



Case Study

Improving biological
performance through
digitized process
development

Ori Biotech



Oribiotech



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Ori Biotech is a London- and New Jersey-based leader in cell and gene therapy (CGT) manufacturing technology that has developed a proprietary full stack, manufacturing platform with the promise to enable widespread patient access to a new generation of personalized, life-saving treatments.

By fully automating and standardizing CGT manufacturing in a closed platform, Ori Biotech offers therapeutics developers the opportunity to seamlessly scale from pre-clinical process development to commercial scale manufacturing.

Company Profile

Number of Employees

75-100

Industry

Biopharma – Cell and Gene Therapy

Corporate HQ

London, England

Reduction in planning time between process runs

Improving efficiency in data handling and analysis, permits research teams to draw conclusions, formulate hypotheses, and conduct follow-on experiments at an increased rate.

Reduction in data entry errors

Automation enhances efficiency by reducing human error, improves scalability for larger volume production, and strengthens quality control for consistent, reliable outcomes.

Reduction in experimental workload

Standardized data capture enables easy access to information spanning multiple experiments, allowing researchers to perform meta-analyses and gain insights which otherwise may be missed.

Challenges with cell and gene therapy process development

Cell and gene therapies (CGTs) are revolutionizing the way we treat diseases. However, several bottlenecks in process development slow the ability to scale and limit widespread patient access to these life-saving treatments.

The vast majority of the CGT process development activities use paper, spreadsheets, and digital point solutions that just can't keep up with the pace of scientific innovation. This causes several critical challenges:

Process Execution	Process Optimization
<ul style="list-style-type: none">• Unstructured process and analytical data capture• Lack of real-time process visibility• Hampered communication within and across groups	<ul style="list-style-type: none">• Manual, labor-intensive data analysis and data management prone to human error• Challenging to search and aggregate historical data to perform meta-analysis

Modernizing cell and gene therapy process development with 'Biology + Engineering + Digital' innovation

Ori Biotech is tackling opportunities to improve legacy CGT process development practices by delivering a platform that will help enable widespread access to next-generation cell and gene therapies. Their solution is built on three principles: understanding and delivering exceptional biology, leveraging automation, and creating a digitally-native system.

“Paper, spreadsheets, and digital point solutions are the enemy of efficiency and scale. There is a need in the industry to move away from data coming from file exports or pieces of paper. Accessing all the data across these point solutions to compare and derive insights from 100s of runs is infeasible”



Shaun Mansfield
Principal Scientist at Ori Biotech

Ori Biotech's Goal #1

Enhance biological efficiency

Consistent and robust biological performance is the foundation of CGT process development. Ori Biotech is working to improve product quality and reduce costs by optimizing quality attributes, improving efficacy and potency, and supporting a wide variety of development processes.

- **Improve biological performance:** Ori Biotech is introducing unique platform-specific techniques that speed up achieving clinically relevant doses, enhance transduction efficiency, provide process adaptability, and ultimately decrease cost and vein-to-vein time.

- **Retain biological flexibility:** Most current approved cell and gene therapies (CGTs) focus on Chimeric Antigen Receptors (CARs) and T-cells. However, as personalized medicine and technology progress, more diverse cell types will be used to create new treatments. Ori Biotech is already positioned for this demand, as their platform is primed to offer the necessary flexibility to adapt to multiple cell types.

Solution with Benchling

Increase biological throughput

Ori Biotech leverages the Benchling R&D Cloud to better track data from experimentation with multiple cell types. This helps them scale the biological throughput of their platform. The two specific ways by which Ori Biotech achieves this are:

- **Track assays and experiments linked to specific donor lots:** As Ori Biotech investigates newer methods and assays to boost biological efficiency, they use Benchling R&D Cloud to link all these assays, variables and experimental data back to the starting donor ID automatically. As a result, Ori Biotech can now study donor characteristics and optimize biological performance faster.

- **Set up customizable templates and configurations to support multiple cell type:** Ori Biotech creates experiment templates and registry hierarchies that work not just for current CAR and T-cell workflows, but can also be customized to support other cell types such as NKs and TILs. Thus Ori Biotech can study multiple cell types simultaneously as needed without affecting throughput.

Outcomes:

Time saved on data management

By optimizing data capture and providing researchers with standardized templates, Ori Biotech was able to reduce the time researchers spend capturing and analyzing experimental data.

Increase in data quality

By using standardized templates, Ori Biotech has seen a reduction in data handling time and eliminated the potential for data transcription errors as they scaled up.

Ori Biotech's Goal #2

Optimize process development

While optimizing biology is usually the first step – the science and the processes must work together. Ori Biotech's goal is to reduce process development timeline with automation, reduce costs by increasing throughput while minimizing manual labor, and ensure quality through process consistency.

- **Reduce process variability:** Variability in the starting donor material for CGT, especially autologous therapies, combined with process variability means achieving a consistent and robust manufacturing process is challenging. Ori Biotech's goal is to systematically address inherent process variability to ensure a consistent product from their platform.
- **Minimize manual labor and process deviations:** Most of the process development unit operations are highly manual, with technique playing a significant role in process outcomes. Ori Biotech's goal is to automate processes to remove manual work, increase consistency and reduce human errors.

Solution with Benchling

Ensure process consistency and success

Ori Biotech uses the Benchling R&D Cloud to standardize and automate their processes to reduce process variability and minimize manual inconsistencies. The two specific ways by which Ori Biotech does this are:

- **Standardize process data capture across runs and sites:** Ori Biotech maps their unit operations onto Benchling with structured input parameters, run templates, and results tables. This ensures that scientists across multiple sites can collaborate effectively, execute process runs consistently, and capture usable data.
- **Automate data capture from equipment and instruments:** Ori Biotech uses Benchling to ingest captured data from their analytical instruments. This allows them to import data faster and with higher accuracy than manual data entry.

Outcomes:

Faster, more accurate data capture

Ori Biotech reduced the time taken to enter process data through data entry standardization in Benchling.

Improved data interoperability

Ori Biotech reduced the potential need for data transcription or data entry due to the ingestion of captured data from their analytical instruments.

Ori Biotech's Goal #3

Create a digitally-native platform

For Ori Biotech, data is an operational tool that helps their teams characterize and understand their manufacturing platform. Thus, Ori Biotech created a platform that is digitally and cloud native, ready for Bioprocessing 4.0, and provides the advanced analytics necessary to reduce timelines, cut process development costs, and improve product quality.

- **Ready for Bioprocessing 4.0:** A lot of newer technologies (IoT, Cloud) and SaaS IT systems (next-generation MES, QMS, LIMS) are disrupting CGT process development. Ori Biotech's goal is to create a platform that treats data as a first-class citizen, ensuring its integrity, security and accessibility as well as integrating with external technologies and systems.
- **Improve platform performance with data analysis:** Traditional data management practices with spreadsheets did not meet Ori Biotech's data goals and scaling needs. They wanted to create a platform with improved data access that would support data analysis including machine learning and statistical analysis.

Solution with Benchling

Drive efficiency with digitization

Ori Biotech uses Benchling to centralize data from multiple sources and analyze data to improve the performance of their manufacturing platform. Two ways by which Ori Biotech attains this are:

- **Democratize data access:** Ori Biotech centralizes all their experimental and equipment data across teams and sites on Benchling. As a result, all data is now findable, accessible, interoperable, and reusable for Bioprocessing 4.0 applications.
- **Enable meta analysis:** Ori Biotech uses Benchling's data warehouse to capture structured experimental data and all related metadata. This allows them to run sophisticated meta analysis by experiment ID or run ID to improve their platform performance. Additionally, the data warehouse also provides a data foundation for future ML and AI applications.

Outcomes:

Faster time to milestone

Ori Biotech can now optimize processes with fewer process runs than previously possible because of FAIR data access and meta analysis possible with Benchling.

Improved scientist efficiency

By reducing the time researchers spend analyzing experimental data or performing low-value tasks, Ori Biotech reduced equipment downtime.

Conclusions

Delivering safe, effective CGTs to patients is dependent upon efficient, scalable, and flexible process development.

Spreadsheets and other point solutions simply can't keep pace with scientific innovation. CGT companies require a modern digital solution that will scale and evolve.

Ori Biotech's manufacturing platform combined with Benchling pushes the boundaries of innovation along the three critical axes of biology, engineering, and data. Scientists are able to reduce planning time between process runs, minimize data entry errors, and decrease experimental workload - resulting in better product quality, lower costs, reduced process development time, and greater process consistency.

This next-generation manufacturing platform will help therapeutics developers bring life-saving products to market faster and enable widespread patient access.

“We can now go to our partners and say, ‘We know this part of the process could be run more efficiently, and here is the data we’ve produced to support it with Benchling and our platform’ — we’re not just talking the talk, we’re walking the walk.”



Matt Todd
Head of Architecture
Ori Biotech