

# FASTFACTS

## A flexible & fully automated process for CAR T cell manufacturing

Sophia Lollies, Miltenyi Biotec

Chimeric antigen receptor (CAR) T cell therapy is leading a revolution in cancer cell therapy, with its recent success in hematologic malignancies. One of the largest challenges in the field of CAR T cell manufacturing is the complexity and labor intensity of the process steps. The CliniMACS Prodigy platform is a flexible and fully automated cell manufacturing system designed to cover the entire clinical workflow from starting material to cell product, providing an all-in-one solution to CAR T cell manufacturing challenges.

### THE CLINIMACS PRODIGY PLATFORM

The CliniMACS Prodigy platform is designed to cover an entire clinical workflow for CAR T cell manufacturing and consists of four main parts (Figure 1).

The CliniMACS Prodigy instrument is a fully automated platform offering integrated solutions to streamline cell processing workflows. An integral capability of the device is the fully automated washing, fractionation, and cultivation of cells to increase reproducibility and standardization. This instrument can be further modulated with the CliniMACS Electroporator, the CliniMACS

Formulation unit, and the CliniMACS workbench, giving centralized control for standardized procedures. MACS GMP reagents are optimized for a full end-to-end approach with proven performance and are validated in numerous manufacturing processes to ensure a high quality final cell product.

In addition, the closed tubing set and consumables provide a closed and safe environment with multiple compartments for every process step within a GMP-compliant cell manufacture workflow. Cell washing, sample preparation and separation, and genetic modification and formulation can be performed inside different

Figure 1. The four-part CliniMACS Prodigy platform.

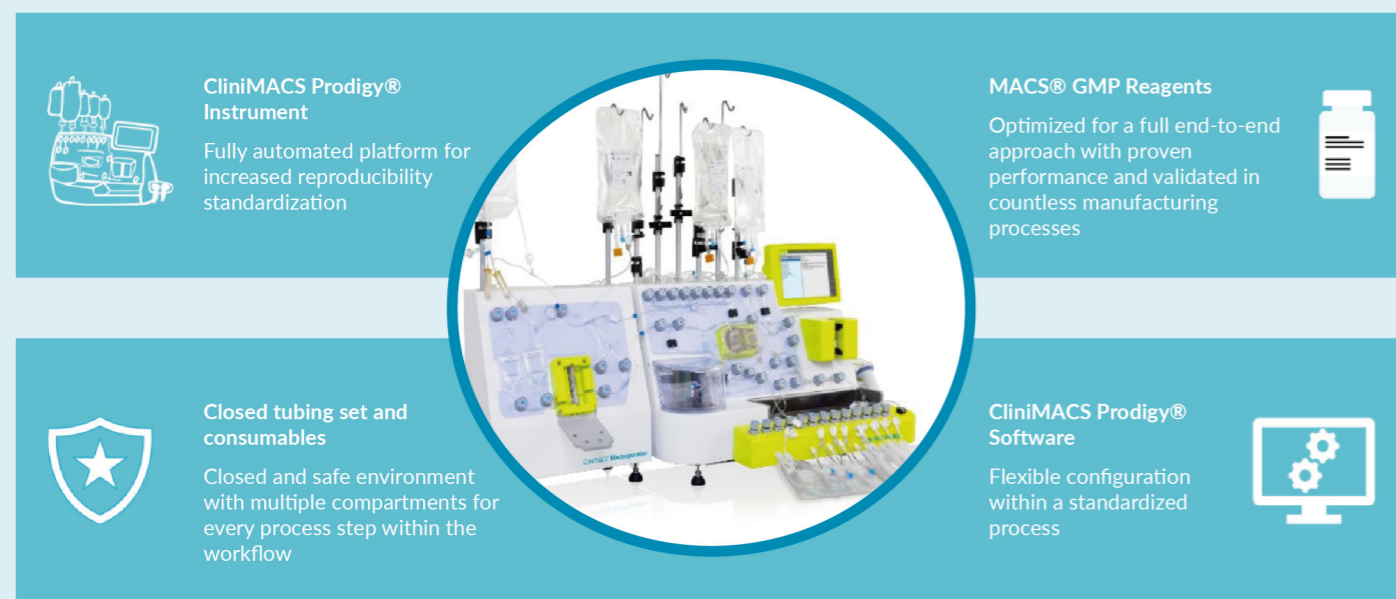
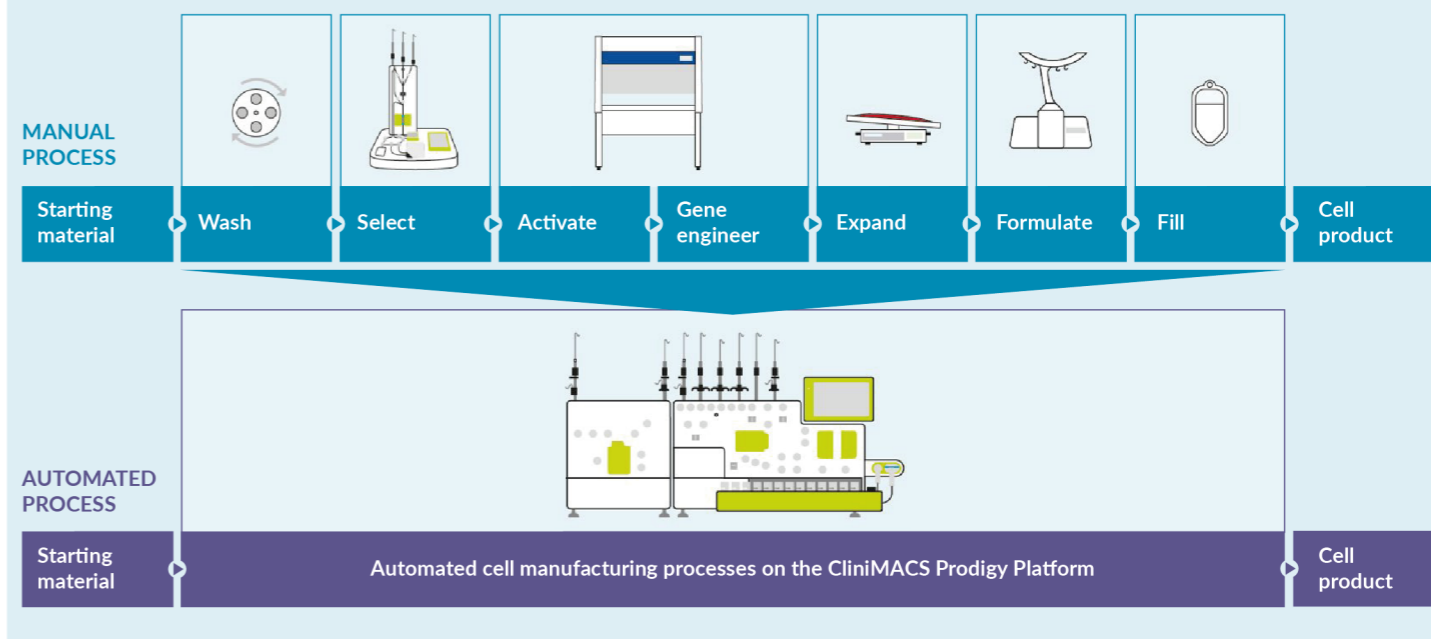


Figure 2. An outline of the automation of previously manual processes using the CliniMACS Prodigy platform.



compartments of the tubing set. The CliniMACS Prodigy software guides the user throughout the whole process with a flexible configuration of either customized or standardized applications.

### FROM MANUAL OPERATION TO AUTOMATION

Manual operations can lead to product risk and failure, as well as increased operational and capital expenditure. Open steps require high cleanroom requirements and are often labor intensive with the need for highly

skilled staff, varying device protocols, and differing service contracts. Many of these risks can be mitigated by utilizing a hands-off, end-to-end process platform from R&D to commercial manufacturing.

The CliniMACS Prodigy platform offers end-to-end automation in a closed system (Figure 2). The benefits of automated cell manufacturing include reproducible and consistent results, as well as reduced operator hands-on time. No extensive training of personnel is required, and production capacities are easily scalable. This in turn reduces costs and lowers the need for multiple devices.