materials and labor — these equipment costs are not significant (particularly at commercially relevant manufacturing scales).
3. Ultimately, economies of scale can be achieved with autologous cell therapy processing. But, in order to widen access to these life-saving autologous cell therapy treatments, it's crucial that manufacturers utilize solutions that can support reductions in labor and material costs. Regardless of where you're at in your cell therapy development journey, it's never too early to think about how you can reduce your cost of goods.

Curious how Cytiva can support your manufacturing process? Check out our automated and closed autologous CAR T workflow solutions.

Glossary

Annual demand (throughput) — target number of patient batches produced each calendar year

Consumables — single-use, disposable kits, such as tubing sets or cell culture bags

Equipment — hardware used to manufacture the end product (e.g., Xuri™ Cell Expansion System W25, Sepax™ system). This excludes analytical equipment and any equipment required for tube welding/connections

Materials — media and reagents, consumables, and viral vector used directly to manufacture a single dose, or batch, of the product

Scale-out — replication of a manufacturing process or workflow in order to produce more material; process scale is kept constant for each production line added

Total equipment purchase cost — upfront cost of hardware required to manufacture equipment

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