

CHALLENGES AND OPPORTUNITIES FOR CLOSED PROCESSING IN AUTOLOGOUS CAR-T MANUFACTURING

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CAR-T Cell Therapy manufacturing processes require handling of small volume process and product components without compromising sterility. Historically, in academic settings, aseptic processing is assured via a combination of controls and testing including material, environment and facility components. Such controls can be costly, time-consuming, and present a risk to product sterility. These controls are a challenge for scaling a CAR-T manufacturing process and can significantly limit facility capacity. As an alternative to open processing, all manufacturing steps would be executed using closed system manipulations, eliminating the requirement for costly and time consuming environmental controls to ensure sterility. Here we present a case study for enabling the closed-system processing of a CAR-T manufacturing process. The solutions enabled significant cost-savings, reduced operator safety risk and increased manufacturing capacity by shortening unit-operation duration.