

## **DEVELOPMENT OF MEDIA PRODUCTION PROCESSES FOR CAR-T THERAPIES**

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Many of the standard cell culturing unit operations utilized by early stage CAR-T manufacturing processes have been derived from benchtop scale academic processes and require further development to become commercially viable. Critical unit operations, such as isolation, activation, transduction, and expansion are often the focus of next generation or automation technologies. Development of ancillary processes such as medium production, however, should not be overlooked and can take advantage of economies of scale and technologies that have been proven in other pharmaceutical industries like biologics. Special consideration should be taken when developing these medium scale-up processes since cell therapies are complex and can be highly sensitive to medium composition changes. In addition, significant changes may be needed to update medium production processes from a process suited for an academic setting to one suited for a commercialized product. This poster discusses Celgene's approach for developing a commercially sustainable media preparation process by applying available filtration and bulk solution preparation technologies and the unique challenges associated with applying these technologies to CAR-T therapies.