TECHNICALLY SPEAKING

An Innovative Approach to Cell Therapy Facility Design

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Background

Cell therapy is a small but rapidly growing segment in biotechnology. This space has seen a large influx in investment by various small and large companies, primarily driven by the success seen in clinical trials for CAR-T therapies. In 2017, our industry saw the first BLA approval of a CAR-T drug by Novartis. Not long after, Kite (now Gilead) received the second. In the ATMP space, we are seeing about 18% year over year growth in the number of clinical trials ongoing and this trend is expected to continue for at least the next several years.

Cell therapies are typically autologous processes where a patient's cells or donor cells are reinjected into the patient after genetic modification. In certain processes, such as in manufacturing a CAR-T, viral vectors are utilized to modify the cells requiring the clean space to be built to BSL requirements. While the manufacturers of these therapies are driving towards automated and closed process platforms, many processes today still require manual operations in BSCs or isolators.

The Need for Innovative Facility Infrastructures

Due to this space being relatively immature, infrastructure for manufacturing such drugs is limited. Large investments into new facilities is common. Challenges include process uniqueness, segregation and containment, flexibility, scalability, and continuity. Many drug manufacturers require an agile facility design that can provide small scale clinical manufacturing capability in the short term, that can be easily scaled in the future for commercial capacity.

One way to tackle many of the above challenges is to utilize a prefabricated, turnkey facility approach using autonomous cleanroom PODs. While large, interconnected, and interdependent facilities can be suitable for a single product facility, such facilities are not conducive to the efficient production of tens or hundreds of batches requiring concurrent production.

Multiple cleanroom PODs can be operated in parallel, each operating independently of one another, providing the segregation and containment needed for a BSL 2 production area. Additionally, PODs provide the ability to rapidly scale out while not impacting or interrupting existing operations. This is critical for autologous therapies, as there is no means to create drug inventories and where shutting down a facility would mean potentially putting patients' lives at risk.

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, PODs allow a decentralized approach with PODs at various locations around the country and globe.

The iCON Solution

In September 2017, IPS and G-CON officially launched iCON, a turnkey facility platform solution. IPS and G-CON designed iCON for multiple applications, cell therapy being one. The iCON approach utilizes a pre-engineered platform design, leveraging the power of concurrent manufacturing of the facility, cleanroom PODs and equipment. iCON is the most flexible, scalable, and rapidly deployable facility platform available on the market.

In late 2017, a pharmaceutical company approached G-CON and IPS to evaluate the iCON approach for a cell therapy facility in an existing unused building. One of the primary goals for the project was speed to market as the therapy to be manufactured addresses an unmet need. The project kick-off occurred in January 2018. The building's modest retrofitting began while the PODs were being designed and built offsite. The simultaneous facility and cleanroom work significantly accelerated the project schedule and allowed for the aggressive timeframe to be met. The first POD will arrive at the customer's site in May 2018, on time and on budget.

DENNIS POWERS TALKS PODs: ENABLING DRUG MANUFACTURERS TO MEET NEW INDUSTRY STANDARDS

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