SARTORIUS

Simplifying Progress

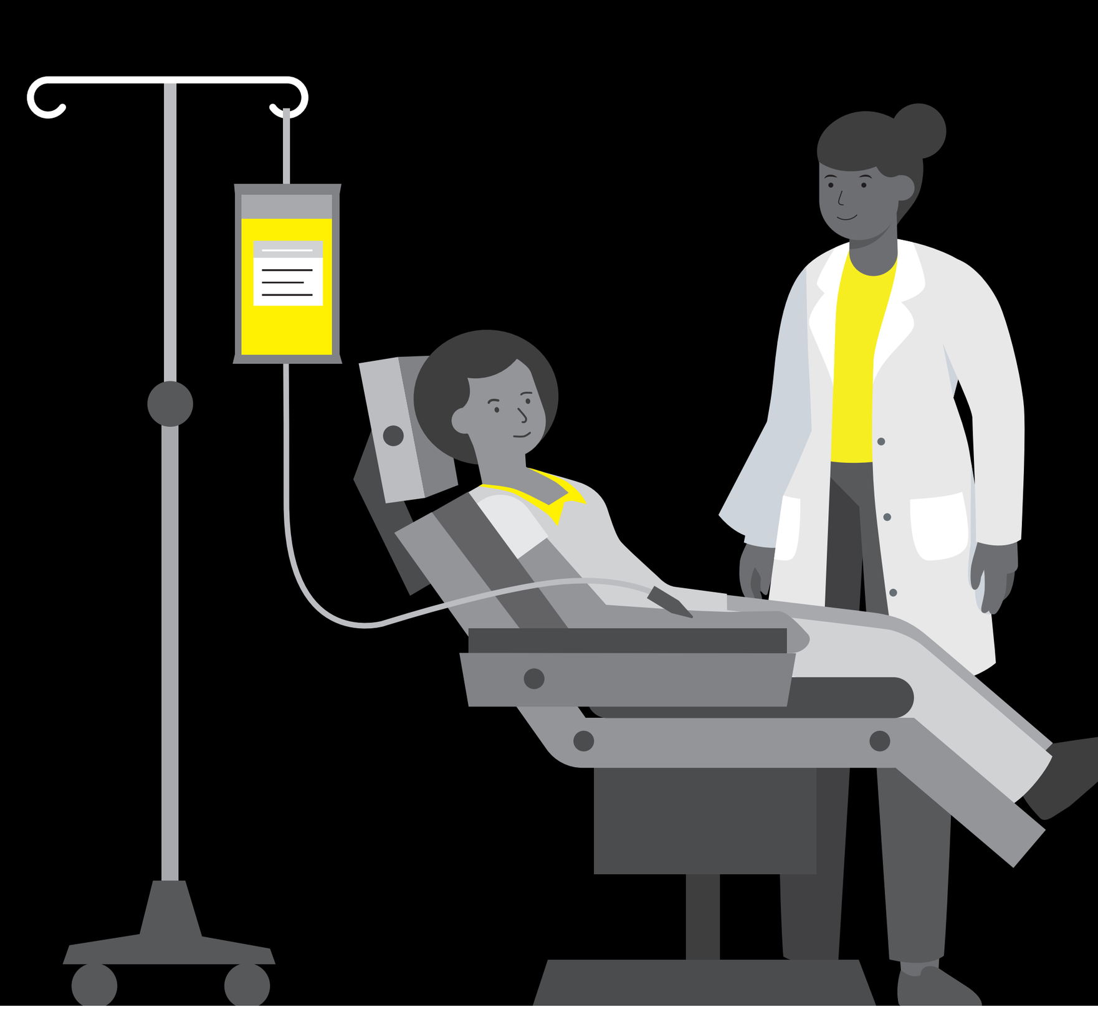
CGT Process Economics

Enhancing Process Performance to Support Scalable Patient Access

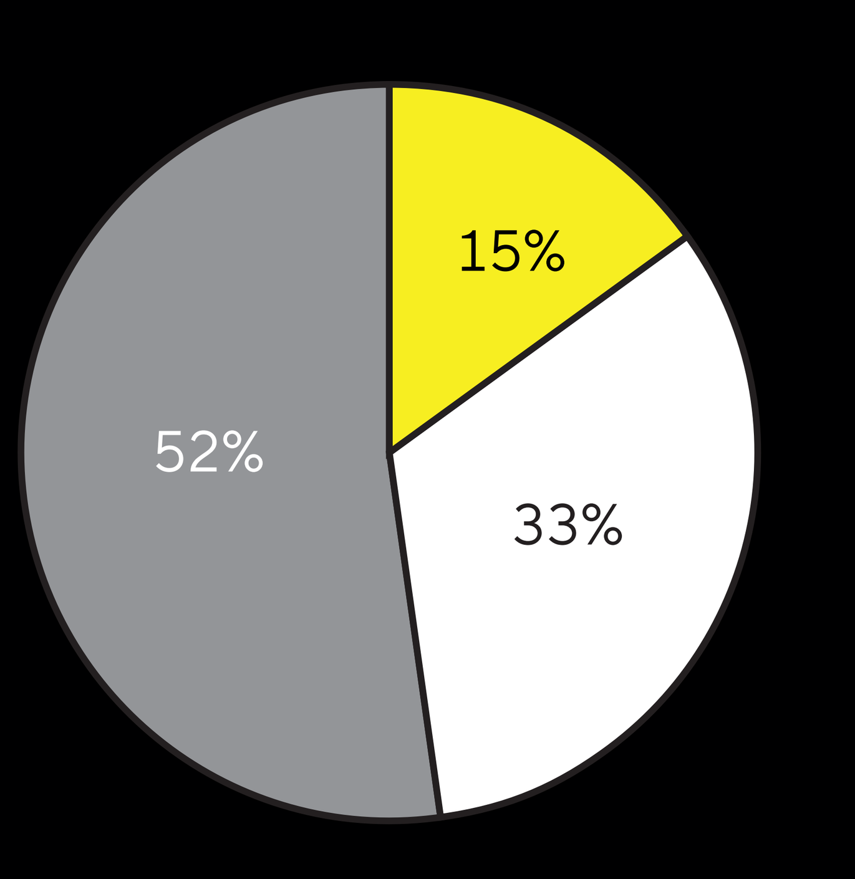
In the journey from cell and gene therapy discovery to delivery, cost considerations are everywhere. Optimizing manufacturing processes is critical to increasing patient access, but finding the right balance between productivity gains and production costs remains a fundamental challenge.

More Approvals But Costs Remain High

Globally, 79 cell and gene therapies have reached market approval*, yet treatment costs remain staggeringly high, from tens of thousands to millions of dollars.



Global Unique Approved CGTs by Modality[1]



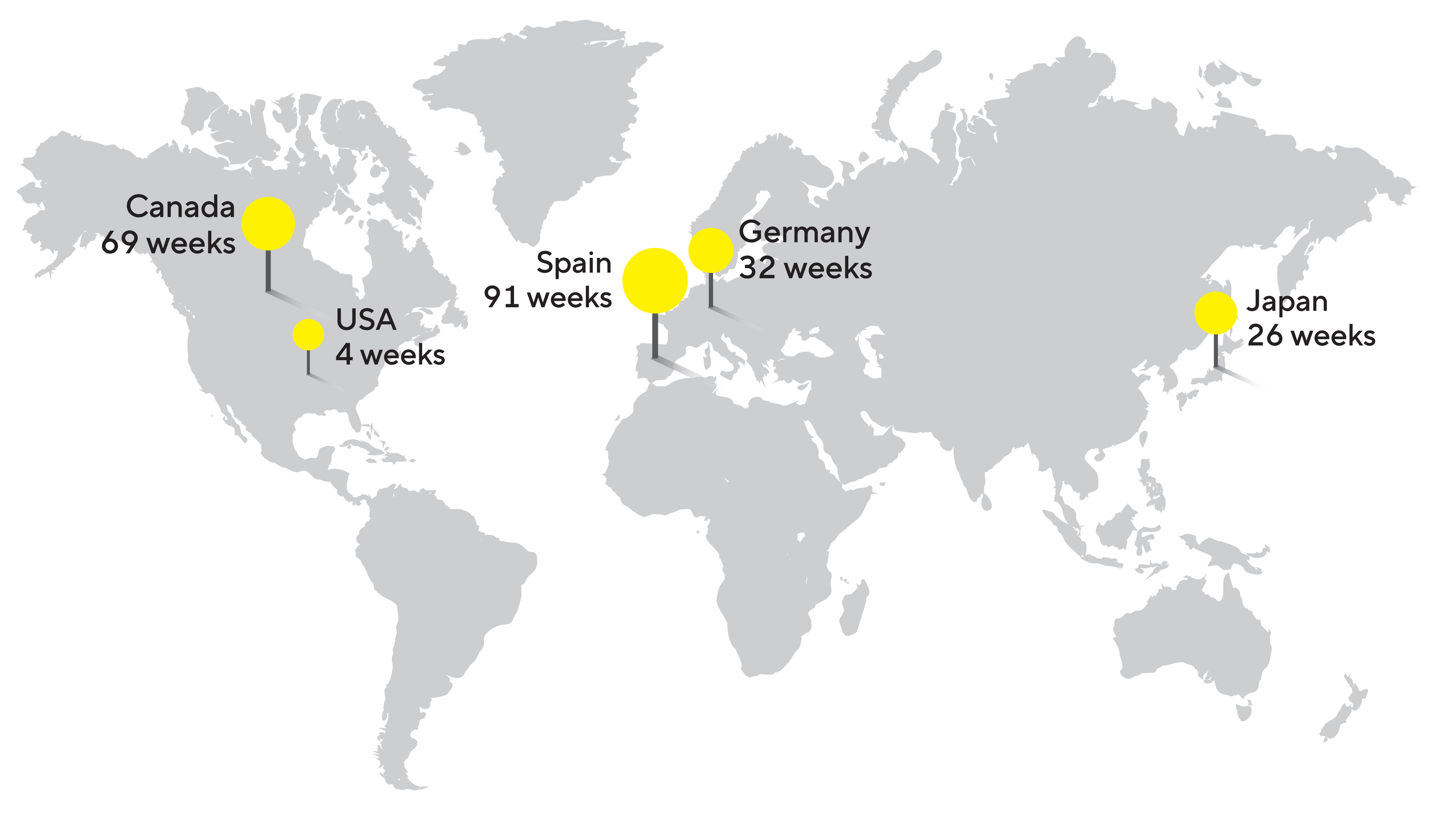
*As of January 2026[1]

Lag From Market Approval to Market Access

Reimbursement pathways are complex and vary significantly across regions, which can delay market access. Key questions during reimbursement negotiations include:

- Does the therapy address an unmet medical need?
- Does the therapy deliver clear, proven benefits over existing options?
- Does the therapy have long-term evidence that supports durability and cost-effectiveness?

Average Time to Reimbursed Access[2-4]



Reducing CGT manufacturing costs can help accelerate reimbursement pathways.

Understanding Key Manufacturing Cost Drivers With Process Economic Modeling

Process economic modeling is a powerful practice to understand data-driven insights into cost drivers and potential savings. Key model inputs include*:

Labor

Labor costs fluctuate with process scale. Early implementation of automation can lower long-term expenses.

Equipment

Capital equipment investments are a necessity as production scales. High upfront costs can result in long-term efficiency gains.

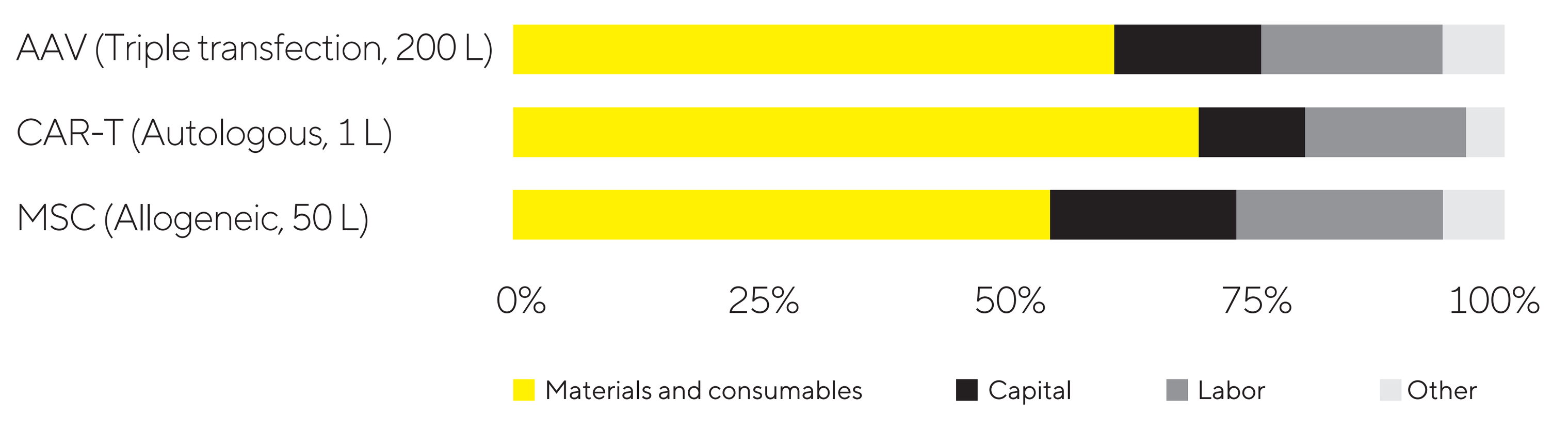
Materials and Consumables

From starting materials like cell sources and plasmid DNA, to ancillary materials including cell culture media, transfection reagents, and cytokines, consumption of these critical materials increases as production scales.

* Additional significant cost inputs throughout the drug's lifecycle include R&D, regulatory procedures, clinical trials, and other operational and administrative costs.

Material Costs Emerge As Key Contributor to Process Costs

Estimated Distribution of Production Costs Per cGMP Batch*



This graph illustrates the cost distribution per cGMP batch for each product type, derived from several process economic models developed from BiosolveProcess 9.0[6].

Model variables include:

- Scale (ranging from 1 L to 200 L)
- Product type (e.g. allogeneic versus autologous)
- Materials/methods employed (genetic modification versus unmodified cell therapy)

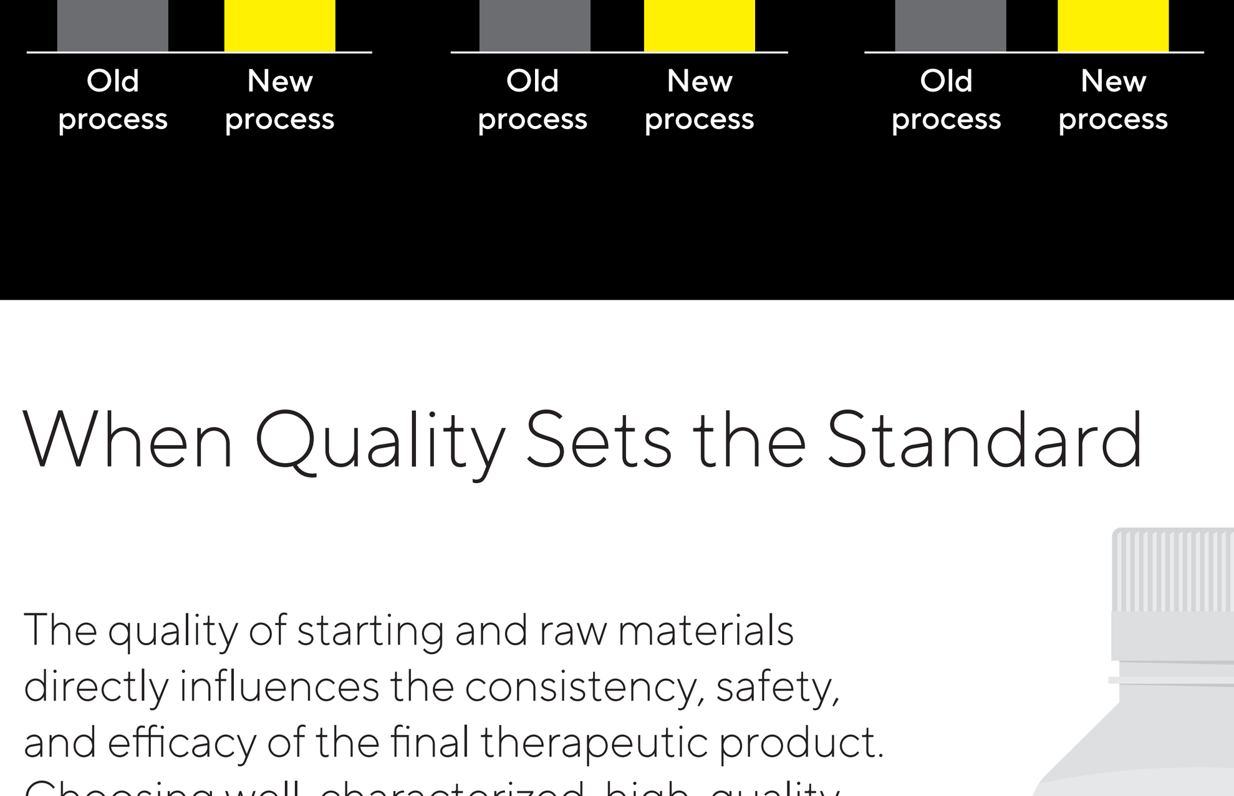
*Quality control is considered within each model.

For these models, the largest portion of batch costs comes from materials and consumables. Understanding the impact of your raw materials on yield and productivity can unlock significant savings to reduce cost per dose.

Improved Productivity, Reduced Cost Per Dose

In this example of an AAV-based gene therapy process, economic modeling was used to understand the impact of process optimization with new, high-quality raw materials. The model simulates future state process productivity, annual batches, doses, and costs at GMP manufacturing scale.

Despite an increased cost per batch, the new process increased both productivity and annual dose production, which decreased the overall cost per dose[5] by 40%.



Model Spec:

Dose Size: $5.3x10^{15}$ vg

Process Size: 200 L

Product Lifecycle Stage: Clinical late-stage and commercial phases

When Quality Sets the Standard

The quality of starting and raw materials directly influences the consistency, safety, and efficacy of the final therapeutic product. Choosing well-characterized, high-quality materials early can be a powerful strategic lever to enhance performance during process development and unlock significantly greater productivity gains during scale-up.

Reaching The Finish Line

As the CGT market matures and industry builds on lessons from early pioneers, manufacturing cost considerations are poised to take center stage earlier in the development process.

Deeper understanding of cost drivers throughout the lifecycle of CGTs can help developers make better investment, design, and operational decisions to reduce cost per dose.

Click here to learn more about Sartorius solutions for cell and gene therapies.

References

1. Global Data (2025, January 31), Global CGTs Approvals. Global Data
2. Mycka, J., Dalal, N., Dellamano, R., Mathew, J., Papa, R., Choudhury, R., Selladurai, S., Pollere, D., & Ashton, A. (2024, May 5–8). Cell and gene therapy access in the US and Europe [Conference poster]. ISPOR 2024, Atlanta, GA, United States.
3. Advancing Cell and Gene Therapy. (2025, January 25). The reimbursement process for CGTs [Infographic].
4. Sundaram, S. (2024, January 10). Cell and gene therapies in the Asia-Pacific region: Evolving reimbursement pathways. Avalere Health.
5. Biopharm Services. (2026). BioSolve Process [Bioprocess economics simulation software].