



Cell Therapy Facility Design; A Look Back and to the Future

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Background

It can be fascinating to reflect and see how our world has evolved over a relatively short time. Five years ago, I published an article on the future of cell therapy and facility design. Reviewing that paper, you can understand how immensely our industry and the world has changed. While many of us are in this space to make a difference in the lives of everyone, we are also often impacted personally one way or another by those same diseases we are looking to cure.

Five years ago, we predicted that the cell therapy space would see an 18% YoY growth by 2023. That number was likely on the low end, and we continue to expect +20% YoY growth in this space over the next 10 years. Additionally, at that point of time, we had 2 BLA approvals for CAR-T Therapies. This has since expanded to 6 approvals with many of those CAR-Ts having multiple indications approved and more importantly moving up in line for standard of care.

The Need for Innovative Facility Infrastructures

While we have seen this space mature over the course of time, the need for more agile and flexible facilities is still a major requirement. Significant investments into infrastructure have continued to take place, but we are seeing the needs continue to evolve and progress as this space becomes more mature.

Of interest, we have seen a smart approach being implemented more often. For example, a scaled out or phased approach is often employed now for new facilities, as opposed to overinvestment too early, which can strain cash flow when a drug ramp up is slower than predicted. One of the current commercially approved CAR-T therapies was supported in such a phased fashion, where not only was a scale out approach utilized, but the leveraging of flexible and agile prefabricated solutions allowed for better master planning and, ultimately supported the transitioning from a clinical to a commercially approved manufacturing site.

Another area of innovation is in the hub and spoke model in this space. Five years ago, I commented:
“Facility continuity is also critical when considering a migration from an original centralized manufacturing facility to a decentralized strategy of multiple smaller

manufacturing sites located at hospitals and treatment centers, closer to the patient base. Being prefabricated, autonomous, and mobile, the PODs would allow an entire facility to be decentralized with PODs at various locations around the country and globe.”

Since this time, we have seen the FDA issue a discussion paper on “Distributed Manufacturing and Point of Care Manufacturing of Drugs.” While not specific to cell therapy, it does provide some insight into how regulatory agencies are evaluating a decentralized manufacturing network to allow the drug developers enhanced flexibility and more agile manufacturing. Additionally, multiple trade organizations are focusing their efforts on mobile manufacturing (also cited in the above paper) to unburden companies with regulations established decades ago. Prefabricated solutions are a key platform in these applications and it will be interesting to see if the market continues to evolve as predicted in these areas.



About the Author:

Pete has over 18 years of experience in pharmaceutical and biopharmaceutical industries. Peter held various roles within the industry, primarily around process solutions and engineering for drug substance facilities. He has extensive knowledge of bioprocess manufacturing and has helped design new facilities and retrofit existing facilities. Pete joined G-CON in 2016 where he now consults with clients in the design of their cGMP facilities utilizing G-CON’s pre-fabricated cleanrooms by capitalizing on his process and regulatory know-how.

Pete received his Bachelor of Science in Chemical Engineering and a Minor in Biomedical Engineering from Cornell University. He received his MEng in Chemical Engineering from Cornell University. He is also very active within PDA where he currently sits on the PDA BioAB, co-Leads the Biopharmaceutical Manufacturing IG, and Mobile Manufacturing Task Force.

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