Article

Cell therapy

Q&A: An insider perspective

How innovation is driving cell therapy

The cell therapy market has been growing rapidly over recent years, from the approval of the first cell therapy by the U.S. Food and Drug Administration (FDA) in 2017 to seven approvals at the end of 2024[1]. To meet this growing demand and enable cell therapy developers to continue bringing life-changing therapies to patients, new innovations and optimizations are needed.

We sat down with Dr. Evan Zynda, Senior Staff Scientist at Thermo Fisher Scientific, to discuss some of the key areas of innovation within the cell therapy industry, particularly within the cell activation, isolation, and expansion workflow stages, and where the industry is heading in the future.

Evan, to start, what are some of the key challenges currently facing the cell therapy industry?

EZ: Within the cell therapy industry everything comes back to three main requirements—for products to be cost-effective, safe, and efficacious. So, to meet these needs, two major challenges for cell therapy developers are around speed and safety regulations.

Speed determines how cost-effective a process can be, meaning that more patients can access a life-changing therapy. It can also impact the therapeutic efficacy of the product, supporting the maintenance of desirable phenotypes. Regulatory challenges also have a direct link to patient safety and effectiveness, as well as impacting the likelihood of a therapy making it to clinical trials and commercial production. Without successfully overcoming these challenges, the accessibility and affordability of these cell therapies will be significantly impacted, with many potential therapies not reaching the patients who desperately need them.

> The automation of manufacturing instrumentation has been a key area of innovation in the cell therapy space

How has the industry started to innovate based on these key challenges?

EZ: Many of the innovations over recent years have been centered around meeting these key needs and challenges. The automation of manufacturing instrumentation has been a key area of innovation in the cell therapy space and one of the ways developers have been able to increase speed while lowering the risks and costs associated with cell therapy production.

By creating more user-friendly, closed, and automated systems, the industry has also started to reduce the need for specialized lab spaces and staffing, decentralizing manufacturing. This has the potential to reduce costs and increase uptake, broadening the addressable patient population and enabling more diseases to be targeted.

Looking at equipment in more detail, how have cell therapy manufacturing instrumentation and software solutions evolved over recent years?

EZ: Even five years ago, cell therapy workflows were using equipment and solutions designed for conventional bioprocessing. Now, we're looking at automated equipment that is extremely specialized for cell therapy manufacturing. And with this evolution, workflows that were maybe 21 days end-to-end, are now being reduced to 24 hours.

In the future, the next goal is around advanced automation—using robotics to eliminate risk, increase speed, and remove the need for highly qualified operators. Essentially, you would press a button and out comes a therapy. But this requires several layers of communication between instruments, so that's part of our focus, supporting the design of an open architecture across platforms. This also enables different instruments to work together and combine to create a complete, optimized workflow. We see this as an essential feature of cell therapy instruments and one of the major ways we can scale and reach the full potential of this industry, getting life-changing therapies to all the patients that need them.

Why are flexible cell separation solutions so important to support future cell therapy innovation?

EZ: Flexibility is critically important right now. As cell therapy production becomes more efficient with advancements in automation, the industry is now turning towards scalability—whether that is scaling up, out, or down. Flexible, modular equipment that can be placed in hospitals and specialized centers, and adapt to any way of working is becoming more prominent to meet the needs of this specific industry.

Additionally, every single customer that we speak to has a different workflow. All workflows have different nuances, instruments, timings, cell types, and even editing techniques. This means that all the solutions we are developing need to be able to adapt to these differences, so we don't need to produce novel solutions for each individual workflow. Whether it's the media, the cell separation reagents, or the instruments, they all have to be flexible and work together to create an optimized workflow.

What role do optimized cell culture media play in supporting cell therapy manufacturing success?

EZ: Cell culture media is endlessly important. I think it gets overlooked a lot, but it's the only product that is in contact with the therapy for the entire time, so it's an important component when it comes to safety and meeting regulatory requirements. It also has a significant impact on the final product in terms of fast you can get to your dose, as well as cell phenotype and overall efficacy. Optimized media—such as one-part, serum-free, and animal origin–free formulations—can help solve a lot of these problems and support a streamlined, closed, and automated process with straightforward regulatory filing.

Are there any specific changes to either media design or formulations that have emerged over recent years to support innovation?

EZ: Regarding media design, we are utilizing bioanalytical tools such as multi-omics and spent media analysis when we are developing our new, optimized media products. By understanding what pathways are being turned off or on by cells we can then manipulate the medium to drive the metabolic process and improve the efficacy and responses to the treatment. In the future, we'll be able to leverage artificial intelligence to make this process even more efficient and less biased.

Looking at medium formulations, developers are starting to request larger-sized, off-the-shelf packaging options. Custom sizing can be very expensive so larger-sized catalog products can help streamline cell therapy scale up, enabling larger workflows. In addition, formulations with different lines of connectivity designed into the packaging can help developers flexibly integrate their desired products into any workflow set up.

For cell therapy developers, what types of support can a supplier play in helping them innovate?

EZ: Cell therapy is such a new and exciting industry, but it is also one that is constantly growing and evolving. A supplier should be working together alongside their customers to find the best solutions. In addition, a supplier should also simplify and de-risk workflows—from having all the documentation on hand to support regulatory filing, to providing access to in-house regulatory specialists.

How is the industry developing future solutions in line with customer needs and challenges?

EZ: We keep our ear to the ground for new industry needs and trends at conferences and through literature, but our biggest source of information is through collaborations and customer interactions. These collaborations provide us with a good understanding of where the industry is and what's coming next, which helps us develop solutions that will directly meet the needs of the industry. Ultimately, we're constantly adjusting our development strategy and roadmap to meet specific customer needs.

Finally, Evan, where is the industry looking to innovate in the future?

EZ: In addition to the innovations I've mentioned, one of the big areas that the industry is working towards is developing solutions for emerging cell types and workflows. As the industry grows, it is moving rapidly into different cell types beyond primary T cells to create more effective cell therapies. We need to quickly respond with solutions that will meet the needs of tumor-infiltrating lymphocytes (TILs), regulatory T cells (Tregs), natural killer (NK) cells, iPSC (induced pluripotent stem cells), iPSC-derived NK cells, and more, supporting the unique requirements of these workflows.

Carve your path to success

The cell therapy industry is constantly evolving with new cell types, workflows, and treatments. Advanced technologies and innovative products can help make sure that cell therapy developers stay ahead of the curve and are able to bring these life-changing treatments to patients.

To innovate your cell therapy process and carve your path to success, read the full article on innovation at thermofisher.com/performance

References

1. CAR-T Cell Therapy Market - Market Size, Forecasts, Trials, and Trends, 2025. GlobeNewswire. 2024. Available from: https://www.researchandmarkets.com/reports/5331298/car-t-cell-therapy-market-market-size.

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