

**SINGLE USE DISPOSABLE BIOSETTLER REMOVES THE DEAD CELLS AND CELL DEBRIS SELECTIVELY TO INCREASE THE VIABILITY PERCENTAGE OF MAMMALIAN CELLS (E.G. CAR-T) DURING EXPANSION**

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Current challenge in a FDA approved cell therapy product for adult B-cell leukemia is reported to be the percentage of viable cells after manufacturing is sometimes out of specified range. As the head of a large contract development and manufacturing organization observed, this fall in viability percentage during CAR-T cell manufacturing is a challenge to the whole industry.

We present a simple and powerful off-the-shelf solution to this big challenge in all mammalian cell culture expansion bioreactor system. Our single use disposable BioSettler has been demonstrated to be uniquely capable of removing dead cells and cell debris selectively from the bioreactor and returning or recycling live mammalian cells back to the expansion bioreactor. The mechanism of this very fine separation of dead cells from live cells is the exploitation of their vastly different sedimentation rates during enhanced sedimentation of live cells on inclined surfaces.

This inclined sedimentation technology has been proven extensively with Chinese hamster ovary (CHO) cells used in commercial manufacture of therapeutic antibodies. As the size and sedimentation velocity difference between live and dead cells are similar for CHO cells and CAR-T cells, our off-the-shelf BioSettler will be readily useful for removing the dead cells and cell debris from the rocking or Wave cell expansion bioreactor and increasing the percentage of viable CAR-T cells being expanded for adult cell therapy.