CASE STUDY: LEVERAGING AUTOMATION AND CUSTOM SINGLE-USE SYSTEMS TO STREAMLINE MEDIA PRODUCTION AND ENABLE SCALABILITY FOR CAR-T MANUFACTURING

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In cell therapy, historical media production methods have typically utilized off-the-shelf, single-use assemblies from blood management suppliers with open connection devices. The use of these assemblies requires open processing in ISO 5 biological safety cabinets (BSCs), with significant manual labor required to aseptically access and transfer media components. Manual and open media production processes create capacity challenges that are only partially alleviated with efficiency improvements to the manual methods. Furthermore, these methods also create potential contamination risks.

An automated media production system has been developed to dispense individual components, mix the components, and fill the compounded media into a large quantity of small-volume bags for use in manufacturing operations. The process has been closed using custom single-use assemblies with aseptic connectors and weldable TPE tubing, enabling the relocation of the operation to a less stringent ISO 8 cleanroom and eliminating the ergonomic strain associated with prolonged BSC operations. Additionally, legacy blood management bag films have largely been replaced with next generation biopharmaceutical bag films, reducing extractables and leachables risk.

The value of this implementation also includes increased capacity (see Figure 1) and decreased direct labor requirements. The large-volume lots produced with the new system reduce media waste and increase volume discounts on raw materials significantly.

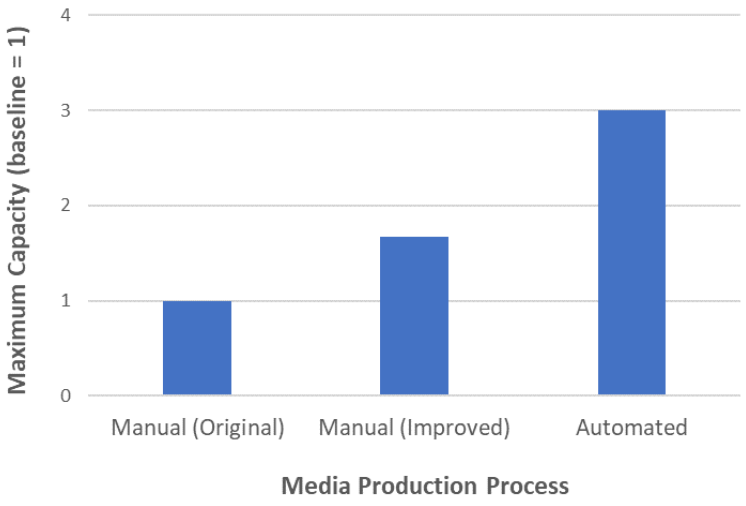

Figure 1. Plant Capacity for Different Processes